AN EXPLORATORY INQUIRY INTO THE IMPLEMENTATION OF PREHOSPITAL THROMBOLYSIS IN THE TREATMENT OF ACUTE MYOCARDIAL INFARCTION: A CASE STUDY OF A PRIVATE EMERGENCY MEDICAL SERVICE WITHIN SOUTH AFRICA

Dissertation submitted in fulfilment of the requirements for the degree of Master of Health Sciences: Emergency Medical Care in the Faculty of Health Sciences at the Durban University of Technology

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Declaration of originality

This is to certify that this work is entirely my own and not that of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). Furthermore, this work has not been previously submitted in any form to the Durban University of Technology or to any other institution for either assessment or for any other purpose.

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Declaration of ethical clearance

I hereby certify that the research undertaken in this dissertation has been approved by the Institutional Research Ethics Committee of the Durban University of Technology, Durban.

Institutional Research Ethics Clearance Number: REC64/16

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Dedication

I wish to dedicate this dissertation to my parents, Frank and Elizabeth, who always did the very best they could for all their children, in acknowledgment of their love, guidance and support, which enabled me to reach the point at which I am in my life today.

Abstract

Introduction

Patency and the restoration of an occluded artery both during and after ST-segment myocardial infarction or STEMI remains the highest priority in acute coronary care. The gold standard of reperfusion therapy is percutaneous coronary intervention, which represents the internationally recommended practice for STEMI. Although technically a non-surgical procedure, percutaneous coronary intervention constitutes a specialised practice, and therefore remains subjective to the limitations of existing clinical resource capacity. Facilities supporting this procedure require specialised equipment and highly trained medical personnel, both of which are often unavailable in the developing and/or underdeveloped regions of South Africa.

Thrombolysis, however, also plays a critical role in the management of STEMI, and is recommended in instances where percutaneous coronary intervention is inaccessible or when time delays are present. In 2009, the Health Professions Council of South Africa (HPCSA) allocated thrombolysis to emergency care practitioners in a move which, it was hoped, would improve patient access to reperfusion therapy for STEMI and, ultimately, the country's national healthcare profile. Unfortunately, since its approval for use by emergency care practitioners, thrombolysis has yet to be integrated effectively into prehospital practice. The current study aimed to analyse the factors associated with the implementation or lack thereof regarding prehospital thrombolysis, despite the evidence and principles supporting its application.

Methodology

The research used a case study based on data that was obtained through individual, semi-structured interviews. Participants in various positions in a private emergency medical service were purposefully selected to participate in the study. The requisite data was collected through the interviews with participants, and was grounded in their perspectives, observations, knowledge and experience regarding the implementation of prehospital thrombolysis. Collected data was analysed through both a theoretical and data-driven approach, with the consolidated framework for implementation research conceptualising the data, and thematic analysis facilitating data coding procedures.

Findings

This study identified four primary themes, eight sub-themes and ultimately a total of 14 discussion points relating to the barriers to prehospital thrombolysis. The primary themes comprised interventional characteristics, inner-organisational settings, outer-organisation settings as well as the characteristics of the individuals involved. Within these primary themes, eight sub-themes recognised barriers relating to cost, complexity, cosmopolitanism,

implementation climate, readiness for implementation, leadership engagement, knowledge or beliefs and self-efficacy. The 14 discussion points were focused specifically on these topics and, in a broader sense, also acknowledged the patterns as well as interrelationships between the themes.

Conclusions and recommendations

Implementation, as a process and science, continues to be underestimated, and within healthcare, affects populations who may have otherwise benefited from new, evidence-based practices, guidelines or policies. Healthcare implementation requires strategic planning, and until key pieces of this process are realised, and implementation gaps filled, the potential to improve outcomes through new practices such as early thrombolytic therapy, will continue to be lost. To narrow implementation gaps, the science, which constitutes this domain, requires further merit, not only from prehospital healthcare providers, but across all healthcare disciplines, especially when attempting change.

Greater capacity is required for implementation research and special focus should be dedicated towards extending existing relationships between healthcare deliverance systems, specifically in terms of the continuum of care. To formulate the safest and most cost-effective means of delivering prehospital thrombolysis, South African emergency medical service providers as well as allied and even other healthcare organisations need to consider at least one or more implementation strategies to foster a stepwise progression towards this ideal.

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Table of contents

Figures and Tables

GLOSSARY OF TERMS, OPERATIONAL DEFINITIONS AND ABBREVIATIONS

ACC (American College of Cardiology)

This is a professional medical association which plays an active role in formulating healthcare policies and supporting cardiovascular research in the United States.

ACS (acute coronary syndrome)

ACS refers to a spectrum of clinical presentations pertaining to decreased cardiac function or efficiency, also defined as a set of signs and symptoms resulting from problems in the circulatory system.

AHA (American Heart Association)

An organisation based in the United States, which promotes and endorses appropriate cardiac care to reduce the morbidity and mortality caused by coronary artery disease or stroke.

ALS (advanced life support)

A set of protocols considered part of definitive emergency medical care, including various invasive techniques and procedures, also defined as the highest level of prehospital emergency medical care.

AMI (acute myocardial infarction)

Commonly referred to as ‘heart attack’ and resulting from a cessation of the blood flow to the heart. Various classifications of acute myocardial infarction exist, including STEMI, non-STEMI and coronary spasm or unstable angina.

CAD (coronary artery disease)

Most common type of heart disease, characterised by the accumulation of atherosclerotic plaque within the coronary arteries, which supply the heart, also referred to as ‘ischemic heart disease’ (IHT).

CCA (critical care assistant)

An emergency care short course of nine to ten months in duration, after having completed basic and intermediate-level training coupled with clinical practice hours, and upon completion of which graduates are registered in the paramedic registration category of the Professional Board for Emergency Care.

CCU (coronary care unit)

A hospital ward specialising in the treatment and continuous monitoring of patients with acute myocardial infarction, unstable angina, cardiac dysrhythmia as well as various other cardiac conditions.

CVD (cardiovascular disease)

A class of diseases related to the circulatory system, generally involving blocked or narrowed blood vessels, including stroke and heart disease.

EBP (evidence-based practice)

EBP refers to the integration between a set of clinical expertise, clinical evidence of systematic research and patient values. Its aim is to inform all decision-making processes in the interests of the best possible patient care.

ECP (emergency care practitioner)

An individual with a four-year bachelor's degree in Emergency Medical Care or a post-graduate bachelor's degree in Technology in Emergency Medical Care – the highest level of prehospital emergency care in South Africa.

ECT (emergency care technician)

An individual with a two-year mid-level qualification with an advanced life support scope of practice, able to practice various invasive techniques as well as administer various medications.

ED (emergency department)

Also known as 'Accident and Emergency' or 'Casualty', this is the department in a hospital responsible for the provision of immediate medical or surgical care to patients in need.

EMS (emergency medical services)

A network of services, providing treatment and transport of people in crisis health situations, which may be life threatening.

ESC (European Society of Cardiology)

This is a knowledge-based, professional association that facilitates diagnosis and standards of care in the treatment and prevention of cardiovascular diseases.

HPCSA (Health Professions Council of South Africa)

A statutory governing body in South Africa, which independently reviews, maintains and monitors the standards for the provision of quality medical and emergency care.

IHT (in-hospital thrombolysis)

The process or procedure of administering intravenous drugs to facilitate the thrombolysis of a coronary artery thrombus performed in a hospital.

NCD (non-communicable disease)

Medical conditions not caused by infectious influences, typically diseases which spread gradually and last for longer periods of time, also referred to as ‘non-infectious’ or ‘non-transmissible’ diseases.

NDIP-EMC (National Diploma – Emergency Medical Care)

A three-year national diploma obtained through a university, enabling the provision of advanced life support within the emergency care profession and sharing the same register and scope of practice as a CCA.

PCI (percutaneous coronary intervention)

A non-surgical procedure using a catheter comprising thin flexible tubing used to open blood vessels occluded by atherosclerotic plaque and performed in specialised, interventional, coronary care units.

PHT (prehospital thrombolysis)

The process or procedure of administering intravenous drugs to facilitate the thrombolysis of a coronary artery thrombus performed within the prehospital setting.

RSI (rapid sequence intubation)

An advanced airway management technique involving neuromuscular blocking agents to produce immediate unresponsiveness in order to establish control of a patient’s airway – deemed the most effective means of controlling an emergency airway.

STEMI (ST-segment elevation myocardial infarction)

Most consequential type of heart attack, diagnosed by distinctive electrical patterns and characterised by absolute or imminently complete coronary artery obstruction as well as full thickness cardiac muscle damage.

WHO (World Health Organization)

An international healthcare authority that is part of the United Nations, and which is responsible for providing leadership or guidance on global healthcare issues.

CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 Introduction

This chapter discusses the objectives and aims of the current study. It also gives a short overview of the conceptual framework of the study. The chapter further sets out the structure of the thesis, and a summary of the chapters to follow.

1.2 Research preface and foreword

South African prehospital emergency care has made significant advances in recent years and is now able to offer better delivery of care as well as a higher quality of care through an extended range of prehospital capabilities (Capabilities of Emergency Care Providers 2016). The advent of the emergency care practitioner (ECP) registered with the Professional Board for Emergency Care Health Professions Council of South Africa has seen additional skills introduced into the skills sets of paramedics, i.e. rapid sequence intubation (RSI) and prehospital thrombolysis (PHT).

However, while RSI appears to be fully implemented, PHT has not been implemented systematically into prehospital care, despite significant evidence advocating its value (Cannon, Sayah and Walls 1999; Coccolini, Fresco and Fioretti 2003; Fletcher, Stewart and Savage 2013). This study aimed to ascertain the reasons why PHT, as an evidence-based practice (EBP) has not been fully embraced, and by extension, implemented within South Africa's emergency medical services (EMS).

1.3 Research background

The early open artery theory (Goel *et al.* 1998) refers to the concept that the attainment of early reperfusion is correlated with improved patient outcomes (Cannon, Sayah and Walls 1999). Fundamentally, the short-, medium- and long-term morbidity or mortality of ST-segment elevation myocardial infarction (STEMI) is determined by the degree of myocardial damage caused by the coronary occlusion (Thygesen *et al.* 2012). Therefore, following the diagnosis of STEMI, the overriding clinical priority is to initiate the prompt restoration of the myocardial blood flow (Libby and Theroux 2005). Reperfusion is typically achieved through one of two clinical methods, either through percutaneous coronary intervention (PCI), a semi-invasive catheter-based procedure, or through the administration of thrombolytic medications.

In developed countries, PCI represents the customary care for STEMI, as international consensus denotes this as the gold standard reperfusion strategy (O'Gara *et al.* 2013). However, despite recent advancements in both healthcare and infrastructure, requisite skills

and resources in relation to PCI are still lacking in South Africa (Stassen *et al.* 2017). This lack of PCI facilities inevitably poses major concerns for South Africa's healthcare profile (Naidoo 2014).

Thrombolysis, specifically PHT, is an established reperfusion strategy serving as an adjunctive therapy or alternative reperfusion strategy especially where treatment delays are prolonged (Bassand *et al.* 2005). With the safety and effectiveness of its use thoroughly documented (Leizorovicz *et al.* 1993), PHT represents a valid and logical solution within contexts where resources and PCI facilities are lacking (Khan *et al.* 2016). Consequently, the Health Professions Council of South Africa (HPCSA) moved towards granting ECPs the autonomy to instigate and administer PHT (Castle, Naidoo and Owen 2006). However, since its initiation, PHT has only rarely – if ever – been provided, with little, or effectively no documented cases pertaining to its use as a definitive treatment strategy.

1.4 Research aim

This study therefore aimed to identify, by means of an inductive approach, possible factors or reasons why PHT is not being delivered by ECPs in South Africa.

1.5 Research objectives

In order to realise the aims of the study, the following research objectives were formulated:

- to investigate the implementation process of PHT within a single organisation, while considering both actual and perceived influences through the lens of implementation science; and
- to attempt to improve the understanding of the implementation process as well as policies and incentives with regard to PHT in South Africa.

1.6 The theoretical framework of the study

The study was guided by the consolidated framework for implementation research (CFIR) which, for the purposes of the study, acted as the main theoretical driver. Developed in 2009 with the support of the United States (US) Department of Veterans Affairs and the Veterans' Health Administration Research and Development Service, the CFIR is designed to address gaps in implementation research (Glanz, Rimer and Viswanath 2008). Stemming from a synthesis of existing implementation theories and supported by a wide range of evidence-based research in the health sciences, the CFIR is formally described as a meta-theoretical framework (Damschroder *et al*. 2009).

Reflecting empirical research across multiple professional disciplines, including healthcare, the CFIR is characterised by 39 theoretical constructs, which are encompassed by five organisational domains (see Annexure D). Based on this, the CFIR primarily addresses

concepts of knowledge in practice and is therefore useful in identifying potential barriers or facilitators in the implementation of new systems, policies or technologies (Breimaier *et al.* 2015). Figure 1.1 below depicts the five organisational domains and thirty-nine individual constructs which constitute the CFIR.

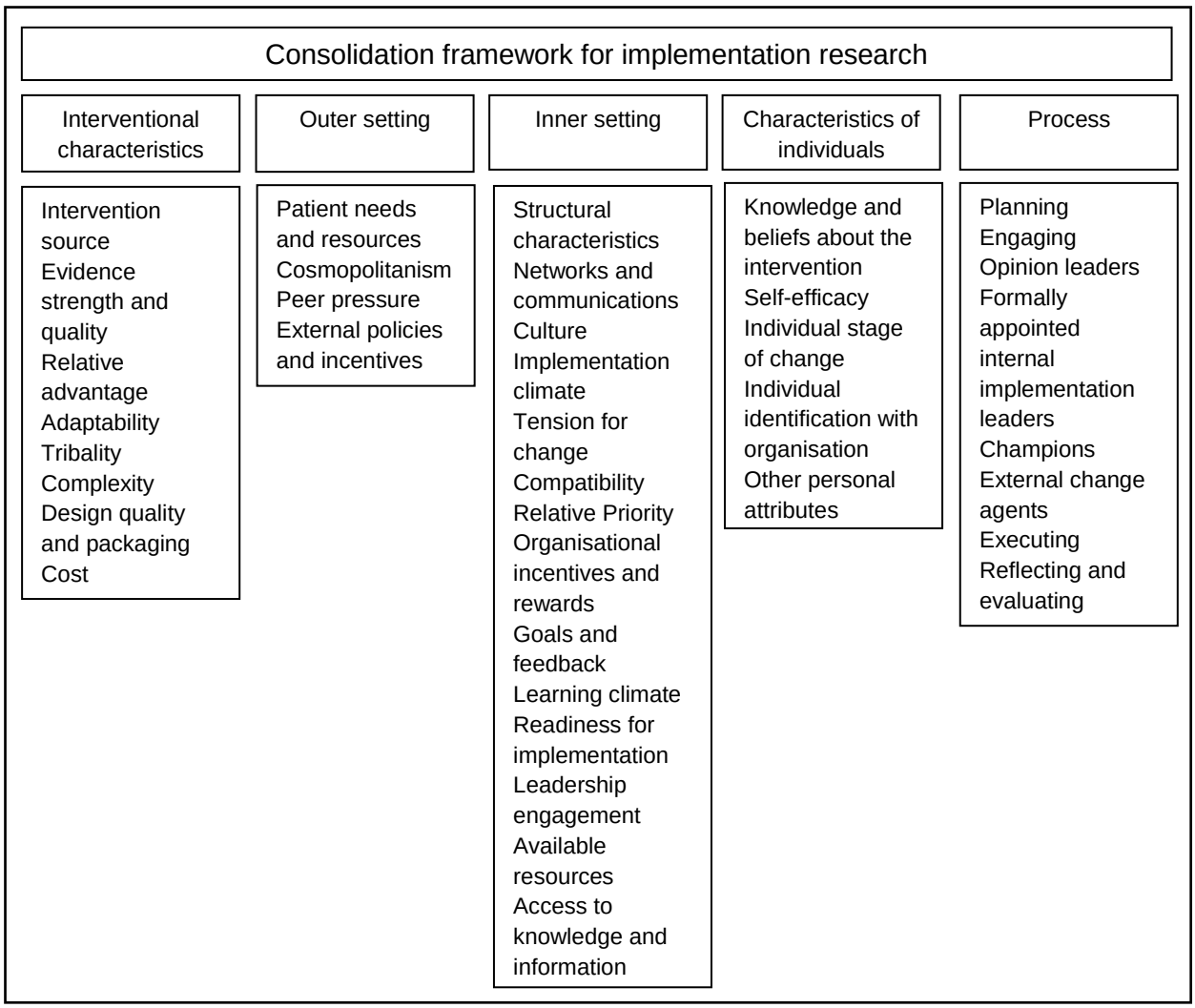

Figure 1.1: Consolidated framework for implementation research

Source: Damschroder *et al.* 2009.

1.6.1 Relevance and context of the theoretical framework

Several theoretical frameworks exist in respect of examining implementation or identifying the transition of research into practice, for example, evaluation frameworks, process models and implementation theories. Evaluation frameworks are unique in their ability to characterise organisational mechanisms, and, through this ability, develop outcomes that are consistent with organisational objectives (Palfrey 2002). Process models, such as the conventional, Ottawa model of research use (OMRU), are designed to describe and guide the translation of

the process of knowledge into practice, although they do not focus specifically on barriers or facilitators. Implementation theories aim to provide an understanding and thus an explanation of certain aspects of the implementation process, which is a fundamental practice in the implementation sciences (Nilsen 2015).

Parallel to implementation theories are determinant frameworks, which – according to experts in the implementation sciences – provide a more comprehensive insight into aspects within the implementation process (Damschroder *et al.* 2009). Beyond the scope of process models and implementation theories, determinant frameworks evaluate influences throughout the various levels of an organisational setting, namely those influences that either enable or prohibit implementation (Stetler *et al.* 2009). This is achieved through specifying the domains, which act either as facilitators or as barriers, thus allowing context and lending recognition to the fact that implementation is a multidimensional phenomenon (Kitson, Harvey and McCormack 1998).

In addition, determinant frameworks enable an appreciation of the integral interrelationships that exist within organisational dimensions, making them potentially useful in case study approaches. As a determinant framework, the CFIR echoes the well-cited promoting action on research implementation in the health services (PARIHS) framework, which seeks to describe and understand implementation outcomes (Damschroder *et al.* 2009). However, beyond the scope of conventional determinant frameworks, such as the PARIHS, the CFIR due to its exploratory nature, also serves as an integral process within the implementation process itself (Damschroder *et al.* 2015).

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter presents a synopsis of available literature on the implementation of PHT in the treatment of acute myocardial infarction (AMI) in South Africa. The chapter begins by explaining the literature search strategy, briefly describing the material resources and structure of the literature review. The review outlines the justification for and the provision of PHT in respect of appropriate cardiac syndromes. This is followed by a discussion of reperfusion strategies, emphasising the rationale for PHT. The review concludes by discussing some of the complexities in the science of implementation, particularly implementation stages, gaps, research and drivers, placing these in relation to PHT in South Africa.

2.2 Literature search strategy

Literature searches were conducted primarily using the Durban University of Technology (DUT) online library database. The literature search was repeated frequently during the research process to ensure that the most current, or seminal information could be cited. Supplementary online searches focused on the medical science and healthcare fields available via Elsevier Science Direct, Springer Link and the PubMed-NCBI electronic records. In order to optimise the precision of search criteria, medical subject headings or MeSH terms, were applied in all sciences, and biomedical databases. These included terms such as ‘thrombolytic therapy’, ‘myocardial reperfusion injury’, and ‘implementation science’.

During all other searches, keywords and Boolean operators included the terms such as ‘prehospital thrombolysis’, ‘barriers to prehospital thrombolysis’, ‘implementation’ and ‘implementation in healthcare’. Aside from science or biomedical databases, additional searches were conducted through the popular online search engine Google Scholar. The structure of the literature review was organised around central concepts pertaining to implementation sciences, PHT including its implementation, and constituted discussions based on the interpretation of the primary research question (Section 1.4).

The aim of the literature review was to determine a classification of the concepts associated with PHT, which in turn could potentially explain some of the barriers in its implementation. In order to try to identify additional studies, all reference lists from relevant articles collected for the study were interrogated, and seminal studies were re-interrogated.

2.3 Coronary artery disease

Cardiovascular disease (CVD) is defined by a host of pathophysiological conditions involving alterations in either the heart or vascular structures. CVD must, however, not be confused with

coronary artery disease (CAD), sometimes referred to as 'ischemic heart disease' (IHD), which is specific to the structures and/or functions of the heart and which, incidentally, represents the most common type of CVD (Rogers *et al.* 2012).

2.3.1 The increasing global burden of coronary artery disease

Upwards of 7 million CAD deaths are reported annually, and this is expected to reach at least 19 million by 2020 (Sanchis-Gomar *et al.* 2016). The rise of CAD has captured the attention of international medical communities (Mathers and Loncar 2006), through which findings have led experts to conclude that CAD will surpass infectious diseases as the largest single cause of morbidity and mortality worldwide (Braunwald, Zipes and Libby 2001). Technically classified as an epidemic, the World Health Organization (WHO) describes CAD as a true pandemic that respects no borders, raising awareness to the fact that CAD is an increasing global trend (Gaziano *et al.* 2010).

In order to provide context on the issue, an international survey conducted in 2010 revealed that approximately 30% of all deaths are associated with or directly attributable to CAD (Nichols *et al.* 2014). Recent and internationally verified reports from the Institute for Health Metrics and Evaluation not only revealed the global inclination of CVD, but also highlighted the significant role of CAD within this trend, ranking it as the leading cause of early death (Findings from The Global Burden of Disease 2017).

In addition to mortality and morbidity associated with CAD, socio-economic factors, such as excessive healthcare expenditure and decreased workforce productivity, have an influence on global economies as an indirect result of CAD (Gaziano *et al.* 2010). It is noteworthy that the subsequent effect on workforce productivity resulting from CAD is higher than that of any other disease, with estimations in the United Kingdom of £7 billion (R118 billion), and in Europe €45 billion (R758 billion) (Leal *et al.* 2006). In the United States, the estimated economic impact of CAD is $215.6 billion (R3.6 trillion) which, to provide context, equates to almost the entire gross domestic product (GDP) of South Africa of R4.9 trillion (Mozaffarian *et al.* 2015).

2.3.2 The local prevalence of coronary artery disease

Representing the majority of the global population, developing nations are currently demonstrating dangerous and alarming trends in non-communicable diseases, specifically CAD (Rai *et al.* 2015). Perk *et al.* (2012) highlight that CAD contributes nearly 80% of mortality rates, which – due to population expansion and socioeconomic disparities – is predicted to become the leading cause of death in developing nations by 2020 (Reddy, Khaliq and Henning 2015).

As a developing nation, South Africa may be said to be an economy in the early stages of industrialisation having not yet achieved sufficient development and economic growth

(Nahman, Wise and De Lange 2009). Historically, South Africa has undergone major domestic transformations in terms of cultural, social, economic, and political developments (Booysen 2007). However, these developments have also led to perceptible changes in the healthcare profile of the nation, with cultural diversity resulting in new behaviours, which are contributing to rising trends in both chronic and co-morbid diseases (Mayosi *et al.* 2009).

The Heart of Soweto study in 2006 emphasised these issues by revealing the level to which the South African population had been subjected to extensive disease states (Stewart *et al.* 2006). In addition to a quadruple burden of disease, encompassing HIV/AIDS, tuberculosis, maternal and child mortality, and traumatic injury occurrences, emerging trends of non-communicable diseases are predicted to reach epidemic proportions. (Bradshaw *et al.* 2003). Prevailing within the category of non-communicable diseases, CAD is responsible for the deaths of more than 71 000 lives each year, with nearly 12 000 of those deaths directly attributed to AMI (Steyn 2007).

While the management and clinical outcomes of acute coronary syndrome (ACS) are well documented in developed countries, there is limited data available for sub-Saharan Africa (Kakou-Guikahue *et al.* 2016). The acute coronary events multinational survey of current management strategies was one of the first observational registries to include both demographics and treatment strategies involving South Africa (ACCESS investigators 2011). The registry comprised 134 sites in 19 countries and the South African cohort accounted for 615 patients with a confirmed diagnosis of ACS. Within the registry, it was found that 26.4% of patients had angina with no cardiac bio-marker elevation, 32.4% non-STEMI, and 41.1% STEMI, highlighting the prevalence of the latter. At the time of the current study, there were no published registries, specifically on the hospital management and clinical outcome of patients presenting with ACS in South Africa (Schamroth 2012).

2.3.3 The manifestation and clinical presentation of coronary artery disease

As a collective term for cardiac diseases, CAD is typically asymptomatic and is characterised by atherosclerosis, which entails the accumulation of plaque or fatty deposit in the coronary arteries (Topol and Teirstein 2015). It is important to note that ACS reflects cardiac disease progression in both pathophysiology and epidemiology, primarily involving life-threatening vascular events, specifically AMI (Cohen, Boiangiu and Abidi 2010).

2.3.3.1 The pathophysiology of acute myocardial infarction and STEMI

While the physiological process of localised blood clotting or thrombosis represents a critical component of haemostasis (Gale 2011), pathological thrombotic conditions such as AMI, and especially STEMI, impede circulatory function and perfusion. During AMI, vulnerable plaque within the artery ruptures, causing platelet activation and aggregation, which in this instance,

leads to the occlusion and, if untreated, results in irreversible tissue damage (Opie 2004). Subjugated to AMI but defined as full-thickness tissue damage, STEMI, involves an imminent or absolute coronary artery obstruction (Van de Werf 2003). Restoration of an affected artery in STEMI is critical, as treatment delays of this condition are correlated with higher morbidity and mortality than in any other classification of AMI (O'Gara *et al.* 2013).

The myocardium is required to function continuously, demanding high levels of uninterrupted energy in order to invariably supply oxygen rich blood to vital organs. Energy is generated through the process of oxidisation, which although limited to enable rapid adaptation according to cardiac demand, requires a continuous supply of oxygen (Gebker and Fleck 2004). With a high turnover of oxygen-rich blood and a limited supply of stored energy, any obstruction in the coronary arteries, i.e. STEMI, starves the myocardium, creating a major circulatory dysfunction. If not corrected promptly via an appropriate reperfusion strategy, either mechanically or pharmacologically, this imbalance results in cardiac-dysrhythmias and heart-failure, which ultimately lead to cardiac arrest.

2.3.4 Reperfusion strategies in STEMI

Clinical reperfusion involving either mechanical intervention, i.e. PCI or pharmacological restoration via administration of thrombolysis as a definitive treatment strategy represents the cornerstone of the treatment in STEMI (Stiermaier *et al.* 2013). If performed within the timeframes stipulated by clinical guidelines, reperfusion therapy reduces infarct size and, ultimately preserves the left ventricular capacity, which is vital for maintaining cardiac function (Lettino 2009).

2.3.4.1 A summarised analysis of international reperfusion strategies

Randomised control trials have demonstrated that primary PCI is more effective when compared to thrombolysis (Otterstad and Brosstad 2003), provided that door-to-balloon time, which is defined as the time from first medical contact to PCI, is less than 90 minutes. However, Otterstad and Brosstad (2003) also acknowledge that findings such as these, remain subjective to further analysis of larger comparative studies involving modern fibrinolytic agents, and moreover, question whether PCI is the solution for all STEMI patients. In a quantitative review of 23 randomised trials, Keeley, Boura and Grines (2003) compared primary PCI with thrombolysis, including fibrin-specific drugs, and concluded that primary PCI is a more effective strategy. However, randomised control trials, and even medical registries, have also demonstrated the link between delays to primary PCI and worsened clinical outcomes.

Steg *et al.* (2012) describe a PCI-related delay as the theoretical difference of time taken to reach primary PCI minus the time from first medical contact to thrombolysis. It is understood that this theoretical difference minimises the advantages of primary PCI over thrombolysis and

in turn helps to clarify why this has been a topic of ongoing debate (Steg *et al.* 2012). The comparison between angioplasty and prehospital thrombolysis in acute myocardial infarction (CAPTIM) study directly compared PHT, to primary PCI, and revealed no evidence that primary PCI was a superior strategy on its own. Instead, the CAPTIM study (Touboul and Bonnefoy 1998), highlighted trends of lower 30-day mortality in patients receiving PHT, which was also confirmed during a five-year follow up analysis (Bonnefoy *et al*. 2009).

However, a key distinction was identified in the CAPTIM, with 70% of patients who received PHT also experiencing facilitated PCI before the 30-day endpoint, and 26% requiring rescue PCI after PHT had failed (Danchin, Durand and Blanchard 2008). It should be noted that these discrepancies did not undermine the effectiveness of PHT and, instead, highlighted the subsequent use of routine PCI after PHT as a combined strategy (Danchin *et al.* 2008). This benefit was corroborated through the strategic reperfusion early after myocardial infarction (STREAM) study (Sinnaeve *et al*. 2014), which evaluated facilitated PCI, the deliberate co-intervention of thrombolysis and PCI, confirming that this combination yielded favourable outcomes over primary PCI alone (Armstrong *et al.* 2010).

The STREAM trial comprised a total of 1 892 patients, all confirmed with STEMI, who presented within a timeframe of three hours, in relation to symptom onset, and who were unable to access primary PCI within one hour. The trail randomised patients into two clinical strategies: early thrombolysis in conjunction with rescue PCI if warranted (n=944), and then primary PCI (n=948). Coincidently, retrospective insights from the STREAM trial also revealed that early thrombolysis yielded a higher frequency of aborted AMI through early thrombolysis in comparison to primary PCI (Maleki *et al.* 2014).

Aborted AMI is defined by a minimum increase in cardiac enzymes and favourable electrocardiogram (ECG) characteristics with the absence of residual tissue damage through early reperfusion after STEMI (Verheugt, Gersh and Armstrong 2006). This definition was originally used in the setting of thrombolytic therapy, and represents the ideal scenario in reperfusion strategies after STEMI (Weaver *et al.* 1993).

The findings of the PRAGUE-2 study, (Widimsky *et al.* 2000) which investigated whether direct transfer to primary PCI was superior to that of PHT, demonstrated similar results to those of the CAPTIM (Widimsky *et al.* 2006). Primary investigators of the PRAGUE-2 study concluded that primary PCI remained the preferred option if patients were transferred to a PCI facility within 30 minutes after arrival at hospital, in which case PCI should be undertaken within an hour (Widimsky *et al.* 2006). However, in the event that these conditions could not be met, the recommendation is for patients to receive immediate thrombolysis, which could also be delivered up to three hours after the first medical contact (Widimsky *et al.* 2010).

Guidelines from the European Society of Cardiology (Roffi *et al.* 2016), advocate primary PCI, subject to a 120-minute period from the first medical contact, on the understanding that it be performed by experienced practitioners. However, the American Heart Association and American College of Cardiology endorses the use and application of PHT over that of primary PCI, emphasising time dependency in terms of reperfusion, rather than choice of reperfusion strategy (Kronick *et al.* 2015). The National Institute of Clinical Excellence (NICE), which is responsible for guidelines on the clinical practice of specific diseases, also supports pharmacologic reperfusion although with fibrin-specific agents (NICE CLINICAL GUIDELINE CENTRE). Additionally, in 2006, NICE cited its guidelines as 'static', implying that the evidence is not subjective to change and thus remain in force without further scheduled review dates (Carville, Henderson and Gray 2015).

2.3.4.2 Reperfusion strategies within a local context

Current national clinical practice guidelines (CPG) set out by the Professional Board for Emergency Care (PBEC) recognise the prevalence of ACS and issues faced by healthcare services (Clinical Practice Guidelines 2018). This includes primary care and logistical challenges faced by EMS and the fact that no definitive care pathway for patients presenting with ACS currently exists in South Africa (Stassen *et al*. 2017).

The PBEC guidelines, stipulate that not all EBP recommendations are feasible at present, specifically in terms of PHT and its full-scale implementation (McCaul *et al*. 2016). In line with assertions presented by Beygui *et al.* (2015), the guidelines recommend that rapid transfer to primary PCI remains the first point of action for patients presenting with a confirmed clinical diagnosis of ACS. These recommendations also include a planned strategy regarding prehospital activation of PCI facilities, which maintain 24-hour capability and ideally onsite cardiac surgery.

The guidelines further acknowledge critical breakdown in the continuum of patient care as well as a lack in development of current emergency care protocols. The CPG therefore advise a shared choice of reperfusion strategies via a STEMI network, which should include hospital and prehospital providers. However, Pandie *et al*. (2016) criticise this approach, confirming that the lack of local STEMI networking structures affect strategic planning in both healthcare sectors (private and public) across the country.

Instead, and at present, it is emphasised that the choice of local reperfusion strategies in all cases should depend on time factors and availability of clinical resources. Moreover, traditional, in-hospital approaches, continue to emphasise timely reperfusion, including primary PCI, if deliverable within two hours. However, if PCI is not achievable within this two-hour

window, then, the administration of thrombolysis and adjunctive antiplatelet anticoagulation therapies are initiated (Pandie *et al*. 2016).

The CPG highlight some of the advantages of PHT, including instances where transport to PCI is delayed, or where direct access to PCI is simply unavailable. The CPG also recommend that such instances be weighed against the resources, or what it would take to fully implement PHT. By the same token the guidelines also assert in accordance with Welsford *et al.* (2015) that transport to PCI is more important than the determinant of the reperfusion strategy decision-making process. The current study argues that such a premise could be somewhat misleading, because the consensus highlighted above clearly recognises the challenges associated with PCI in the South African current healthcare climate.

Furthermore, and in terms of thrombolysis alone, the CPG concede that PHT is superior to in-hospital thrombolysis (IHT), which by its own merit should provide a compelling drive towards the implementation of PHT both as a supportive and definitive reperfusion strategy. A systematic review by McCaul, Lourens and Kredo (2014) found that PHT accurately reduced critical time factors in deliverance and administration, highlighting the potential for improved clinical outcomes. Additionally, there was inadequate evidence that PHT was not more effective than IHT, and based on clinical outcomes of high-income countries, McCaul, Lourens and Kredo (2014) concluded that PHT has the potential to limit the burden of STEMI, in low- and middle-income countries.

2.3.5 The choice of reperfusion strategies

Lozano, Rondan and Avanzas (2010) explain that the initiation of reperfusion takes precedence over the choice of the actual reperfusion therapy; thus, the decision is not which reperfusion therapy, but reperfusion therapy itself. Furthermore, Lozano *et al.* (2010) argue that guidelines need to be improved to address early reperfusion as the priority of care, instead of encouraging the notion or potential of wide-reaching PCI capabilities as best clinical practice.

Attributed to the cardiovascular specialist Eugene Braunwald (Abreu 2019), the expression often heard within medical circles, ‘time is muscle’, echoes this sentiment, through which international consensus of STEMI management highlights critical time factors as the priority of care (Antman 2008). To this point, pharmacological and mechanical strategies could achieve successful reperfusion, with both methods being deemed highly effective treatment strategies (Steg *et al.* 2012), and thus fully embracing supportive or even alternative options to PCI would truly resemble best practice.

Through what can be described as a reason-based categorical imperative, organisations such as the American Heart Association and the American College of Cardiology, support choice of

options despite certain prevailing guideline recommendations, by inferring that reperfusion strategies remain circumstantially dependent (Mehta *et al.* 2008). Subsequently, the issue of treatment strategy has begun to shift from recommended choice of clinical therapy to that of population demographics, fundamentally how to increase the number of patients receiving reperfusion instead of reviewing merits among reperfusion strategies.

King (2011) also maintains that the prevailing guidelines are simply not applicable to populations without access to PCI, and advises a paradigm shift through considering available resources and potential outcomes in terms of PHT. The provision of PHT should be readily available, specifically in instances where resources, cost-effectiveness and time delays play a significant role in actuation of PCI (Van de Werf 2003).

Simoons *et al.* (1997) agree with the prevailing trends in relation to implementing PHT as an alternative or, at least, as supportive therapy in case of PCI. They further concur with the notion of not granting further insight into research that would facilitate PCI as a primary or mainstay strategy over the potential of PHT. Likewise, it would be an error of clinical judgment to focus only on protocols governing the purposeful primary activation of PCI, as opposed to the benefits of PHT (Boersma *et al.* 1996). Instead, research should be directed towards early reperfusion strategies regarding PHT to improve patient outcomes by decreasing the time between onset of ACS and reperfusion.

2.4. Thrombolysis

Thrombolysis was first used in the early 1900s when it was discovered that haemolytic streptococcus, a group of pathogenic bacteria, possessed fibrinolytic properties, which caused disintegration of biological cells in human fibrin (Gray 2006; Ouriel 2004). Deemed one of the greatest 20th-century discoveries in cardiology (Mehta and Khan 2002), thrombolysis has since established itself in acute coronary care and emergency medicine, where it continues to play a significant role in the management of STEMI (Iyengar and Godbole 2011).

2.4.1 A synopsis of reperfusion terminologies

Thrombolysis and fibrinolysis are pharmacology reperfusion processes, comprising a combination of thrombolytic or fibrinolytic agents supported by anticoagulants and anti-platelet agents (Knuttinen *et al.* 2010). As the name suggests, thrombolytics break down thrombi, whereas fibrinolytics, usually within the broad category of thrombolysis, target specific proteins in the blood referred to as ‘fibrin’ (Becker 2008). It is important to note that several classifications of thrombolytic and fibrinolytic agents exist, relating to enzymatic, biochemical properties or pharmacological actions (Knuttinen *et al.* 2010). Within the current study, the term ‘thrombolysis’ was used in the broader sense to describe the pharmacological procedure, without citing specific drug properties, actions or classes.

2.4.2 Thrombolytic regimens

The section below highlights the drugs within the South African prehospital ECP scope of practice at the time of this study, and provides a short description of each:

THROMBOLYTIC AGENTS

Streptokinase
Tenecteplase
Classification: Enzymes
Schedule 4

Since its initial clinical application in relation to the treatment of AMI in 1958, streptokinase, known as a 'first-generation thrombolytic agent', had slowly begun to shift the focus of reperfusion therapy (Ouriel, K. 2004). Controversy surrounded the use of thrombolysis in AMI until 1986 when the Gruppo Italiano per la Sperimentazione della Streptochinasi nell'Infarto Miocardico (GISSI) trial was conducted (Sikri and Bardia 2007). The trial not only validated streptokinase as an effective therapy for AMI but also founded some of the first guidelines for its use (Sikri and Bardia 2007).

Tenecteplase, a 'third-generation', genetically engineered fibrin-specific agent, has, through numerous clinical trials, which contrasted its use to other thrombolytic agents, and even reperfusion strategies, demonstrated high levels of effectiveness (Melandri *et al.* 2009). The early ST-elevation myocardial infarction therapy (WEST) trial (Armstrong 2006), involving nearly 300 patients with a 30-day follow-up, confirmed results from the CAPTIM. It further highlighted that tenecteplase, when administered promptly, yielded results similar to primary PCI (Armstrong 2006).

2.4.3 The physiology of thrombosis and lysis

While understanding the cardiovascular system and the pathophysiology of ACS are central to practicing thrombolysis (Naidoo and Castle 2012), a key aspect of thrombolytic therapy is the time in initiating reperfusion (Kaila *et al.* 2007). Understanding the physiology of thrombosis, and in turn, lysis, and how these affect reperfusion times, represents a central component of thrombolytic therapy (Ali *et al.* 2014). Thrombolytic agents simulate the body's intrinsic mechanisms, converting zymogens into enzymes, which lyse thrombi (Adivitiya and Pal Khasa 2017). However, due to the inherent nature of clotting processes, thrombolytic agents are only able to dissipate newly developed thrombi (Czaplicki *et al.* 2017).

Mature thrombi, those typically beyond recommended reperfusion guidelines, attain increased amounts of fibrin polymerisation, a crucial element involved in haemostasis (Undas and Ariëns

2011). Forming the end-product of the clotting process, fibrin polymerisation stabilises platelet adhesion, making thrombi more durable, determining the time-critical nature of thrombolysis (Becker 2008). Subsequently, thrombolytic agents are most effective when administered within three hours of symptom onset upon diagnosis of STEMI (Armstrong *et al.* 2010). In non-symptomatic patients, thrombolytic therapy is indicated up to twelve hours of symptom onset (Langer *et al.* 1996).

2.4.4 The effect of time in thrombolytic therapy

Published data noticeably demonstrates the relationship between coronary artery occlusion, pharmacological reperfusion delays, and worsened clinical outcome (Antman 2008; Jennings, Steenbergen and Reimer 1995). The GISSI trial, which not only determined the safety and efficacy of streptokinase, was also one of the first trials to test this time-to-reperfusion relationship, observing significant benefits in patients who received thrombolysis within six hours of symptom onset (Estevez-Loureiro *et al.* 2014).

The fibrinolytic therapy trialists, who in a metanalysis of studies, comprising more than 1 000 patients with STEMI, confirmed these results, while attempting to understand the relationship between reperfusion delays and short-term mortality better. Boersma *et al.* (1996) tabulated data from 22 seminal studies, each comprising no fewer than 100 patients. Through a non-liner regression curve, referred to as the Boersma curve, Terkelsen *et al.* (2003) concluded that benefits of thrombolysis were still present within a 12-hour delay, although maximum benefit existed within a two-hour window period.

While the Boersma curve remains widely accepted, and to date, indisputable, Terkelsen *et al.* (2003) question whether it is a reliable indicator in terms of the relationship that occurs between symptom onset and reperfusion. It is argued that the formula, representing the number of saved lives for every 1 000 patients in the Boersma curve, bears uncertainty, specifically in terms of the actual effect of thrombolysis at various treatment intervals, and thus, may even underestimate the potential of early thrombolysis.

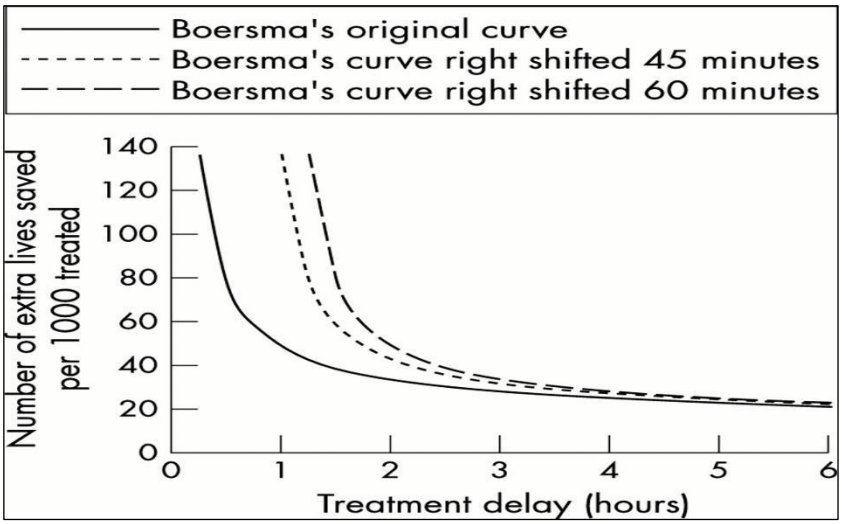

Figure 2.1: The Boersma curve demonstrating the effects of timely reperfusion through the time from symptom onset to reperfusion therapy.

Source: Terkelsen *et al*. 2003.

2.4.5 The deployment of thrombolysis

With early reperfusion widely accepted as the goal of STEMI management, the focus of care has started to shift towards clinical outcome potential instead of the choice of reperfusion therapy (Bassand *et al.* 2005). In attempts to minimise time delays and improve clinical outcomes, the administration of thrombolysis has been redeployed from the traditional coronary care unit (CCU) to the emergency department (ED) (Hourigan *et al.* 2000). Benger (2002) proposes that a similar rationale be applied to relocate thrombolysis into the prehospital domain, maintaining that paramedics are adequately trained to deal with potential complications. This assertion is supported by Castle, Owen and Hann (2007) who also continue to advocate ED-administered thrombolysis for complex cases, specifically developing AMI or patients self-presenting to the ED.

2.5 Prehospital thrombolysis

Prehospital thrombolysis, as the name suggests, refers to thrombolytic capabilities within the realm of prehospital care. The notion of early reperfusion, and by extension, early thrombolysis, is widely accepted; however, the concept of PHT, namely incorporating the prehospital element, often appears to be more controversial than IHT. The following section briefly discusses PHT within context, as well as some of the perceived barriers. This is followed by the rationale regarding the implementation of PHT in South Africa, or lack thereof.

2.5.1 Prehospital thrombolysis within an international context

Recommended time guidelines for patients being transported to a PCI facility remain a challenge, with developed countries, such as the United States, making ongoing efforts to improve emergency transport times (Mehta *et al.* 2008). However, considering the multiple factors which constitute reperfusion treatment delays, the United States has, in some respects, redirected focus on the applicability of pharmacologic reperfusion, specifically PHT. Trials, such as the Early Retavase Thrombolysis in Myocardial Infarction (ER-TIMI) 19 (Morrow *et al*. 2002), have explored the applicability of early thrombolysis in rural, semi-rural and even non-rural locations. The results of these trials almost unanimously led to the consensus that PHT is in fact a feasible approach towards decreasing mortality by improving patient outcomes in STEMI (Braunwald and Sabatine 2012).

The Ottawa Heart Institute Regional STEMI system in Canada (Rashid *et al.* 2016), has applied precedent guidelines based on geographical location in respect of patient proximity to the PCI facility. This has resulted in patients within 90 kilometres of a PCI facility being transported for primary PCI, and those outside this parameter receiving pharmacological reperfusion followed by transfer to a PCI facility. European countries have also recognised the outcomes of CAD in conjunction with the complex logistics around emergency transport times and healthcare deliverance systems. The result of these have likewise shifted towards implementing localised strategies, which incorporate the deliverance of PHT, specifically by trained and qualified paramedics (Quinn, Butters and Todd 2002).

2.5.2 Prehospital thrombolysis within a local context

Transporting patients to a PCI facility in South Africa presents multiple challenges, including vast geographical landscapes, poorly maintained infrastructure, and limited resources. Moreover, MacFarlane, Van Loggerenberg and Kloeck (2005) draw attention to the fact that no official, agreed-upon, emergency response time, currently exists in South Africa. In 2009, the Eastern Cape Department of Health published standardised guidelines, which called for a 45-minute response time in urban areas and 60 minutes in rural areas. However, less than 3.5% of emergency responses met these criteria, with an average response time approaching four hours (Meents and Boyles 2010). Finlayson (2017) also found that the ‘norm’, in terms of EMS response times, as set out by the KwaZulu-Natal Department of Health, of 15 minutes for urban areas, and 40 minutes in urban areas, was unrealistic and, at present, is unachievable.

Dehmer *et al.* (2014) note that most patients presenting with STEMI reside far from PCI provisions, this in consideration of geographical disparities and limited number of facilities, circumstances in which Bjorklund *et al.* (2006) argue PHT would be more viable. Stassen *et*

al. (2017) confirm these disparities within a local context by highlighting that there are only 62 PCI facilities located within eight major centres throughout South Africa. This implies that the majority of patients requiring primary PCI, could reside at least 200 km, or in some instances, as far as 500 km away from the nearest PCI facility.

In the United States, Canada and Europe, the introduction of PHT in order to overcome challenges regarding distance and time to reperfusion has proved to be successful (Danchin, Durand and Blanchard 2008). However, there appears to be reluctance or a lack of appreciation for the implementation of PHT in South Arica, despite evidence as well as context supporting its use (Meel 2016).

2.5.3 Investigating potential barriers to prehospital thrombolysis

To date, there is limited published data regarding barriers to PHT; however, prompted by low uptake of PHT (less than 13% of eligible patients treated) in rural Scotland, Bloe *et al*. (2008) have attempted to understand why there are barriers to PHT. Through a qualitative study, using open ended questions regarding incentives and prohibiting factors in terms of PHT, Bloe *et al.* (2008) predominantly highlighted issues around training, experience, equipment and organisational structures.

Despite their focus on PHT, Bloe *et al.* (2008) did not include paramedics; instead, they refer to local doctors, maintaining that they play a central role in the implementation process of PHT. Interestingly, most physicians involved in the study demonstrated a degree of reluctance, believing that PHT as an emergency intervention was not within their scope of practice but should remain the responsibility of paramedics. This was largely ascribed to limited experience and skill retention in emergency medical care, which in turn raised concerns around administration procedures.

By contrasting, in a cross-sectional study designed to determine the beliefs and attitudes of paramedics regarding PHT, Alanazi, Alrashidi and Aljerian (2014), found that paramedics were confident in their ability to administer PHT. The study, which included more than 130 paramedics, signified that 72% of paramedics believed they could safely deliver PHT. Perhaps more important, however, was that almost all paramedics involved in the study recognised PHT as an essential strategy in overcoming treatment delays; yet, they also felt that hospital oversight was a crucial component in the success of PHT.

With the intention of understanding the implementation process of PHT in the United Kingdom better, research was undertaken in Sweden where approximately 70% of hospitals successfully deployed some form of PHT (Benger, Karlsten and Eriksson 2002). The study comprised interviews at hospitals, dispatch centres and ambulance stations throughout several counties, including Dalama, which has one of the most extensive facilities for PHT globally

(Benger, Karlsten and Eriksson 2002). Through identifying the stages of successful implementation within Sweden, several potential barriers to change were identified, these again including issues such as cost, equipment, training and especially organisational factors.

It should be noted however that, unlike other countries, emergency medicine, specifically prehospital emergency medical care, was not officially recognised in Sweden around the time that PHT was instigated (Skogvold, Wiking and Lindström 2015). Yet despite this, PHT remains a highly successful component of both hospital and prehospital emergency medical care in Sweden (Benger, Karlsten and Eriksson 2002). This suggests that beyond more discernible barriers – which include logistics, such as training, cost, equipment and even organisational implementation factors – other barriers may include actual healthcare systems.

In a retrospective practice review, in which patients were examined based on the eligibility for both in and out of hospital thrombolysis, Hanson and Williamson (2006) attempted to investigate influential factors regarding the uptake of PHT. After reviewing 57 patients, it was concluded that one of the main barriers of PHT was the rigidity or constraints associated with the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines, specifically regarding patient inclusion or exclusion criteria for thrombolysis.

Inclusion criteria for thrombolysis reflect the inclusion criteria for randomised control trials and depend on two main variables, clinical history and ECG findings. While these variables remain consistent for both IHT and PHT administration, inclusion criteria for PHT guidelines tend to be more conservative, typically excluding complicated cases, such as post-cardiac arrest patients or patients who have had recent surgery.

These stricter guidelines are driven by the perception that the prehospital environment is less predictable than an in-hospital setting and has limited resources or supporting systems for managing adverse outcomes. Naidoo and Castle (2012) acknowledge that while guidelines and/or protocols prove to be effective in guiding the clinical decision-making process, if too restrictive, could inversely limit utilisation and, thus, could affect implementation indirectly.

When comparing the JRCALC with the current South African PHT guidelines, the South African PHT guidelines prove to be less conservative as they mention no upper age limit and allow an extended window for symptoms characteristic during the onset of STEMI. Therefore, the South African PHT guidelines are more aligned with thrombolysis guidelines used in hospital and are subsequently less restrictive than the JRCALC guidelines. However, since South African PHT guidelines are generally based on principles similar to standard PHT guidelines, such as the JRCALC, and especially without having undergone critical testing or analysis, the question remains whether these may present similar barriers.

Thrombolysis checklist

Indications: Acute ST-elevation myocardial infarction within 12* hours of onset of symptoms.

	Primary assessment: Can you confirm the following?	**Yes**	**No**
1	The patient is conscious and able to understand that clot dissolving drugs will be used?		
2	The patient has symptoms that are characteristic of a heart attack (sever, continuous pain in a typical distribution of 15 minutes duration or more without remission?)		
3	The symptoms started less than 12 hours ago? **NOTE:** Consider "stuttering start" MI – many infarcts start this way.		
4	The pain built up over seconds and minutes, rather than starting abruptly?		
5	Breathing does **not** influence the severity of the pain?		
6	**Systolic** blood pressure is more than 80mmHg and less than 180mmHg and **diastolic** is below 110mmHg despite treatment? i.e. Analgesia & GTN for blood pressure and fluid challenge / atropine for hypotension).		
7	The electrocardiogram (ECG) shows abnormal ST-elevation of 2mm or more in at least 2 standard leads or in at least 2 adjacent pre-cordial leads, not including V1. **NOTE:** ST-elevation can sometimes be normal in V1 and V2.		
8	The ORS width is 0.16 seconds (4 small squares) or less, and the left bundle branch block is absent from the tracing? **NOTE:** RBBB is permitted only with qualifying ST elevation. LBBB = QRS 140 ms or greater, small narrow R wave in V1 & V2 with big S wave; tall upright monophasic R in standard Lead 1 and V6.		
	Secondary assessment (contra-indications): Can you confirm the following?		
9	The patient is not likely to be pregnant, nor has delivered within the last 2 weeks?		
10	The patient has not had an active peptic ulcer within the last 6 months?		
11	The patient has not had a stroke of any sort within the last 12 months and does not have any permanent disability from a previous stroke?		
12	The patient: has no diagnosed bleeding tendency, has had no recent blood loss (expect normal menstruation); and is not taking Warfarin (anti-coagulant) therapy?		
13	The patient has not had any surgical operation, tooth extractions, significant trauma, or head injury within the last 4 weeks?		
14	The patient has not been recently treated for any other serious head or brain condition?		
15	The patient is not being treated for liver failure, renal failure, or any other severe systemic illness?		

If all answers are YES…Thrombolysis should commence.

Figure 2.2: South African thrombolytic checklist

Source: Naidoo 2014.

2.6 Evidence-based practice and the transition to clinical application

Healthcare is constantly evolving, and healthcare professionals are continuously presented with new healthcare research aimed at optimising patient care and clinical outcomes. Continuing research in healthcare has given rise to the concept of EBPs, which represents the method of combining the best and most current research evidence with relevant and clinical expertise (Sackett *et al.* 1996). However, despite the purpose and intensions of EBPs, they are typically slow to assimilate from the stage of development to installation and actualisation within actual practice. Gallagher-Ford *et al.* (2011) highlight that, whilst numerous EBPs have come to fruition, along with validation of their merits, there has historically been less emphasis on the means and understating of requirements or processes needed in order to install EBPs.

A prime example of this is represented by the implementation of PHT, an EBP, which has demonstrated a reduction in mortality rates by reducing the time from cardiac symptom onset to drug administration, and thus could improve the healthcare profile in South Africa. Not unique to South Africa or PHT however, the integration of newly adopted healthcare policies, effective practices and the healthcare systems have traditionally been a problem area for many healthcare organisations (Kristensen, Nymann, and Konradsen, 2016). Research has shown that nearly 50% of all patients in the United States and Europe are disadvantaged because of not receiving new, evidence-based healthcare interventions, which have, at some level, failed implementation (Haines, Kuruvilla and Borchert 2004).

Published data demonstrates that new healthcare innovations, even those supported by compelling evidence, take an average of 17 years to actualise in the field (Green *et al.* 2009). A primary example of this actualisation delay or failure to innovate in healthcare, is routine X-rays in pregnancy, a detrimental practice that continued for more than 20 years after well-documented evidence had advocated change (Benson and Doubilet 2014). This phenomenon of delayed actualisation not only resonates within healthcare practice in general, but also in the prevailing healthcare climate in South Africa, where despite advancements in EBP research, it appears that EBPs such as PHT remain inactive, and/or subject to a form of 'passive diffusion' (Forland *et al.* 2013; Young *et al.* 2016).

Regardless of the ability of EBP to reduce health disparities, the lack of relevant knowledge, in terms of how to implement EBPs at a level required to have an effect and across different contexts or environments, has given rise to the field of implementation science. The consideration is that evidence-based research has traditionally been conducted in a controlled setting or an 'ideal world' environment (Green 2008), and the issue then presents itself in translating research findings into feasible, acceptable, cost-effective and setting-specific interventions (Green *et al.* 2009). However, this disconnect between research supporting EBPs and their clinical actualisation or practice, as well as how to build strategies designed to implement EBPs has since been well documented in the implementation sciences.

2.6.1 Implementation science

> The way in which a change process is conceptualized is far more fateful for success or failure than the content one seeks to implement. You can have the most creative, compellingly valid, productive idea in the world, but whether it can become embedded and sustained in a socially complex setting will be primarily a function of how you conceptualise the implementation-change process (Sarason 1996: 78).

As highlighted by the current study, the key to understanding why PHT has not been actualised in South Africa lies in identifying with the process of implementation and the sciences that constitute this domain.

The term 'implementation' refers to the realisation of an intervention becoming routine practice, essentially involving the process of engaging an idea or design and providing it within a real-world context (Fixen *et al.* 2005). Despite appearing at times to be a seemingly straightforward concept, numerous industries or organisations, including healthcare, often struggle with the process of implementation (Brownson, Colditz and Proctor 2012).

Bauer *et al.* (2015) highlight the misapprehension of implementation by explaining that it is neither a spontaneous nor a passive exercise but, instead, it resembles a series of incessantly complex processes. Fixen *et al.* (2005) further explain that the development of an intervention is typically the first step in any process involving change, thereafter, transferring and maintaining these changes in a real-world setting, require extensive measures. Another consideration is that clinical research is typically conducted within a controlled or ideal world environment, which essentially has no bearing on whether the findings can be translated into feasible, cost-effective, setting-specific innovations (Suvarna 2018).

Additionally, relevant knowledge of how to implement or develop innovations to scale and across various contexts, has been for the most part, unavailable, that is at least until the emergence of implementation science (Bauer *et al.* 2015).

The field of implementation science evolved from the desire to recognise and overcome challenges related to the systematic uptake of research or evidence-based theories into actual clinical practice (Bauer *et al.* 2015). Barriers to implementation often arise at various levels due to the multiple dynamics located throughout organisational settings, especially within organisations which are not susceptible to or distinctively ready for change (Rogers 2003). Retrospectively, challenges regarding organisational change reflect a lack of appreciation or understanding of the complexities inherent in the implementation sciences (Kitson *et al.* 2008). Described by Fixen and Blase (2009) as the missing link between research and practice, or 'the how-to in science to service', implementation science bridges gaps between theory and practice, promoting methods that support and sustain knowledge transition.

Prior to the emergence of implementation sciences, clinical research and, by extension, EBPs were empirically driven and therefore were guided purely by either observations or experimental outcomes. This developmental change by observation and/or experimentation is typically referred to as 'passive diffusion', and despite its inefficiency, it remains common across professional disciplines. Due to its inability to achieve or sustain implementation,

passive diffusion has since resembled what Eccles *et al.* (2005: 108) describe in clinical research as an “expensive version of trial and error”.

In terms of the utilisation or application of implementation science, however, a systematic review of 235 studies detailing implementation processes over an almost 100-year period indicated that less than 23% had applied implementation theories (Davies, Walker and Grimshaw 2010). This suggests that implementation science and theoretical underpinnings of implementation strategies are undervalued, neglected or altogether misunderstood

2.6.2 The clinical concept and stages of implementation

The word ‘implement’, comes from the Latin *implere*, meaning to enact or carry an intention into effect, while ‘implementing’, represents the gerund form of ‘implement’, referring to the process or action, which is derived from the verb itself (Peters *et al*. 2013). Meanwhile, the term ‘implementation’, although also referring to the process of implementing, more accurately depicts the stage that is reached once the implementing process has concluded.

Although seemingly irrelevant, as the current study highlights, the semantics among these concepts are essential, as they reflect whether PHT, as an EBP, has yet to be implemented, or has been implemented, but remains to be instigated in South Africa. Moreover, it is also important to distinguish between ‘instigation’ and ‘implementation’, the former referring to incitement or causation, and the latter resembling an applied or accepted practice. Subsequently, instigation, also an active process, refers to influential actions or driving forces within the context of implementing and therefore the current study would argue, represents a sub-domain of implementation.

To reiterate, the concept of implementing represents a series of specific and purposeful actions, which if carried out or implemented, constitute an accomplished as well as accepted activity that is uniquely adapted to but also sustained within its intended setting (Lane 1981). The issue in this regard, as highlighted by Fixen *et al.* (2009), is that organisations tend to underestimate this series of actions within the implementation process, causing innovations to fail in transcending past installation, and/or initial implementation, towards full or actual implementation. In order to conceptualise the clinical concept of implementing and, in turn, implementation, the functional stages of the implementation process are outlined below:

- Exploration

The stage of exploration resembles a critical starting point in the implementation process, essentially improving the success of implementation by identifying resources required for the innovation and assessment of the readiness or suitability of the environment (Romney, Israel

and Zlate 2014). Through primary exploration, this initial stage assists in creating adaptability, which is especially useful when the innovation is set to reach the final stages of the implementation process (Smith *et al*. 2014). Moreover, the exploration stage identifies the need for change and reflects steps that would otherwise have been taken prior to the installation and/or implementation of PHT in South Africa, which would include clinical validation research.

- Installation

Once key resources as well as processes have been identified and recognised, the installation stage is designed to acquire and appropriate the resources and processes in order to engage the innovation. This stage includes multiple logistical aspects, which characteristically encompass access, policies, guidelines and even staff or tools required to actualise the intervention (Saldana 2014).

- Initial implementation

During this stage, the intervention is primarily put into action with the aim of analysing its performance and functionality in the intended environment, after which it adjusts either the intervention or implementation supports that enable the intervention. Joyce and Showers (2002) cite initial implementation as one of the more complex stages in the implementation process, explaining that to be successful, initial implementation requires extensive supportive measures from both internal as well as external sources. Schofield (2004) concurs with the difficulties of initial implementation by further explaining that in addition to external bearings and inner organisational substructures, dissemination strategies must be established. In contrast to other stages, initial implementation also bears the awkwardness that may follow from challenging the so-called status quo, specifically in terms of existing practices and formulated perceptions regarding change (Fixen *et al*. 2009).

- Full implementation

Full implementation, as the name suggests, represents implementation completion, and is achieved when an innovation is considered standard practice with a suitable form of quality control or governance overseeing the way in which it is performed (Smith *et al*. 2014). Alternatively, Fixen *et al.* (2009) explain that full implementation is determined when an innovation has reached a capacity of at least half of its constituents, in other words when 50% or more of the intended individuals are engaging in the use of the innovation. Lastly, the consideration is that full implementation is inherently difficult, especially within the organisational setting. Amongst multiple influential factors within an organisation, policies develop, staff turnover, and systems evolve, creating ongoing challenges in the ability to adapt to change (By 2005).

- Expansion and Scale-up

Expansion and/or scaling-up represents an added final stage of implementation (Smith *et al*. 2014), and the goal of the which is to expand the innovation in order to sustain its effectiveness and maintenance. This additional stage ensures innovation fidelity and is achieved by purposely expanding the innovation across organisational sites that intend to benefit from actively using the innovation.

2.6.3 Implementation gaps

Described as the result of poor or insufficient implementation, implementation gaps are considered one of the fundamental challenges within the implementation process, signifying implementation failure or inaction (Rasmussen *et al.* 2018). Through an alternative perception, Adams (2016) however argues that implementation gaps, while perhaps resembling a degree of inaction, should not imply failure, suggesting that such interpretations of implementation gaps are based on rational tenets, which naturally shape normative expectations. To this point, the argument is that implementation gaps instead of failure, represent policy change and additionally offer value in terms of opportunities to reflect critically, therefore allowing a better perception of implementation and the challenges that lie within this process.

While implementation gaps may in some circumstances be deemed useful, this is outweighed by the consideration of policies or guidelines, which if implemented effectively, could maintain cost-effectiveness or improve clinical outcomes (Haines, Kuruvilla and Borchert 2004). Moreover, the understanding of implementation gaps is that adopted innovations are not always employed with fidelity, and interventions even if employed with fidelity, are not always sustained indefinitely (Fixen *et al.* 2005). Moreover, even when an adopted intervention is employed with fidelity, this does not imply that it would be on a scale sufficient to solve the social problem at hand or even have an effect within its intended environment (Carroll *et al.* 2007).

Conclusively, the concept of fidelity in implementation refers to the scale to which the intervention has been delivered with higher levels of fidelity correlated with greater success across various implemented programmes or practices (Carroll *et al.* 2007). Capable of measuring fidelity through observation and experimentation, implementation research aims to address implementation gaps by attempting to understand challenges within the implementation process effectively.

2.6.4 Implementation research

Despite the terms often used interchangeably due to similar objectives, and perhaps broad or sometimes misleading descriptions, as the current study highlights, implementation research

differs somewhat from implementation science. While both constructs seek to bridge the gap between what is known in literature and what is done in the field, implementation research intends to understand exactly why or how interventions function within their intended environments and examines methods on how to improve these functions. In contrast with implementation science, which refers to the body of knowledge regarding the systematic uptake of EBP, implementation research focuses on specific variables and/or conditions, which influence change, thus represents a crucial sub-domain of implementation science (Peters *et al.* 2013).

2.6.5 Implementation drivers and diffusion

Critical towards the capacity and functional infrastructure, which in turn would support and/or enable implementation, implementation drivers primarily fall into three categories, namely competency, organisation and leadership. Considered mechanisms, competency drivers refer to training and development in order to improve and sustain interventions, while organisational drivers relate to supporting systems within the environment (Halle, Metz and Martinez-Beck 2013). Leadership drivers on the other hand, comprise strategies designed to address challenges related to inadequate leadership and provide guidance as well as support in terms of management processes (Jackson 2000). While most organisations would likely attest to already having specified or selective staff, internal training and/or development programmes, as well as supervision, Fixen *et al.* (2009) explain these often lack a lens of implementation.

2.6.6 Implementation sciences in healthcare

Recent years have demonstrated a paradigm shift in terms of thinking about how to deliver better care to patients, especially in instances of critical care, and how to improve these levels of care on a continual basis (Vincent and Creteur 2015). Change does not occur accidentally or passively through osmosis, but instead requires agents of change to activate steps in order to initiate and then manage the change process properly (Wensing 2015). This is especially true in diverse or specialised disciplines that comprise multilevel influences, i.e. healthcare, which functions as a result of numerous intertwined units, communities, resources, services and policies (Al-Abri 2007). Fundamentally, context matters, especially within complex settings, and implementation science helps us understand why change, such as new technologies, medical procedures or clinical skills, are not taken up across an entirety or ubiquitously within healthcare.

2.7 Conclusion

If new policies or guidelines are to reach full implementation and in turn benefit their intended populations, they must be accompanied by effective dissemination, and by extension, by implementation strategies. South African EMS as well as other healthcare organisations

should acknowledge or at least consider the application of implementation strategies, specifically those which evolved from healthcare interventional trials and that would embrace or support PHT as an EBP. Healthcare organisations, departments and even government need to make concerted efforts to improve healthcare outcomes by supporting research environments, specifically those which focus on scaling up healthcare innovations efficiently.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Introduction

This chapter provides an outline of the methodology applied in the study, namely a description of the research design, an overview of data collection, data analysis procedures, and verification strategies. The chapter also provides a summary of the constraints of the study, and describes some of the measures taken to reduce them. The chapter concludes with a summary of the ethical principles adhered to during the study.

3.2 Research design

The study comprised a qualitative inquiry based on a design of a case study within a South African private emergency medical service (EMS) being conceptualised as the 'case'. The primary aim of qualitative research is to study phenomena within their natural environment and without imposing any measure of control variables, essentially investigating events within a real-world setting (Creswell 2009). In terms of investigating, Van Griensven, Moore and Hall (2014) emphasise the inherently complex nature of issues within the health sciences, often as a result of multiple associated dynamics and thus assert that investigative processes require in-depth analysis. Malterud (2001) supports this assertion, although arguing that qualitative research methods provide a unique and valuable contribution by enhancing conceptualisation through efforts aimed at improving understanding.

In relation to the qualitative paradigm, case study analysis is described as a strategy comprising empirical investigation regarding specified, contemporary phenomena, within an authentic context (Darke, Shanks and Broadbent 1998). In addition, case study methods are particularly appropriate to intricacy as they allow for the multi-faceted exploration of nuanced phenomenon within a natural environment through their application and when conducted thoroughly (Crowe *et al.* 2011).

It may be said that the key to in-depth understanding lies in contextualisation, which may be achieved by accounting for influential factors within or around the phenomenon under investigation (Bradshaw, Atkinson and Doodly 2017). Contrary to research methods involving experimentation, those which typically admit artificial events, case study methods appreciate and enable a real-world perspective (Yin 2009). This is because case studies occur as a result of the detailed investigatory processes that facilitate insights which might not have been possible if other conventional research methods were used (Grey 2014).

Although there is no exact definition of a 'case study', consensus describes the method as theoretical generalisability, rooted in focused investigation and involving an entity plus its

environment (Gustafsson 2017). Unlike experimental research, a case-study does not intend to replicate phenomena in an experimental setting, and instead appeals to the ability to greater understand phenomena (Yin 2009). The rationale for the research design in the current study is encapsulated in the view of Yin (2009: 18), of a case study as “an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between the phenomenon and context and not clearly evident” Conclusively, a case study enables researchers to investigate phenomena and appreciate uncontrollable mechanisms within a given natural environment, thus enriching the quality of the resultant understanding (Iacono, Brown and Holtham 2011).

3.2.1 Case study classification

Among various types of case studies that exist, the most common comprises either a multiple or single-case study design with the decision to apply one over the other generally being guided by the research aim. This decision to refer either to a multiple or to a single-case study design is based primarily on whether or not the intention of the research is inherently descriptive, exploratory or comparative (Baxter and Jack 2008).

It should be noted that, while qualitative analysis and, by extension, case study analysis enable an in-depth perspective relevant to explaining a phenomenon, it can also constitute a wide-open data corpus (Darke, Shanks and Broadbent 1998). This implies that data can typically create an input or testimony overflow that could then potentially complicate either detailed and/or specific analysis. While the nature of this research was exploratory and thus incorporated a case study methodology, a single-case study design was employed to focus the information on targeted variables to provide a more detailed analysis.

3.2.2 Case study setting

Together with a two-tier medical system that incorporates various levels of healthcare across both public and private sectors, South Africa encompasses nine provinces, which are self-regulating, each possessing regional healthcare governing structures (Katuu 2018). In the current study, this resulted in explicit challenges with regard to a single, qualitative case study design since the research question attempted to address the phenomenon in question on a national level. Although operating under a national emergency number scheme, and national healthcare law, public EMS, known as ‘provincial services’, fall under regional healthcare governance and are therefore under provincial jurisdiction (Huyssteen 2015.) Alternatively, specific private EMS operate on a self-dispatching number scheme and in terms of precinct, maintain a national footprint (Holgate 2015).

While the study may not have ensured the widest possible patient demographic, as the private healthcare sector represents approximately 17% of the population (Council for Medical

Schemes 2015), it was felt that including a nationalised service would create the capacity for uniform data. Furthermore, it could be recognised that South Africa's private healthcare sector often acts as catalyst in facilitating change within the country's general healthcare profile; notably, the private EMS being the first to initiate prehospital RSI, (Gunning *et al.* 2013), thus, selecting a private EMS was deemed appropriate. Accordingly, a single, nationalised private EMS was used in the study. Incidentally, during the initial planning of the study, inclusion of provincial EMS data was considered, while the choice of province(s) was to be supported by the regional statistics of STEMI prevalence. However, the inclusion of provincial EMS as a research site was declined by the respective EMS authorities.

It is noteworthy that private EMS operate on a private-for-profit basis (Huyssteen 2015), which in some instances may be considered mutually exclusive to medical health insurance clients. However, all ambulance providers are ethically obligated to treat all patients equally, and they are subject to scrutiny by the National Department of Health (DoH), which requires all EMS systems to meet national healthcare standards (National Health Act 2003).

Operating from several private hospitals located throughout South Africa, the EMS selected for the purposes of the case study comprised a range of both national and international emergency services. These encompassed emergency response vehicles, advanced life support (ALS) units, aeromedical services and the provision of ECPs who were able to perform PHT as part of their scope of practice. Thus, in addition to the considerable resources which generated an acceptable database, the case study, through its autonomy of ECPs, fulfilled the requirements of the research in terms of the national interest of the study.

3.3 Methods and techniques

The next section outlines the methods adhered to within the study, detailing the procedures and measures employed.

3.3.1 Sampling methods and criteria

Qualitative research often attracts criticism as a result of concerns about the reliability of generalising the research findings, specifically in view of the limited sample sizes and the question whether it provides an accurate representation of the data (Anderson 2010). In contrast to random sampling, purposeful sampling methods result in participants being selected based on selective criteria, but at the same time, objectively sound judgment. As a result of a well-recognised sampling strategy (Vehovar, Toepoel and Steinmetz 2016), purposeful sampling identified participants as key informants who could contribute to the study, based upon knowledge and expertise.

Specifically, the participants represented divisions and/or branches of the EMS, including but not limited to managerial, governance, educational and clinical operational positions. The

sampling method was further facilitated by a snowballing technique, which refers to a process whereby participants identify other participants with the required characteristics relatable to the study in question (Brink, Van der Walt and Van Rensburg 2012).

In view of the fact that purposeful sampling is not based on a minimum or maximum number of responses, sampling continues until data saturation has been reached, i.e. a point at which no new data is emerging (Guest 2006). Thus, the sample population is not predetermined; instead, it is based on data analysis processes, specifically the ability to identify new information directly. In this study, eight participants were approached, with all but one agreeing through primary responses to participate in interviews.

Although larger sample sizes may be beneficial, they do not always apply to qualitative studies and are often considered unnecessary due to the increased involvement of the researcher and the participants (Thompson 1999). In addition, intentionally increasing the sample size may lead to additional cost and/or time constraints and extend the risk of ethical dilemmas unnecessarily. Guest (2006) supports the notion of a limited sample population and concludes that a smaller and more defined sample size could provide the information needed to meet all the qualitative research requirements.

However, a limited sample size is appropriate if the chosen sample population has the requisite skills and expertise in the field of investigation or can at least testify from a reputable and informed position (Malterud, Siersma and Guassora 2015). Since the primary focus of this study required a detailed explanation and not generalisability, the specific sample size was narrowly defined and supported a thorough understanding of the issue, in line with the study objectives.

3.3.1.1 Inclusion criteria

The section below outlines the eligibility criteria, identifying the participants who were included within the research study, namely selected emergency care/prehospital providers of the chosen private EMS, including:

- clinical operations, specifically emergency care/prehospital providers registered with the HPCSA on the Emergency Care Practitioner register;
- clinical governance, managers or directors or chief executive officers, encompassing various departments or branches within the selected private EMS; and
- educational or academic staff directly related to the selected private EMS, i.e. mentoring staff and independent or external contractors operating or providing teaching or training.

3.3.1.2 Exclusion criteria

The section below outlines the ineligibility criteria, identifying participants who were excluded from the research study:

- emergency care or prehospital providers not registered on the Emergency Care Practitioner register were excluded as PHT does not fall within their scope of practice, apart from persons within the selected private EMS in certain organisational positions and with relevant experience or knowledge, i.e. those who can contribute to the study, such as managers or directors.
- emergency care or prehospital providers from public EMS; and
- smaller (non-national) private ambulance services based on limited geographical scope and resource capabilities.

3.3.1.3 Pilot test procedures

A pilot test of the research questions was undertaken to highlight potential study design weaknesses (Van Teijlingen *et al.* 2001). The pilot study was conducted as a 'mock' interview involving operational and academic ECPs. Those individuals involved in the pilot tests were excluded from the main study group. While Connelly (2008) recommends a sample size of 10% of the actual larger, parent study, Hertzog (2008) cautions that the determination of pilot test samples may not be straightforward due to multiple influential factors, such as the unavailability of benchmarks pertaining to the parent study samples.

As the focus of the pilot test was to scan for extraneous variables not previously considered during question design, it was decided to undertake as many pilot tests as possible with the purpose of limiting undetected, confounding factors as well as to attempt to achieve optimal performance in preparation for the parent study. The pilot test resulted in four recorded interviews which, when assessed retrospectively, was well within the recommended pilot test guidelines given the parent study sample size. The 'mock' interviews resulted in minor changes to the structure of the questions to improve the flow of questioning.

3.3.1.4 Data access and gatekeeper permission

In compliance with the Protection of Personal Information (POPI) (Act No. 4 of 2013), which pertains to section 14 of the South African Constitution, specifically the right of access and organisational compliancy regarding personal information, a formal request was admitted to the EMS organisation. Once potential participants had been identified, permission to access individuals within a professional capacity and strictly for research purposes was sought from the EMS organisation (Annexure A).

In addition, participant information was sourced through the snowballing technique as a collective resource technique, enabling access to contact information which may not have been readily or previously available. The participants were initially contacted telephonically, allowing for informal introductions, after which participants were emailed formally and provided with a follow-up briefing as well as full information letters (Annexure B).

3.3.1.5 Data collection methods

The research was conducted through separate sessions facilitated by the recording of notes and audio recordings (Annexure B). All interviews were carried out by me as the researcher, to guarantee that the people involved were treated anonymously and confidentially. The interviews were conducted at the preferred location of the participants and at a convenient time. Cohen, Manion and Morrison (2000) explain that interview methods are valuable means of collecting data if carried out systematically and are capable of providing sound, reliable data.

Creswell (2009) concurs with this assertion, and explains interviews as an integrative system to gain an in-depth perspective by enabling interviewees to participate in their analysis of a phenomenon. Wildemuth (2009) explains that interviews afford the researcher the possibility to collect a variety of information, while Seidman (2006) maintains that interviews create a unique continuity of order and freedom, as opposed to surveys, which can be restrictive.

The interviewing strategy used in this study was that of semi-structured interviews and described by Longhurst (2010) as a conversational interchange where researchers obtain information from participants through a selection of questions. Compared to ad-libbed or unstructured interviews, semi-structured interviews provide consistency across interviews, which in turn creates reliable results (Wildemuth 2009). Semi-structured interviews are also inherently adaptable, enhancing the exploratory aspect of the interview, making it a useful technique for the investigation of new phenomena or phenomena for which very little research has been carried out (Creswell 2009).

The combination of pre-prepared questions and semi-structured interviews helped me to focus on the research issue while allowing participants to discuss the topic from their own viewpoints. In other words, I was able to maintain control over interviews without influencing direction, while also allowing participants freedom to express ideas and opinions, delivering what was to their best knowledge, authentic testimony.

The interviews were created using a scheduler application, Doodle, an online calendar tool that allows parties involved to log in safely and synchronise times and dates accordingly upon invitation (Kyei-Blankson *et al.* 2015). All individual online interactions were regulated by Doodle, making all activities invisible to shared or other users and safeguarding participants' rights through confidential features.

Once the times and dates had been specified by Doodle, the study participants were contacted individually by e-mail to confirm their participation and to establish a location. At the participants' discretion, possible locations were place of work, private residence or, alternatively, a neutral venue, such as a public place. Based on the preferences of the participants, the majority of the interviews were conducted at the workplace or private residence of the participant and only one interview was conducted in a neutral location with prior verbal consent from the local administration.

Semi-structured interviews were conducted with no repeat or follow-up interviews deemed necessary. Interview discussion times ranged from 17 to 47 minutes, with an average interview time of 30 minutes. No interviews were terminated early, or failed to reach completion, with all questions receiving a level of satisfactory response. Transcripts were stored securely and not disseminated back to or among participants for comment or correction. Data saturation was reached during the fourth interview, and was confirmed in subsequent interviews, which eventually totalled seven.

During all interviews, participants were ensured of their rights and provided confidentiality assurances. Furthermore, the use of audio and video recording devices was explained for the purpose of participant consent. During interviews, camera angles were reversed, focusing on me as interviewer, allowing additional confidentiality and the potential for interviewees to feel comfortable, which was explained to participants again. While reverse camera techniques might be criticised for missing 'reaction shots', it also limits distractions, and enables interviewers to maintain eye-lines, which in turn allowed the participants to focus on the discussion, instead of on the interview procedure.

Finally, Creswell (2009) recommends the use of an interview protocol guide for semi-structured interviews, with the aim of including all relevant details, such as the date, time, and place of the interview. An interview protocol guide not only ensures uniformity across interviews, but also serves as a reminder for concluding statements as well as acknowledgments, and provides the necessary prompts for detailed answers. Following this structured approach, I created a protocol guide, which included introductions, a description of the study, assurances of confidentiality as well as a list of direct questions with follow-ups and prompts (Annexure C).

3.3.1.6 Data collection tools

The study adhered to the framework domains provided by the CFIR, including intervention characteristics, the external organisational environment, the internal organisational environment, individual characteristics and processes. The CFIR interview guide, a well-adapted tool for exploratory and qualitative research (Damschroder *et al.* 2015), informed the interview questions on this subject. The CFIR guide provides a taxonomic system of questions

that allow an ideal starting point to develop and customise researchers' own questions (Breimaier et al. 2015)

It is important to note that the CFIR guideline is non-specific, although it is oriented towards implementation, and therefore implies that not all the structures in its field address the needs of individual studies (Keith *et al.* 2017). In order to select and ensure the most appropriate questions for this study, a priori assessment was adapted to determine the choice of structures. Once a priori assessment had been completed, a menu-of-constructions approach was applied (Keith *et al.* 2017), including the most relevant CFIR constructs and questions from the questionnaire guide, which were determined to be in line with the objectives of the study.

During this process, I independently evaluated questions in terms of their importance and degree of influence, in particular their ability to identify barriers to PHT in South Africa (Annexure C). Once formulated, questions were examined for context and applicability by my supervisors and submitted to the pilot test as a further confirmatory measure. I conducted scheduling interviews after my supervisors and I had completed the questioner tool, which was considered appropriate and relevant for the purposes of this study.

3.3.2 Data analysis and interpretation

Evaluating qualitative research can sometimes spark controversy, where researchers objectively debate the stifling of methodological development in terms of whether the variety of qualitative approaches should be subjected to more defined criteria. (Hammersley 2007). In order to suit both sides of this qualitative controversy and in order to assure quality of the research, a template analysis approach, in conjunction with thematic analysis, was employed, through the theoretical framework of the study, i.e. the CFIR.

While the study did not adhere to a mixed methods approach in that it only incorporated qualitative data, it did however, combine both a theoretical and data-driven strategy, allowing a heterogeneous method of data analysis (Darke, Shanks and Broadbent 1998). The data-driven strategy was supported by the conceptual framework, CFIR and the theory component was based on thematic analysis. While both strategies possess merit, theory-driven approaches are somewhat favourable within scientific environments due to predictive accuracy, while data-driven approaches are preferred in industrial analysis because they typically allow for a wider demographic. Mason (2006) asserts that linking data and theoretical approaches extends the logic of qualitative explanations and therefore provides an ultimate theorisation in terms of a research conclusion.

3.3.2.1 Theory-driven approach

As the conceptual framework and main theoretical driver of the study, the CFIR played a key role in identifying barriers within the context of the objectives of the study and facilitated

implementation strategies in line with recommendations of the study. The CFIR is not only capable of determining implementation barriers within implementation processes but it can also reinforce implementation strategies capable of mitigating barriers and even leveraging potential facilitators (Smith *et al.* 2015).

Identifying or facilitating removal of barriers, testing and further developing implementation strategies are crucial components of the implementation sciences. However, the process of developing specific implementation models is inherently difficult, not only because of the complex nature of implementation itself, but also as a result of discrepancies within the implementation sciences. Waltz *et al.* (2014) consequently set out to stabilise research efforts and ultimately advance the field of implementation science by developing a universally strategic implementation matching tool.

With the intention of refining implementation strategies, selective panels of experts in the field of implementation science developed the expert recommendations for implementation change (ERIC). The ERIC is deemed an effective implementation matching strategy tool (Annexure E), comprising 73 established implementation strategies, which align with specific CFIR constructs (Waltz *et al*. 2014). Data from the current study was uploaded into the ERIC tool within Microsoft Excel software, and then a series of potential implementation strategies was computer generated (Annexure F).

The ERIC tool was also employed to calculate the top 10% of matching strategies, which included individual percentile strengths of each strategy. The matching strategies were then assessed based on their relevancy in line with both the conceptual framework and study objectives, which in turn provided the basis for the recommendations of the study.

3.3.2.2 Data-driven approach

In line with the exploratory nature of the study, thematic analysis was also employed during the data interpretation and analysis phases of the research project. As an effective mode of inquiry in qualitative research, thematic analysis allows researchers to investigate phenomena fully in order to obtain a detailed understanding of such phenomena (Elo and Kyngas 2008). Fundamentally, thematic analysis serves to compartmentalise data by describing the meaning of segments within the literature accurately and identifying categories that result in patterns otherwise referred to as ‘themes’ (Maguire and Delahunt 2017).

However, since there are no fixed rules about what constitute themes, and given its flexibility in supporting both deductive as well as inductive approaches, thematic analysis has, at times, been criticised (Attride-Stirling 2001). Nevertheless, despite drawing criticism regarding various levels of flexibility, thematic analysis is viewed as reliable in relation to objective, systematic and content analysis and represents a well-established qualitative research method

(Joffe 2012). Subsequently, concerns of criticism regarding any level of flexibility were mitigated through incorporating a reputable theory-driven element, referring to the CFIR.

Primarily, the principle of a theory-based approach imbedded within the study through the conceptual framework would otherwise account for predictable results and promote trustworthiness beyond that of an exclusive data-driven hypothesis (Nowell *et al.* 2017). Other criticisms of thematic analysis or qualitative analysis in general were moderated in consecutive sections within this chapter, specifically in discussions of trustworthiness and mitigation of biases.

Through the identification and analysis of patterns, thematic analysis goes beyond impressionistic observation and codifies content to enable a more specific and objective understanding (Braun and Clarke 2006). From a research perspective, thematic analysis is unobtrusive, inexpensive and capable of providing measurable, replicable text comprehension while capturing large amounts of information (Herzog, Handke and Hitters 2019). Braun and Clarke (2006) offer a six-step thematic analysis guide, namely data familiarisation, code generation, theme identification, review, definition and reporting. The next section outlines the six-step guide that was used in the study, and highlights the process and constructive thinking.

- **Data familiarisation**

  In order to identify patterns of meaning within data, the first step involves becoming familiar with the data and, therefore, it encompasses a degree of reading, observation and transcribing (Braun and Clarke 2006). With the aim of familiarising myself with the data, I began this phase by investigating the entirety of the content by listening to the recordings of the interviews and transcribing the data accordingly. Once all the recordings had been documented, the next task was to ensure a comprehensive understanding of the data.

  This was achieved by a purposeful and focused reading of the transcripts. In other words, I read the transcripts with the research question in mind and thus, instead of skim reading, I attempted to understand the content fully and to draw statements from the text. Each transcript was purposely read multiple times with intervals between the reading periods to allow for renewed perspectives and to determine whether new information could be detected.

  In addition, I drafted handwritten notes during all the reading sessions to summarise the content and support the formation of concepts, generating a more complete understanding of the data. Braun and Clarke (2006) suggest that reading meaning into data prematurely could narrow the researcher's analytical vision by limiting the focus to selective aspects instead of the data in its entirety. However, Tuckett (2005)

dismisses this notion by arguing that early and concentrated engagement with literary work sensitises researchers to the data, thus enhancing the data analysis. While aspects of thematic analysis may prove to be laborious, they are also advantageous, allowing researchers to immerse themselves in the data – an integral part of the analysis phase (Braun and Clarke 2006).

- **Code generation**

  Coding can be done either manually (by hand) or through a computer software program. In this study, the coding procedure was performed manually. Code generation involves categorising the content and then systematically compiling the data to create specific information quantities. In contrast to the theme identification, which is typically broad and aimed at the identification of units of analysis, coding characteristics of the raw data allow for a more meaningful evaluation (Boyatzis 1998).

  Although it is useful, Pope, Ziebland and Mays (2000) are cautious about the use of computer software programs designed for qualitative analysis, which can be costly and often involve difficult learning needs. In addition, 'hand transcription' is unique in that it offers an opportunity to become more familiar with the analysis process and the data (Braun and Clarke 2006). I therefore transcribed the codes using a variety of highlighters in order to generate valid concepts, specifically what was most compelling about the data. This included highlighting relevant words, phrases, sentences and/or sections relating to concepts based on the views about why PHT had not yet been implemented.

  Creswell (2009) suggests that researchers consider codes based on what the reader would normally expect to see and any findings that are unusual. However, Braun and Clarke (2006) reject the notion of expected results, suggesting that the discovery of patterns is not an active process, but rather a passive account. Braun and Clarke (2006) also argue that rigidity and strict rules on the identification of the themes are not always applicable, but that sound researcher judgment should be applied. Although selected themes are required to capture even trivial information relating to the research question if they are to be effective, themes need to represent a clear, patterned response.

  Finally, coding is either data-driven, in which case themes are compelled by raw data, or theory-driven where themes are reliant on a conceptual framework for guidance (Braun and Clarke 2006). Again, as the main theoretical driver, which also cites a code book, the CFIR guided the coding process through a template analysis approach, thus resulting primarily in a theory-driven analysis. However, since thematic analysis was

also applied, together with the reinforcement of the CFIR, in prior and subsequent analysis steps, this study can arguably be said to be in line with both theory-driven and data-driven coding principles.

While I found the process of manual transcribing and coding at times tedious, it allowed me to immerse myself in the data, which in turn enabled me to contextualise the research effectively. The process of coding also highlighted the importance of accuracy in identifying themes that instilled a sense of mindfulness of not affixing or projecting my own interpretations onto the data.

- **Theme identification**

  During this phase, the content was further summarised with the development of organised themes, which then interrelated with the conceptual framework and refocused the analysis to define concepts in the study (Braun and Clarke 2006). Multiple coordinating methods formed the theme identification process, including the use of tables, mind maps or different sorting strategies, such as keywords or repetition of words. However, Braun and Clarke (2006) argue that themes should not necessarily stem from repetition or prevalence, but rather from important research aspects.

  The CFIR also provided me with a clear and structured guide for theme distinction, enabling me to separate essential and non-essential data and ultimately give credence to the most relevant information provided through interviews with participants. Therefore, the CFIR provided a sound theoretical basis, enabling codes to be categorised into themes and sub-themes once they had been created.

- **Theme reviewing**

  As an integrative process, the theme review allowed themes to be re-examined in order to ensure compliance with data patterns and, in essence, to capture the study outline through the research objectives. Once all topics had been categorised, they were retrospectively examined to evaluate the calibre and extent of the data supported in relation to the study objectives and primary research. This process included a dual conceptual criterion for the assessment of thematic categories, which Patton (2002) initially cited, refers to both internal and external heterogeneity. In particular, this involved examining themes in order to determine their significance and then to ensure clearly identifiable characteristics.

  In addition, the theme review involved two stages, namely the review of the coded data in order to ensure that it systematically translated into themes and then the evaluation of the themes in order to evaluate their relationship with the data body. Braun and

Clarke (2006) recommend using a thematic map when organising large amounts of information into structures, which can then be translated into themes.

By creating a thematic map, I was able to examine the themes using an analytical paradigm to determine whether they formed coherent patterns, maintained relevance and had identifiable characteristics. Those not considered relevant to the research question or uniquely different from each other were returned to the identification of the themes during which the themes were subsequently revised. Based on this process, some of the themes were supplemented by other themes, classified into smaller components or discarded in favour of new theme applications.

- **Theme defining**

  This step typically involves a selective process in which themes are further defined to conceptualise and refine the study data with specific definitions. Braun and Clarke (2006) explain the theme that defines and refine the concepts, identifying both data-related themes and data-related aspects in the general sense. As a useful tool for the collection, coding, analysis and reporting of data, the CFIR once again provided the context for the topics through its range of evidence-based constructs (Keith *et al.* 2017).

  It is important that themes conform to the broader narrative of the study, which involves a detailed analysis of the individual themes relative to the research question (Braun and Clarke 2006). Additional measures therefore included negative case analysis, a well-sustained method for validating data in qualitative research that takes into account topics by confirming emerging patterns (Mays and Pope 2000). In particular, this process involves actively searching and ultimately eliminating identifiable elements within data that were either not supportive or which contradicted existing patterns.

- **Reporting**

  Once the themes had been identified, the findings which were reported and transcribed were interpreted. The defined themes attempted to capture the essence of why PHT, despite the necessity and authority for its use, has yet to be implemented within South African practice. The reporting phase is presented in Chapter 4 and in Chapter 5. Figure 3.2 below reiterates the research methodology in a clear and systematic way, specifically outlining the area of inquiry and data collection procedures undertaken. The analysis phase consisting of both theory and data-driven aspects, schematically highlights the link between coding procedures and the conceptual framework of the study.

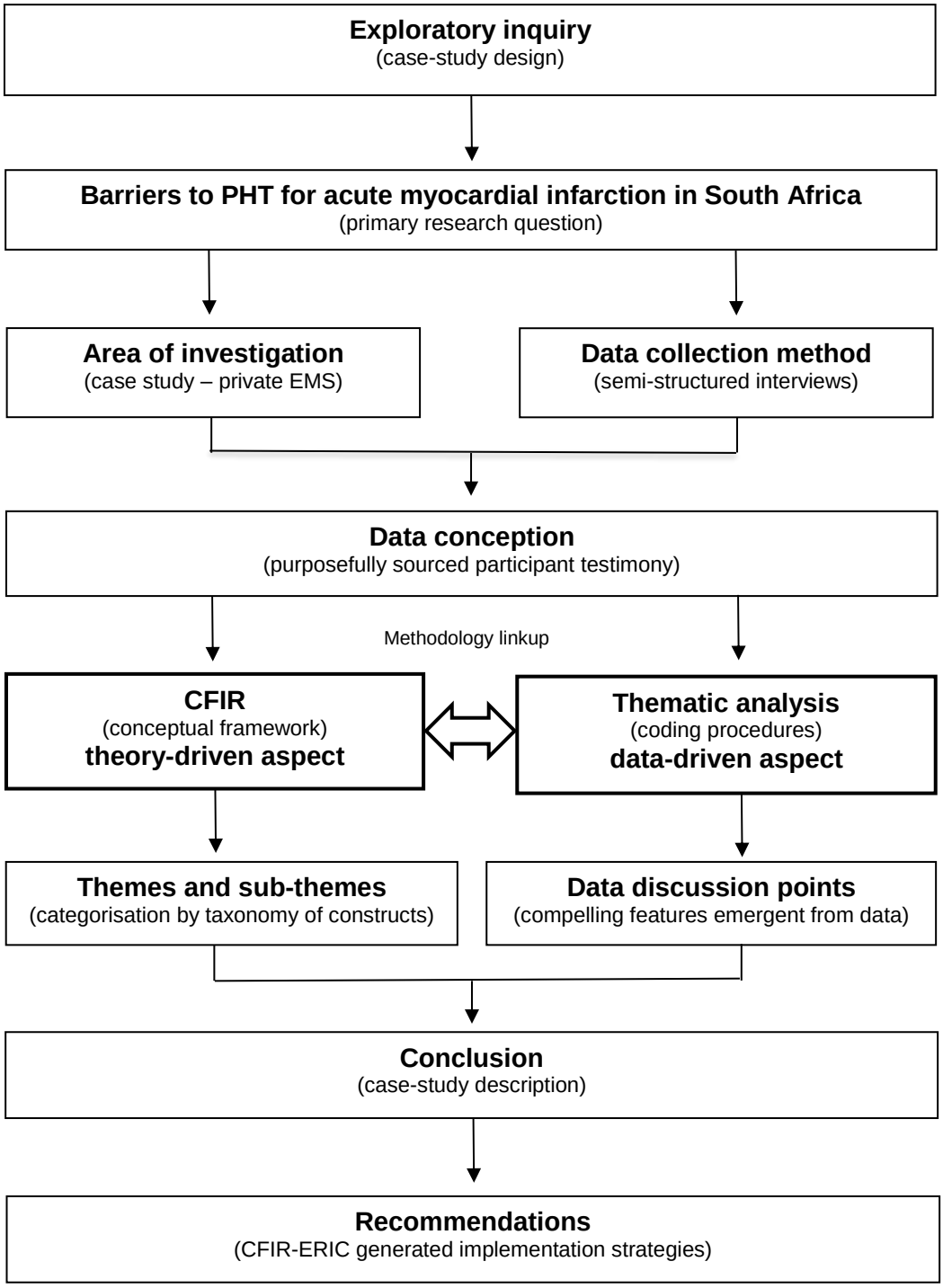

Figure 3.1: Schematic representation of applied methodology within the study

Source: Author's own compilation

3.3.3 Data storage and maintenance

All data collected will be stored in accordance with the data retention policies of the DUT, which require archiving information for a minimum period of five years. In addition to recordings and,

in the event of technical errors, Creswell (2009) recommends that researchers compose handwritten notes during interviews with the participants. In terms of data maintenance, all hardcopies are safeguarded by me as the primary researcher, and electronic information is secured in a computer file, on a password-protected computer. Data disposal procedures will ensure that hard copies are shredded and recycled, electronic data deleted, and any other physical data destroyed in order to maintain confidentiality after a period of five years.

3.3.4 Research bias and qualitative rigour

It is acknowledged that qualitative research falls within the humanistic or interpretative paradigm, which in effect, however, makes it difficult to dismiss individual values or ideas or to dissociate these completely from what can be concluded objectively in the research findings (Hammarberg, Kirkman and De Lacey 2016). Subsequently, and in contrast to quantitative research, qualitative studies are sometimes criticised for lacking scientific rigour, especially since personal accounts and the direct involvement of researchers are subjective, or vulnerable to bias (Morse *et al.* 2002).

It is important to note, however, that bias exists in various degrees, at different levels, and essentially, across all research designs, which presents distinct challenges in eliminating its presence entirely (Smith and Noble 2014). Consequently, the question is perhaps not so much whether biases exist, but rather how this would – in other respects – influence research methods, analysis or conclusions. Therefore, the central tenet in this regard is the extent of measures taken, not only in terms of mitigating bias, but also to ensure trustworthiness of the research findings.

3.3.5 Trustworthiness in qualitative research

Trustworthiness is a crucial component of qualitative research designs, as this enables researchers to illustrate qualitative virtues, those typically outside of quantitative parameters (Given 2008). The essence of this appeals to the believability and reliability of information acquired from external sources, ultimately determining the value of the research (Anney 2015). Kim *et al.* (2012) argue that the analysis of qualitative research findings is essentially as good as the capabilities of the investigator; thus, comprehensive verification methods remain essential to ensure sound results as well as trustworthiness.

However, various definitions, including specific standards or criteria, for defining and evaluating trustworthiness, can be found, with some arguably not suitable for judging the validity and quality of qualitative research (Korstjens and Moser 2018). In order to define the language, and concepts used within the qualitative realm better, as well as to provide a robust level of research validity, Lincoln and Guba (1985) created a series of criteria for establishing trustworthiness.

Extending across multiple research designs and recognised as the pillars of conventionalism in qualitative research, this criteria includes credibility, dependability, transferability and confirmability. Intended to mitigate against potential biases and to enhance validity, which in turn, supports quality of qualitative research, this study incorporated the trustworthiness criteria outlined by Lincoln and Guba (1985) and systematically defines each specific criterion in sections 3.3.5.1–3.3.5.4.

3.3.5.1 Research credibility

Conceivably the most important aspect of quality within qualitative research, credibility resembles a mode of internal validity, referring to the level of truth or confidence that can be entrusted to the research findings, effectively determining whether data is plausible (Korstjens and Moser 2018). Triangulation, a technique that involves the use of multiple data sources, is a well-established validation strategy in the social sciences, which promotes credibility of research findings (Yeasmin and Rahman 2012).

Thurmond (2001) highlights some of the key advantages of triangulation, as it offers a clear idea of the issues, creates innovative ways of understanding phenomena, and challenges integrating theories, which in turn, boosts confidence in the data. Essentially, this is achieved through cross-verification, in which an external source or data point is verified through a convergence of information pertaining to other sources, as a strategy to test its validity. Despite this, however, Patton (2002) cautions against confusing the purpose of triangulation, with expectations of achieving consistency. Patton also points out that inconsistencies should not be regarded as weakling the evidence. Instead, he argues that inconsistencies, if any, should be viewed in a productive sense, as further opportunities, for deeper, more meaningful data to be discovered than might otherwise be the case.

Patton (2002) goes on to describe four central triangulation methods, namely methodological, theoretical, analytical and data triangulation, otherwise known as source triangulation (Carter *et al.* 2014), which also defines the triangulation method employed in this study. Based on this, data sources for the current study encompassed a heterogeneous mix of informed perspectives, delivered from an array of organisational stature and levels of experience. Specifically, data was collected from participants comprising various roles and positions within the case study or organisation in question, including managerial, directorial, operational and clinical governance. However, the result of variant data sources was acquired within the scope of a uniform data collection method and case study, i.e. semi-structured interviews within a single organisation, thus, also ensuring consistency.

Furthermore, credibility was enhanced by the incorporation of a structured pilot study test, which enabled objective and relevant feedback from experienced pre-hospital practitioners. It

was noted that an understanding of the real and perceived barriers to PHT was at the basis of this research. The nature of the research question (Section 1.4) indicated that qualitative research was an ideal methodology for research.

3.3.5.2 Dependability

Another crucial aspect of trustworthiness, dependability, adheres to consistency, specifically referring to research findings over time, as well as the reliability of the research instrument, which incidentally, in qualitative research, is the researcher (Pezalla, Pettigrew and Miller-Day 2012). A particularly reliable method of ensuring consistency, and in turn, dependability, is a code–recode procedure, which entails a review process, whereby data is analysed, stowed periodically, and then objectively reanalysed (Korstjens and Moser 2018).

Both the manual hand-scribing technique used for code generation, and the theme reviewing process within the thematic analysis method, also described in Chapter 3, facilitated a code–recode procedure, in which codes were analysed, checked and reanalysed. In order to maintain consistency, negative case analysis, included in the final stages of Braun and Clark's (2006) analysis approach, i.e. 'theme review' and 'theme definition', was employed as an additional verification strategy.

Through these, themes were retrospectively and thoroughly evaluated in order to identify and dismiss elements in the research findings that did not contribute or conform to emerging data trends. This systemic revision process not only reinforces consistency by confirming patterns in the emerging data, but as Mays and Pope (2000) explain, also provides a detailed explanation of the majority of the research findings.

3.3.5.3 Transferability

'Transferability' refers to the applicability of research findings, and whether a sample population is comparable with that of a population demographic, essentially, how relatable the study participants are to other contexts or time periods (Korstjens and Moser 2018). A representative sample population is key in this instance, with the intent to nominate participants who are not only well informed, but also representative of diversity, in order to ensure that they are both compatible and applicable (Gentles *et al.* 2015).

The combination of purposeful sampling and snowballing, described in Chapter 3, ensured that participants were nominated based on prerequisite knowledge and capacity in relation not only to the research question, but also to the general community related to the topic. In order to verify this degree of applicability and ultimately transferability, an account of basic although relevant participant information was captured during interviews.

Beyond observations, and as an icebreaker designed to ease any tensions during interviews, participants were asked to describe themselves briefly, which included expressing their roles,

responsibilities or experiences within the organisation and profession. Out of the total number of participants, the gender split which, subsequent to snowball sampling, occurred randomly, comprised two females and five males. While ages were not specifically recorded at the time of interviewing, testimonies from participants revealed a diverse array of operational or clinical experience in the EMS, ranging from less than six months, to more than twenty years in the profession.

While the study specifically set out to include ECPs, the inclusion criteria also allowed for a variation of credentials, particularly participants either within relevant EMS positions or those with suitable knowledge pertinent to the topic under investigation. Subsequent to this, the research design incorporated a diversity of EMS education and backgrounds, which it could be argued, aptly reflected the South African general EMS population. Moreover, and as Dingwall (1992) explains, allowing a wide range of perspectives, reduces potential biases, again maintaining trustworthiness in the research findings.

3.3.5.4 Confirmability

'Confirmability' essentially refers to neutrality, supporting observations over input and confirming that research findings are shaped by participants rather than the researcher (Anney 2015). Characteristic of maintaining credibility, triangulation also supports confirmability (Yeasmin and Rahman 2012) and ensures that participant realities are not overshadowed by personal idealisms or experiences of the researcher. In conjunction with thematic analysis and code–recode procedures, a template analysis approach was employed through the theoretical framework of the study, namely the CFIR. Through a variety of adaptable structures and evidence-based constructs that support pre-specification, the CFIR enables researchers to make accurate predictions about interpretability (Keith *et al.* 2017).

While acting as an additional source of conventionalism, the CFIR was able to capture actionable findings and contextualise factors that could otherwise have emerged extemporaneously from the data. Conclusively, and in addition to guiding coding procedures, the CFIR was used to frame the analytical phase of the study, which assigned a rigorous, systematic structure, mitigating any concerns regarding the inherent nature of qualitative research. Due to its comprehensive range of constructs, the CFIR, in addition to providing rigour, also allowed flexibility, and thus, ultimately created a harmonious data analysis method. The integration of the theoretical framework in this regard was again particularly useful, as it allowed me to detach myself further from my own suppositions, whilst at the same time, it allowed me to be able to maintain a level of affinity with the data.

3.3.6 Reflexivity

Despite intentions to understand phenomena and their ability to produce vast amounts of in-depth, rich data objectively, qualitative research remains prone to subjectivity (Whittemore, Chase and Mandle 2001). Personal attributes, including belief systems, political ideologies, even social principles, can translate into subjectivity, potentially shaping the way research is conducted, evaluated or, at times, presented (Diefenbach 2009). Reflective commentary or reflexivity is an important aspect of research methodologies and qualitative research in general, which limits subjectivity and does so primarily through establishing transparency (Morse *et al.* 2002).

In contrast to a single interpretation, however, reflexivity exists on a spectrum, ranging from an objectivist standard, including ideas or sentiments, to an epistemological paradigm, which appraises qualitative theories and interrogates methodological decision-making (Dowling 2008). Smith and Noble (2014) point out that, while quantitative studies use a 'statistical approach' as a means of initiating validity and research quality, qualitative studies focus on methodology to ensure trustworthiness. Thus, whereas not attempting to satisfy the full spectrum of reflexivity, the current study systematically reflected on its methodology and supported trustworthiness and maintained a well-reasoned degree of transparency.

3.3.7 Qualitative reporting

Due to numerous methods of inquiry and epistemological approaches, qualitative research tends to be quite broad and, as mentioned above, sometimes controversial, which could create challenges for reporting (Peditto 2018). The consolidated criteria for reporting qualitative studies (COREQ) used in this study, aimed to promote transparency throughout all aspects of qualitative research by outlining key elements and establishing a comprehensive set of standards by which to report. The standards comprise a checklist for identifying personal characteristics, potential relationships in terms of the study, the theoretical framework, collection and analysis methods, as well as the reporting process itself. While these standards may not apply to all qualitative designs, they are especially useful in studies which constitute focus groups or interviews (Tong, Sainsbury and Craig 2007).

3.3.8 Research dissemination strategy

Disseminating research findings remains an essential aspect of the research process, which enables knowledge contribution and facilitates practice change through feedback or advices acquired in research findings. In terms of contributing to relevant knowledge, Edwards (2015) explains that publication has the potential to reach the widest possible audience. Edwards, however, cautions against expectations that this will also conclude practice change. In order to encourage the systematic uptake of knowledge, and in turn, practice change, Wilson *et al.* (2010) encourage researchers to employ theoretically informed dissemination strategies.

While the CIFR is categorised as a determinant framework, it retains critical elements of a dissemination strategy, which not only explains or facilitates implementation, but as outlined in Chapter 5, through the CFIR-ERIC, also guides dissemination (Lambert-Kerzner *et al.* 2018). Another key element of dissemination is awareness, which Pathman *et al.* (1996) argues, needs to be achieved prior to innovation acceptance and adherence. In this regard, Widyahening *et al.* (2014) maintain that high levels of awareness alone do not necessarily lead to adherence; however, they conclude that awareness, coupled with a theoretical strategy, improves systematic research uptake. In conclusion, this study intended to relay its findings, which included the 'dissemination strategies', i.e. the CFIR-ERIC, and committed itself to publishing opportunities in hope of creating an awareness-to-adherence pathway.

3.3.9 Ethical considerations and responsibilities

Ethical considerations play a key role in research involving human participants, as this research involves both legal and moral security aspects, including the researcher. Ethics also protect the integrity and well-being of research participants and are therefore regarded as both a discipline and a practice (Guraya, London and Guraya 2014). In line with Brink *et al*. (2012), ethical considerations should encompass human rights principles, including the right to self-determination, privacy, anonymity, confidentiality, fair treatment and protection from harm and/or discomfort.

As the primary researcher, I closely adhered to ethical principles, which throughout the study, prompted the privacy rights as well as the professional standing and reputation of all participants and the organisation involved. Based on the premise of ethical commitments, approval for the study was granted by the DUT Institutional Research Ethics Committee (IREC 64/16), and gatekeeper permission was provided by the organisation.

3.3.10 Autonomy assurance

In terms of autonomy assurance, Longhurst (2010) cautions researchers against jeopardising participant confidentiality, especially while recording and/or transcribing research in the field. Kaiser (2009) elaborates on this by explaining that autonomy presents unprecedented

challenges for qualitative researchers in their quest to present rich, detailed data while also trying to maintain the confidentiality of participants. In order to conform to these tenets, I applied deductive disclosure relating to any identifying information and allocated pseudonyms to participants, which Wiler *et al.* (2008) emphasise as effective means to assure anonymity.

3.4 Conclusion

The data analysis reported in this chapter was guided by Braun and Clark's (2006) analysis approach with the CFIR, as the conceptual framework also playing a pivotal role within the methodology of the study. The aim of the current research study was to explore the barriers inhibiting the implementation of PHT for acute myocardial infarction in South Africa. The study focused on a single private EMS organisation with the purpose of effecting a valid analytical generalisation, which would facilitate the answering of the research question.

The study used a purposeful sampling strategy to obtain relevant input which, in turn, would justifiably represent an accurate account and description of the phenomenon under investigation. Verification strategies were incorporated into the analysis approach and, as an additional measure of trustworthiness, the methodology included negative case analysis and data triangulation. The findings were concluded through inductive reasoning, which incorporated both thematic analysis and the conceptual framework, which underpinned the study.

Mays and Pope (2000) emphasise that rigour in qualitative research can be achieved through the development of a systematic research design and the accurate interpretation and communication of the research results. They suggest that the methodological and analytical procedures should be adequately recollected, and logical and consistent arguments should be provided to support the explanations of the phenomenon. Mays and Pope (2000) recommend both triangulation and negative case analysis as methods for validating qualitative research.

CHAPTER 4

ANALYSIS AND DISCUSSION OF FINDINGS

4.1 Introduction

This chapter illustrates the four main themes and eight sub-themes, which were identified through the conceptualisation of the CFIR framework. The thematic analysis of the interview transcripts using an inductive approach further indicated a total of 21 discussion points, which formed the basis of this chapter. All parent themes, subsequent themes and discussion points represent an analysis emergent from the data, which was focused on possible or potential barriers in the implementation of PHT in South Africa.

4.2 Analysis of themes

Central to understanding the analysis of themes within the application of implementation theories lies the consideration that themes do not exist on a linear spectrum, nor are they fully independent (Braun and Clarke 2006). This may be observed in almost all aspects of thematic analysis, including the identification as well as the construction of themes with certain themes constituting reciprocity and which are, to some degree, either reticulated or complementary in relation to other selected themes. Fereday and Muir-Cochrane (2006) support this notion by attesting that thematic analysis, through its inherent nature, resembles a reciprocal process and, if ever, is rarely that of a linear formation.

4.3 Presentation of findings

All the themes were inferred from the perceptions of the research participants and thus were representative of the key stakeholders in the case study. The discussion was structured around meaningful sub-themes. The CFIR was used in conjunction with Braun and Clarke's six-step thematic analysis guide (Braun and Clarke 2006), which facilitated the emergence of pertinent discussion points. The analysis guide focused on the data within the context of the study objectives, exposing underlying meanings and encapsulating the evidence which was also supported by direct quotations drawn from the data extracts. Supporting quotations from participants are reproduced verbatim and unedited, and the selection criteria for quotes, were based on those deemed to be most telling and/or representative of the data.

Table 4.1: Emerging themes with sub-themes and discussion points

Themes	Sub-themes	Literary inferences and key points of discussion drawn from data
Theme 1 Interventional characteristics	**Cost**	● Ethical considerations ● Supportive equipment and the diffusion of responsibility ● Pharmaceutical disbursements ● Medical coding and billing procedures
	Complexity	● Logistical factors and the process of innovation
Theme 2 Outer organisational setting	**Cosmopolitanism**	● Healthcare divides and inter-professional collaboration ● A continuum of care and perquisite for thrombolysis
Theme 3 Inner organisational setting	**Readiness for implementation**	● Healthcare system inadequacies ● Adoptive behaviour versus status quo
	Implementation climate	● Task difficulty and level of enthusiasm
	Leadership engagement	● Leadership influence and initiative
Theme 4 Characteristics of individuals	**Knowledge and beliefs about intervention**	● Perceptions of the requirement of thrombolysis ● Scepticism and associated risk perceptions
	Self-efficacy	● Confidence and competency ● Education and training ● Continual professional development

4.3.1 Theme 1: Interventional characteristics

Within an organisational setting, strategic mediators typically exercise a considerable degree of influence over the successfulness of an intervention through the process of implementation (Williams 2016). Interventional characteristics relate to specific influencers in relation to their actual content and function within an organisation (Greenhalgh *et al.* 2004). This implies that the key attributes of or relating to an intervention – in this instance, barriers to PHT – have a major influence on whether or not the intervention will be implemented successfully.

4.3.1.1 Sub-theme 1.1: Cost

Cost is an inherently complex issue within the realm of implementation, especially among disciplines, such as healthcare, where it resembles a multifaceted entity including various confines, such as access, investment and significant resources. It should also be noted that cost, including analysis as well as efficiency, represents one of the most profound influencers regarding new interventions and specifically implementation in healthcare (Mosadeghrad 2014). Cost is not only difficult to estimate, depending on the stage of the implementation process to which it aligns, but perhaps resembles an understudied dynamic, thus, an often-misunderstood component of the implementation process (Bauer *et al.* 2015).

To assert or at least identify influences in relation to cost, it is imperative to identify the reason why certain costs exist as they do, how they are enabled, as well as how they compare with alternative measures. In addition, external influences, such as ethics, play a significant and dynamic role in healthcare, especially regarding cost (Graham and Logan 2004).

- **Ethical considerations in relation to the cost factor**

Medical practice is governed by ethical principles which in turn inform conduct, professional relationships, clinical decision-making processes and even the implementation of medical practice (Limentani 1999). Ethical principles constitute philosophical terms concerning the distinction of right from wrong based on knowledge, which provides the framework for such determination. Considered an invariable concept, although related to ethics, morality is behaviour which is in line with customs or traditions and which also exerts a major influence over medical conduct, practice and implementation (Gillion 1994). As a degree of optimism in terms of support for new healthcare practices or innovations, including PHT, and specifically from an ethical standpoint, was alluded to by one of the participants:

> *[W]e're moving so rapidly in this industry that the augmenting or the supporting functions of governance and for treatment and for understanding what we are actually doing wrong and right, is going to come up so quickly that in the next couple of years, we'll probably see a difference (Interviewee 3).*

Increasingly, service providers are often required to balance ethical processes with that of the cost of healthcare, often in the form of healthcare rationing. Eichler *et al.* (2004) highlight that it is a commonly performed practice for service providers, in both the public and private healthcare sectors, to adopt or apply results based on cost-effectiveness, which in turn informs practice strategies. This approach, which attempts to identify the optimal allocation of resources in order to maximise healthcare, tends to be value-based and, unlike EBP, is not patient-centred (Epstein and Street 2011). Despite a clear appreciation of the benefits that

PHT could provide in terms of being an EBP, cost appears to be a prohibitive factor as mentioned by the following participant:

> *[I]t is expensive, we can get it, it's just, we got to start looking at cost versus use. … If you look at some of the complexities, again let's look at it from a business perspective, I mean we have to make, or justify it [PHT], currently, in the current funding market (Interviewee 5).*

Objectively, healthcare is a costly enterprise requiring extensive expertise, which influences the quality of care provided and continuous resources, which relate directly to cost. Between these, a tension exists that reflects the complexities of not only cost but also of the surrounding dynamics such as ethics (Furrow 2012). While the provision of PHT may hinge on more discernible cost factors, ethics and economics remain a consideration due to their innate influence over healthcare practice.

- **Supportive equipment and the diffusion of responsibility**

Reliable and relevant equipment remains an integral component of healthcare, especially emergency medical care, which aims to stabilise or minimise systemic injuries through appropriate and necessary interventions (Varghese, Kellermann and Lormand 2005). A wide range of equipment is involved in coronary care; however, the 12-lead electrocardiogram (ECG) is central to clinical decision-making in patients presenting with ACS (IJkema *et al.* 2014). In support of this assertion, Giugliano and Braunwald (2014) conclude that the prevalence of STEMI in patients with ACS is 29–47%, thus making the 12-lead ECG, with its detection capabilities, a crucial piece of equipment in relation to these patients. Furthermore, in accordance with international as well as national guidelines, the use and confirmation of a 12-lead ECG monitor with data transmission capability (telemetry) are mandatory prior to the commencement of PHT (Introduction of New Scope of Practice for Registered Emergency Care Practitioners 2009).

Subject to market value or commodity pricing, however, a single 12-lead ECG, which is typically set to industry requirement and standards, is valued in the region of $10 000 and $40 000 (R120 000 and R470 000) (US Price List 2009). It is clear that the clinical overheads, maintenance and operating costs of such commodities have the potential to limit healthcare innovations, specifically PHT, which relies directly on the utilisation of such equipment. In addition, it is an important consideration, with respect to the scope of clinical amenities provided by the private healthcare sector and organisations, as services are delivered on a private-for-profit basis. This suggests that equipment related to innovations, specifically, the 12-lead ECG with telemetry systems, which is required prior to PHT, might not pose a barrier, at least not within the same context as the public healthcare sector, alluded to by participants:

Top equipment, every vehicle, no problem, so every, at least one response car at every base has a twelve lead, done, sorted, whereas, obviously, whereas, you know, you try push it to make, you know an ECP should have that (Interviewee 5).

The service that I work for has got that equipment, okay, it's in place, we've got monitors that's got the capability of doing telemetry, in certain places it's set up already (Interviewee 3).

However, it is equally important to consider the diffusion of healthcare responsibility in South Africa in terms of the extent to which an intervention, such as PHT, may be implemented on a national scale. The private sector, although an inextricable component of healthcare in South Africa, provides comprehensive service to less than a quarter of the population with nearly 84% of the population dependent on public services (Mayosi, Phil and Benatar 2014).

In terms of the provision of care, this highlights the degree of influence which the public sector has over national healthcare policy and directives as well as the level of commitment required regarding the services offered. Pertinent to this point is the fact that healthcare innovation on a national scale requires a diffusion of responsibility or, as Cankar and Petkovsek (2013) describe it, cross-sector collaboration between the public and private sectors. While supportive equipment may not be an issue in certain private EMS, combined with smaller, non-national organisations and, arguably, an under-resourced public sector, this may yet present a barrier to PHT as highlighted by a participant:

If we start talking about provision of care, who's going to be able to do it? So, it will only be one or two components of the healthcare system that's going to be able to do prehospital thrombolytics? … It's a huge capital outlay to actually get that equipment in place, and, if you look at the provincial sectors, and not in any specific provincial [service], or any specific province, you'll see that the level of equipment on the ambulances won't allow you to do a 12-lead ECG, so they can't employ thrombolytics, so there's several barriers that lies there (Interviewee 3).

Although outside of selective, non-commodity equipment issues, medical investment, resources and inventory continue to play major roles in healthcare implementation across both the public and private sectors. This is especially evident in areas in which the costs of resources are less likely to constitute long-term investment, specifically disposable supplies, such as pharmaceuticals, which may present barriers. Deemed one of the fundamental reasons why EMS, clinics and even certain hospitals are not equipped with thrombolytic capabilities, the cost of pharmaceuticals has been at the forefront of many healthcare discrepancies, which was highlighted by a participant noting the scarcity of relevant drugs:

[S]ometimes you go out to hospitals in the rural areas, and if you go to a clinic there, and they don't have that, those drugs there, then we don't have it, so we can't start the treatment there (Interviewee 2).

- **Pharmaceutical disbursements**

Although perhaps sometimes overlooked, direct pharmaceutical expenses represent a major determinant in the commodity and healthcare cost pressures. Drug development involves cost factors, which include medical research, trials, manufacturing, production as well as the need for marketing (Morgan *et al.* 2011). In addition, other considerations, such as target population, also influence pharmaceutical costs by influencing market prices and subsequent demand. As demonstrated by Ghandehari (2011), there is also the all-important manufacturing cost, highlighting the fact that one of the main reasons for the lack of thrombolytic drugs in the developing countries is the inordinate value of constituting the recombinant tissue plasminogen activator (r-tPA). The impact of cost was therefore understandably identified during face-to-face interviews:

If I look at it from a business perspective, an outsider, the clinical, it is expensive, so that's, you know, if you say, well, thrombolysis, you immediately say, wow, it's expensive (Interviewee 5).

Prehospital thrombolysis, all I know is that it's very expensive, and I think that is one of the biggest issues why thrombolytics is not used. … We're not issued with that drugs, and I think it's due to financial, I think it's mostly financial, first of all the reasons that we don't carry that drugs (Interviewee 2).

It's very expensive, that's the bottom line, that's the biggest issue we have with it (Interviewee 7).

However, Mark *et al.* (1995) refer to pharmaceutical disbursements as a paradox, citing the global utilisation of streptokinase and tissue plasminogen activator for occluded coronary arteries study (GUSTO) for their views. The GUSTO highlights that, while certain thrombolytic agents are costly and therefore difficult to acquire, it is not uneconomical to support these costs. Conclusively, thrombolytic agents result in increased future value determined by healthcare economic analysis and measured in quality of adjusted life years in relation to disease burdens, specifically CAD (Weintraub 2003). This implies that costs are reduced in respect of the short- and medium-term outcomes; thus, it is economically cheaper to provide thrombolytic drugs than patients admitting patients to hospital for long periods.

When assessing the individual costs of thrombolytic drugs, it is imperative to recognise and contrast the available options, particularly those options that present a more cost-effective way while still maintaining similar outcomes. As the first to be introduced, now the most widely used in hospitals in the treatment of STEMI, the National Department of Health classified

streptokinase as the least expensive thrombolytic drug in South Africa (Standard Treatment Guidelines and Essential Medicines List for South Africa 2015). In accordance with the British National Formulary, a series of pharmaceutical reference guidelines, streptokinase costs approximately £80 (R1 320) (XE Currency Converter 2017) per patient.

As a non-fibrin-specific agent, streptokinase has a significant history in thrombolytic therapy, although, as a foreign bacterial protein (antigenic), it also creates antibodies, which may deactivate the drug and therefore, prohibit re-administration (Lee 1995). However, while fibrin-specific agents, such as r-tPA, may be more convenient in terms of administration and time as a single bolus solution, these often require co-therapies, specifically the administration of heparin, which in turn constitutes an additional cost (Leah *et al*. 2004). When comparing drugs, the most important consideration remains safety profile and efficacy, both marginal in a comparison with streptokinase and r-tPA (Cherng *et al.* 1992).

The American Heart Association and American College Cardiology recommend fibrin-specific drugs preferentially while also emphasising early, available reperfusion regardless of specificity (Linderbaum *et al.* 2013). Based on these same principles, the European Society of Cardiology and the National Institute of Clinical Excellence do not make any recommendations within their guidelines in terms of specific thrombolytic drugs. Furthermore, it should also be noted that the South African Society of Cardiovascular Intervention, a special interest group in affiliation with the South African Heart Association, subscribes to the European Society Cardiology guidelines (Delport 2014). This then leaves the question open as to whether the cost of thrombolytic drugs actually poses a direct barrier to PHT, or the perception of one.

- **Medical coding and billing procedures**

In South Africa's healthcare system which is partly socialised and partly privatised (Delobelle 2013), there are billing practices with regard to medical procedures, diagnostics, and drugs. These billing practices involve classification systems of transfiguring healthcare activities known as medical coding, which translate procedures, services and the utilisation of equipment or drugs into a generic alphanumeric code (Tatham 2008). By providing a unified 'language', medical providers are able to capture costs and bill medical insurance schemes or healthcare coverage providers. However, the medical processing systems in South Africa tend not to be absolute and, although clinically useful, may according to participants, potentially obstruct access to healthcare innovations as outlined by participants:

> *[C]ost is already a problem, medical aids don't [reimburse], because you remember the reimbursement, the reimbursement profile of emergency services is based on transport and level of care, not on drugs provided or procedures done (Interviewee 3).*

[W]e don't have an ability to bill it currently, okay, so there would be a whole lot of things we would need to go and fix, with the schemes, with [the] board of healthcare funders, getting a NAPPI [National Pharmaceutical Product Index] code, and being able to bill it, okay (Interviewee 5).

The South African Medical Association published the first procedural coding systems in 1994 (Maritz 2015) and has continued to update the guidelines annually based on submissions received by speciality groups (Grootboom and Sonderup 2014). These groups include individual practitioners, clinical specialists, medical schemes, the South African Department of Health, the Council for Medical Schemes and the Board of Healthcare Funders. While numerous entities may prove to be constructive through collaboration, a multigroup healthcare system through varying levels of control may also have a negative influence on practices, especially on innovations and/or implementation processes. Kochevar and Yano (2006) explain that innovation complexity in healthcare naturally increases when interventions are directed at a greater number of potential role players, which was also expressed by participants:

[I]t really comes down to a need to have contact with all of the different role players, okay, have to contact with all the different role players, and there needs to be a system in place, otherwise it's impossible (Interviewee 3).

The National Pharmaceutical Product Index denotes a national medical coding system for medications in South Africa, and comprises a general as well as a comprehensive medical database (Moodley and Suleman 2019). Medical coding in both public and private healthcare involves various levels of complex systems and procedures, although some of these appear to be lacking criteria or development. Coding systems in South Africa were historically designed for physician practices and not emergency medicine or, by extension, emergency medical care (Grootboom and Sonderup 2014). This is perhaps most evident in the EMS where, no dedicated coding structure currently exists as also highlighted by the participant below:

They are going to have to empower the providers to actually bill for what they are doing, because if there's no code to bill for something, then the medical aid, well, you can't bill for it, so they need to create codes (Interviewee 3).

Concluding statement on Theme 1: Interventional characteristics

Sub-theme 1.1: Cost

Healthcare systems, including organisations and service providers, undoubtedly face challenges of limited resources and growing demand, which often influence decisions around allocation of medical supply as well as mode of delivery in terms of care. Despite cost factors continuing to play a major role in the capabilities and limitations of healthcare systems, organisations and service providers have an important obligation to 'do no harm'. Based on which, organisations and service providers are responsible for providing relevant as well as appropriate levels of care and thus, in the management of STEMI, the onus is on the service providers and organisations to reduce time delays by improving reperfusion strategies. Consequently, the identification of implementation barriers and efforts to promote EBP strategies, specifically PHT, should be an integral component of cost analysis in EMS and also other healthcare organisations.

4.3.1.2 Sub-theme 1.2: Complexity

'Complexity' in this context refers to the understood or at least anticipated difficulty of the implementation process, often as a result of latitude, militancy or wilful desire in respect of engaging the effort required either directly or indirectly involved within the process (Grol *et al.* 2007). It is clear that the more profound an intervention with regard to the level of complexity, the more significant the effort required by the organisation or user group to adapt or implement such an intervention (Rycroft-Malone 2015). There are several well-understood factors in the realm of complexity, including perception, pervasiveness, scope, impact, radicalness, magnitude, disruptiveness and duration of innovation, all of which are significantly intertwined (Greenhalgh *et al.* 2004). As a result, the focus of complexity in the instance of interventional characteristics has been defined by logistics, innovation and policies.

- **Logistical factors and the processes of innovation**

Perhaps more specific in terms of the intervention itself, several innovative or logistical factors may be present in the implementation of PHT, including administrative actions or change, product storage and service delivery (Grol *et al.* 2007). The process of innovation is sometimes referred to as divisibility or scaling up which, although a broad definition, in implementation science refers to the diffusion or advancement of an innovation within an organisation (Charif *et al.* 2017). This activity is perhaps best described as a "process of expanding, adapting and sustaining practices, programmes and policy across different areas over time in order to affect large numbers of people" (Hartman and Linn 2008: 8). However, the process of scaling up, especially in terms of logistical factors which may and often do stifle new innovations, could present a series of complex events as acknowledged by some of the participants:

Okay, so, there's a couple of things, purely in clinical practice, so if we take it from the bottom going up, equipment, procurement, instalment, storage, and governance of the actual drugs and equipment, so, giving the paramedic on the ground the capability to actually perform the skill okay (Interviewee 3).

I mean, how is this governed? Is it independently practice-driven? Is it medical officer-driven? What's the procedures for giving it? And, all of these things complicate its use actually (Interviewee 5).

Regarding complexity, specifically logistics and innovation, the type of intervention plays a major role, depending on whether it is a technical or an administrative process. Technical issues regarding product service and delivery are inclined to be more practical while the adaptation of administrative processes tend to affect organisational social structures and practice, and are inherently more complex when compared to technical issues (Greenhalgh *et al.* 2004). Prehospital thrombolysis, in common with most modern-era innovations, is a hybrid of both, incorporating various technical aspects as well as administrative actions and incentives.

Concluding statement on Theme 1: Interventional characteristics

Sub-theme 1.2: Complexity

Throughout any organisation, although especially in healthcare, multiple complexity and especially logistical factors have a significant influence on whether or not an implementation process will be successful. Edmondson, Bohmer and Pisana (2001) explain that the key to confronting challenges of this nature lies within organisational acceptance. Fundamentally, only once an intervention has been fully embraced, will an organisation provide what is necessary in order to adapt the policies or procedures required to facilitate it. Therefore, a greater awareness and appreciation of PHT, including all its risks, benefits and potential, are required to curb resistance to its implementation and create a more receptive EMS culture.

4.3.2 Theme 2: Outer organisational setting

Unlike the organisational structure, which includes a typical hierarchal arrangement, organisational settings, specifically outer organisational settings, incorporate external policies, incentive, pressure from industry, patient needs, resources and cosmopolitism (Keith *et al.* 2017). In terms of implementation, Greenhalgh *et al.* (2004) explain that, while a political directive, influenced through either external forces or organisational collaboration does not increase capacity, it enacts a fundamental role in increasing motivation.

4.3.2.1 Sub-theme 2.1: Cosmopolitism

The extent to which an organisation is extraneously linked with others or the degree of cosmopolitism supports and actualises the implementation of practices through shared

innovation (Greenhalgh *et al.* 2004). Organisations that reinforce and advocate shared innovation systems are not only better equipped to accommodate new practice strategies but are also more inclined to adapt to the challenges of implementation. In this instance, 'cosmopolitism' refers to the network or relationship between EMS and other components of the general healthcare system, such as hospitals, clinics and departmental representatives.

- **Healthcare divides and inter-professional collaboration**

Comprising various groups, departments and organisations, coupled with multi-directional objectives as well as multi-disciplinary personnel, healthcare, in general, is deemed an astonishingly fragmented industry (Herzlinger 2006). The result is an array of nonlinear relationships, which are not conducive to either effective collaboration in terms of optimal patient care or healthcare innovation. The South African healthcare system is no exception to fragmentation and systematic failures, particularly due to its unprecedented history, burdensome public health demands and intricate, two-tier governing structures (Coovadia *et al.* 2009).

> *[I]t [question of PHT] goes back to this breakage in the system, the EMS, the EMS system, and our healthcare system is broken, to the point that I can't see it ever making sense, implementing thrombolysis (Interviewee 5).*

The WHO (McIntyre *et al.* 2008), confirms this sentiment by describing the past as well as the current state of the South African healthcare system as one of the most fragmented on the African continent. Fragmentation or industry divides in healthcare creates individual or, in some cases, opposing perspectives, incentives and aspirations along partisan lines, which potentially facilitate healthcare innovation failures (Herzlinger 2006). While the individual components of the healthcare system have independent roles and, therefore, make a unique contribution to patient care, the key to delivering successful, high-quality care lies in collaboration between the disciplines (Ndoro 2014). A multidisciplinary approach to STEMI and, by extension, thrombolysis remains a priority, demonstrating reduced risks in standardised mortality rates through improved patient outcomes (Kronick *et al.* 2015). The requirement of an interdisciplinary approach, which is currently deemed to be non-existent– at least at the level which is required – was highlighted by a participant:

> *You see, and that's the biggest thing with, within EMS, I'm talking EMS prehospitally, we do things in isolation, you know, prehospital care has to match in-hospital capacity and capability, there's no point in us dreaming up things in the prehospital system, that get blocked, or aren't available in an in-hospital system (Interviewee 5).*

In the same vein, multidisciplinary approaches are also required in implementation, especially for innovations, such as PHT which, through acute and secondary care provisions, typically

cross healthcare boundaries. Fragmentation, which is responsible for system discontinuity as well as the barriers associated with implementation, occurs as a result of what Stange (2009) describes as an unintended consequence of specialisation. Technological advancements, such as specialisation, represent an integral aspect of healthcare, creating the ability to integrate or prioritise information, and provide focused care.

The specialisation of emergency medicine in 2004 played a major role in transforming the face of emergency medical care in South Africa, leading to the further and necessary development of the prehospital profession (MacFarlane, Van Loggerenberg and Kloeck 2005). Despite the success of prehospital developments, it has been felt that certain specialised interconnectivities that would otherwise facilitate innovations such as PHT, are lacking as alluded to by a participant:

> *We have tried, and I wouldn't say failed, but we have not succeeded in setting up a cardiac network to the extent of actually getting cardiologists involved in the prehospital decision, because from a governance point of view, it's important that a patient, a decision be made for a patient at point A, follows through to point B, C and D, okay (Interviewee 3).*

As a comprehensive system of emergency medical care, EMS are continuing to expand their function and abilities in order to keep pace with constantly changing healthcare environments (Al-Shaqsi 2010). South African EMS have demonstrated significant advances since they professionalised in the mid-nineties, transforming from a traditionally physician-directed system to a self-regulating, autonomous profession. This move saw the EMS gaining responsibility for the development of medical protocol, guidelines and associated clinical decision-making, most notably in procedures such as RSI and, potentially, PHT.

While specialisation has enabled a more advanced care to be brought to the patient, Stange (2009) refers to the unintended fragmentation, causing a subtle inter-disciplinary drift, in turn affecting practice, innovation as well as implementation. The main consideration is that, under a physician-based or medical-directory-based system, collaboration with hospitals is strongly maintained, thus facilitating the deployment of multi-disciplinary strategies, especially in practices where a continuum of care is required as expressed by the following comments:

> *There's no reason why you can't but it's going to take everybody, like, sitting around a table and getting it right and obviously then a level of trust from the cardiologist and the hospital side. … It's a systems approach, it's a team approach (Interviewee 5).*

- **A continuum of care and obligation for thrombolysis**

The term 'continuum of care' refers to the concept of an integrated healthcare system intended to guide and oversee a patient's journey through a wide range of healthcare services (Evashwick 1989). The key to a continuum of care lies in both inter-professional collaboration

and the combined effort of multiple healthcare professionals, which in turn have an influence on the effectiveness of healthcare interventions. Extending across relevant levels and intensities of medical care provision, and serving as the link between healthcare resources, a continuum of care provides the system interconnectivity which has demonstrated improved patient outcome in CVD (Dzau *et al.* 2006). The lack of healthcare system collaboration in South Africa was identified as a barrier to the implementation of PHT by a participant:

> *Taking it one step further into hospital, we know that even with simple stuff as giving Aspirin and Plavix together, there needs to be a network and a continuum of care that flows through from prehospital care into the hospital and further okay … That continuum of care does not exist in this country, across the prehospital and in-hospital [environment], both in private and in the state (Interviewee 5).*

In this regard, goal-driven incentives from an EMS perspective are to ensure that measures of prehospital care complement the definitive care strategies that are either intended or designated in hospital. However, despite efforts encouraged by some EMS agencies or their counterparts, there remains an evident operational gap between prehospital and in-hospital systems in South Africa (Kula and Fryatt 2014). Collaboration between in-hospital and out-of-hospital systems has become almost futile, affecting clinical practice of strategies negatively, such as PHT, which relies on a continuum of care. This was highlighted by participants in their responses below:

> *There's such a breakdown between the prehospital system and the in-hospital system, great, you go and thrombolyse the patient on the road and then what? Is that care ever going to be carried on through the in-hospital? (Interviewee 5).*

> *[I]f I make a decision for a patient that I'm going to thrombolyse rather than doing primary PCI, then that must be the same decision that the cardiologist wants to make when we get to hospital. … The point here is that I shouldn't be making a decision in isolation, I should be making it in a network, a cardiac network, and we have not been able to set up a cardiac network to that extent (Interviewee 3).*

Concluding statement on Theme 2: Outer organisational setting

Sub-theme 2.1: Cosmopolitanism

Models of organisation and service delivery must to be advanced with EMS which is, to some degree, isolated from the other health services but being encouraged to integrate with these other health services. It is recommended that EMS, through re-evaluating aims, could phase out the term 'emergency medical services' and instead reinforce the description of prehospital care, which may serve as a reminder that EMS is inseparably tied to the hospital. While EMS enjoys the freedom in the field to make decisions independent of the hospital, greater efforts should, however, be made to interact with hospital staff. Certain private and even public EMS need to take advantage of unique shared relationships through association with the hospital. A greater awareness – both in and outside of hospital disciplines – of inter-disciplinary divides is essential to bridge existing gaps which may be affecting patient care negatively.

4.3.2 Theme 3: Inner organisational setting

Intertwined with the theme of the outer organisational setting, the inner organisational setting relates to the culture and implementation climate of the organisation, including structural characteristics, networking, communications and the essential readiness of an organisation in terms of action, activity or innovation (Keith 2017).

4.3.2.1 Sub-theme 3.1: Readiness for Implementation

At present, no commonly accepted definition of 'readiness for implementation' exists, although the Promoting Action on Research Implementation in the Health Services framework describes 'readiness' as an evaluation of environment, culture, and leadership (Kitson *et al.* 2008). In addition, some definitions tend to characterise organisational readiness in more structural terms, citing organisational constructs, such as financial, material and informational resources (Bloom *et al.* 2000; Snyder-Halpern 2001). Weiner (2009) explains that, although organisational readiness is seen as a fundamental precursor to innovation and implementation, it nevertheless remains a highly complex, multi-level, multifaceted construct, which at present lacks theoretical development.

- **Healthcare system inadequacies**

'Systems' in this context of the current study refers to healthcare access, service delivery or clinical resources and whether these systems support or are ready for the actualisation and implementation of PHT. Local observational experience from the current study's research has seen some ECPs colloquially describing PHT as a 'first world solution in a third world country' implying the level of unpreparedness for new innovations in South African healthcare systems. Although somewhat provocative, this refers to healthcare system inadequacies. Similarly,

Coovadia *et al.* (2009) describe the state of South African healthcare as a 'three-way collision' between dysfunctional systems and widespread communicable and non-communicable disease epidemics. It may be the perception that PHT appears to work effectively in developed healthcare systems as well as in some countries which may, arguably, have fewer requirements regarding its practice:

> *We don't have a cardiologist who is available to be a reference point for practitioners to engage with (Interviewee 5).*

Regardless of medical and technological advancements over the years, integrated procedures, such as PHT, have not evolved in South Africa, probably due to a lack of supportive healthcare structures (Delobelle 2013). Concerns in this respect appear to be attributed to low numbers of specialist physicians, including cardiologists, and even emergency physicians, whose role is crucial in the diagnosis and treatment of cardiac conditions. South Africa has approximately 175 registered cardiologists, of whom approximately 35 are active in public services, with none in five of the nine provinces (Molelekwa 2017). With an estimated population of 57 000 000, and about 175 actively practising specialists, this suggests that there is only one cardiologist for every 326 000 inhabitants. The shortage of specialists constitutes a barrier according to the following participant:

> *I think there's, like, less than sixty cardiologists, like this tiny number of specialists, cardiologists in the country. So how does that work? You're not going to have a cardiologist at every hospital (Interviewee 5).*

Despite a relatively small number of specialists, telemetry incorporates an automated communications process allowing information to be transmitted regardless of location or time (Marouf *et al.* 2017). Regarding specialists, the concept of what this role or position may constitute may vary while still improving patient outcomes. Despite an ideal setting in which cardiologists could be the first point of contact for every scenario, the rationale for relying solely on such specialists is not clear, considering the availability of other medical specialists and the evolution of coronary care as an expanding speciality (Morrow *et al.* 2012). In healthcare, a specialist refers to as a person who is highly trained in a particular branch of medicine or has relevant expertise (Cleary 1988), thus, an emergency physician, specialised coronary care nurse, or even senior medical resident may, arguably, qualify in this regard. This opens up the question whether the lack of supportive structures, specifically the lack of specialists, represents an actual impediment to PHT or is just another perceived barrier.

- **Adaptive behaviour versus status quo**

Organisational commitment presents an inevitable barrier in terms of implementation, specifically regarding new or intended practices which otherwise rely on support within an

organisational setting. Bradley *et al.* (2011) attribute a lack of organisational commitment to change to the status quo, explaining that organisational systems typically evolve by maintaining those strategies which contribute to growth, although doing so also generates resistance to change. In this context, at the time of the study, the status quo or impediment to the implementation of PHT appeared to be the established prehospital treatment of STEMI, including the administration of morphine, medical oxygen, nitrates, and aspirin (MONA).

However, there are concerns about the use of MONA as an independent or, in some cases, adjunctive treatment strategy for STEMI with Giannopoulos *et al.* (2016) citing drug–drug interactions, specifically the interaction of morphine and antiplatelet drugs, as one such concern. More imperatively, the MONA strategy, while allowing provisional vasodilation for perfusion and moderate to mild pain relief, does little to resolve the underlying issue of myocardial occlusion (Neto 2018). Yet, despite concerns around paradoxical drug interactions or the fact that the MONA strategy resembles a poor substitute for thrombolysis, it remains the status quo in terms of current prehospital STEMI management as alluded to by participants:

> *[P]ossibly fear and a lack of knowledge would be your biggest thing, and a lack of emphasis on prehospital thrombolysis. We're taught MONA until it comes out of our ears (Interviewee 6).*

> *I think, you know what, they've been doing this now for so long, and for them to go and now for them to say okay, but why must we go and now suddenly change this, it must come from the people above, and, I don't think they understand (Interviewee 2).*

Concluding statement on Theme 3: Inner organisational setting

Sub-theme 3.1: Readiness for implementation

As a multi-level, multi-faceted construct, 'readiness for implementation' refers to preparedness of the organisation for change, which includes the perception of recipients, although it also tends to lean towards environmental resources (Weiner 2009). In terms of perception, organisational change would require a combined, coordinated behaviour at individual level, and in order to facilitate environmental resources, a variant of processes or tools may be required. These might include but are not limited to electronic healthcare records or databases, acute and chronic healthcare deliverance models, patient safety systems and quality improvement programmes in accordance with PHT.

4.3.2.2 Sub-theme 3.2: Implementation climate

Climate represents a significant factor in terms of interventional characteristics and refers to the extent to which an intervention is either supported, counted upon or compensated for in

terms of supporting structures (Klein and Sorra 1996). Components of the implementation climate comprise various organisational factors, such as resistance to change, compatibility of the intervention, applicable primacy, as well as organisational goals and feedback. Greenhalgh *et al.* (2004) appropriately describe implementation climate as the ability or absorptive capacity for change within an organisational setting.

- **Task difficulty and levels of enthusiasm**

In relation to implementation, climate is not an independent factor and instead is an organisational factor that depends on context, which often varies widely between systems, departments and organisations (Jacobs, Weiner and Bunger 2014). Furthermore, implementation climate is innovation-exclusive, referring to the specifics regarding each innovation, idea or concept about to be introduced. Furthermore, Weiner *et al.* (2011) explain that multiple implementation climates may co-exist within organisational settings. This may explain why some innovations initially succeed and others require additional support.

The rationale why some innovations within the context of South African EMS succeed and others do not, can be related to RSI, an advanced airway technique, which was introduced by the HPCSA around the same time as PHT. In 2009, PHT was officially introduced as a stand-alone intervention for use by ECP (Louw 2015). However, whilst RSI has been successfully implemented, the same is not true of PHT. It should be noted that RSI, in terms of procedural planning, risk analysis and clinical decision-making procedures, remains a highly complex skill, which in some instances explains why RSI remains controversial in the prehospital setting (Gunning *et al.* 2013).

Given the high-risk nature of RSI and intricate decision-making involvement, the current study would reason, that when compared to PHT, in terms of clinical decision-making and risk factors, RSI is arguably no less complex. Despite this however, it can also be argued that RSI was easier to implement, perhaps as it replaced an already imbedded skill, namely drug-assisted intubation (intubation facilitated by sedatives or other medications, excluding neuromuscular blocking agents). To date, as the current study again highlights, PHT continues to remain in the implementation infancy stage, despite evidence for its actualisation, as noted this participant:

> *[W]e could implement it in our organisation, we have a good clinical governance system, if you look at RSI, it works, and it's effective. … In our organisation, RSI works, we do an RSI, we write a review, it gets, the case gets reviewed and if something didn't go a hundred per cent, we discuss the case, and we make improvements for the next one (Interviewee 1).*

It is difficult to explain with certainty why RSI has been widely accepted into clinical practice while PHT has not – especially considering the international evidence base for PHT (Johnston, Brightwell and Ziman 2006). However, social constructivism and – by extension, implementation climate – provide at least some explanation why this varied implementation may have occurred.

Primarily a concept of social constructivism, implementation climate was adapted from Klein and Sorra's (1996) model of implementation. The model cites two main determining factors, namely the climate for innovation, which is based on the perception of ground-level staff and the value of the innovation or shared perception among top organisational stakeholders. While implementation climate includes factors such as skills, incentive and the absence of obstacles, the value of innovation, as perceived by the stakeholders or leaders, has a profound effect on the effectiveness of the implementation (Dong, Neufeld and Higgins 2008).

Concluding statement on Theme 3: Inner organisational setting

Sub-theme 3.2: Implementation climate

Related to readiness for implementation and also a multi-level construct, implementation climate essentially refers to the organisational context associated with implementation effectiveness. Essentially, the concept of implementation climate refers to the manner in which an innovation, specifically PHT, is collectively perceived, supported and incentivised by the organisation (Jacobs, Weiner and Bunger 2014). Stakeholders, should seek and engage in opportunities to communicate as well as interact with individuals regarding perceptions or experiences in order to measure the implementation climate. This would enable leaders to develop guidelines which would facilitate PHT, or at least allow an understanding of and the ability to predict implementation effectiveness.

4.3.2.3 Sub-theme 3.3: Leadership engagement

Often defined as the art of motivating an individual or group to act towards achieving a common goal (Sharma and Jain 2013), leadership is primarily responsible for cultural growth and organisational development (Bass and Avolio 1993). With a distinctive and compelling ability to influence behaviours as well as beliefs, leadership is capable of inspiring the change necessary for organisational growth and, on the other hand, also of stifling it. The commitment and responsibility of leadership engagement has been shown to have a direct effect on the success of an innovation or implementation (Lukas *et al.* 2007).

- **Leadership influence and initiative**

Any lack or wavering degree of leadership, especially in relation to leadership engagement, could influence the beliefs and behaviours of followers resulting in failed innovation attempts. Repenning and Sterman (2002) explain that anything less than 'wholehearted support from organisation leadership' has severe consequences and may, ultimately, hinder or even disrupt the entire implementation process.

> *[E]ven if my company gave me the drugs today and said, right, you can thrombolyse the next STEMI you see, I probably wouldn't feel that I have the necessary support, I feel I'm maybe … if anything were to go wrong, I would be prosecuted for it (Interviewee 1).*

The effect or influence of leadership is not new to scientific inquiry, although previous studies have demonstrated a tendency to focus on specific leadership roles, specifically management and directorship, in turn limiting the scope of analysis. O'Reilly *et al.* (2010) insist that the key to understanding issues related to leadership fully is to analyse issues through multiple organisational levels simultaneously, as multiple leadership roles with various levels of influence exist within organisations, especially in professional disciplines. Although deemed a controversial topic, perhaps as a result of criticism or marginalisation based on organisational successes, leadership remains a central point of discourse in terms of implementation.

> *[W]e cannot, people on the road, in Ops [operations] or whatever, they cannot drive this initiative if the people on the top are not fully involved in this (Interviewee 2).*

Concluding statement on Theme 3: Inner organisational setting

Sub-theme 3.3: Leadership engagement

Both theoretical and empirical evidence suggest that highly effective and engaged leadership correlates highly with effective and engaged organisations, especially those willing or attempting change. Therefore, in the interest of implementation regarding healthcare practice, leadership engagement should be considered a primary focus. Based on which, leaders are required not only to engage but also to adapt their skills, abilities and personal perspectives to fit the dynamic trends inherent in the implementation of healthcare strategies. It is also recommended that leaders determinedly challenge their own ideas, strategies, biases and behaviours through an objective lens of innovation. This would ensure leadership actions or behaviours are not limiting or restrictive in respect of the implementation of new practices but, instead, endorse the growing culture of healthcare innovation.

4.3.3 Theme 4: Characteristics of individuals

Individual characteristics represent an integral component of an organisation and includes, with varying degrees of importance, individual perspectives, experiences, awareness and opinions, especially relating to factors associated with change or development. Ajzen (1991)

explains that the extent to which any new action or activity is perceived as either productive or non-productive within an organisation may, typically, influence any motive for change; thus, acting as a precursor to new developments.

4.3.3.1 Sub-theme 4.1: Knowledge and beliefs about the intervention

The perceptions, ideas or opinions of healthcare professionals operating in the field and especially among those responsible for organisational change or development, may affect emotions related to new healthcare strategies. Strong beliefs or opinions, specifically those which are negative or contrary to supported facts, may essentially create potential influencers in terms of barriers to the implementation regarding the clinical practice of PHT in South Africa.

- **Perceptions regarding the requirement for thrombolysis**

The consideration is whether PHT is either a primary or a non-primary care issue, and fundamentally, as a practice, whether PHT constitutes a requirement or non-requirement. This consideration is based on perceptions of the clinical effectiveness of PHT, specificity in relation to environment comprising urban populations, and alternative measures such as PCI. Questions surrounding.

Perception of whether PHT constitutes a requirement or effective clinical therapy in urban populations may derive from conceptions of metropolitanism in which urbanised environments are contrasted to non-urbanised settings. Since urban areas are typically characterised by infrastructure development in comparison to their less urban counterparts, they tend to have superior medical capabilities. This is often expressed as an evident lack of concern about or, in some cases, even an argument against the implementation of PHT in lieu of alternative strategies, specifically PCI located in urban areas, and was demonstrated by participants:

> *I don't think there is a strong need for prehospital thrombolysis, especially if the hospitals are so nearby and if you can start treatment, working through your MONA protocol, and then initiate that, and then alert the hospital or, and the Cath-lab [cardiac catheterization laboratory] en route, and then they can have everything ready (Interviewee 4).*

> *[W]orking in the urban environment my necessity for it is less as I'm closer to most hospitals (Interviewee 6).*

In line with the notion that PHT should be reserved for rural cases, Stephenson, Wardrope and Goodacre (2002) call into question whether, in fact, PHT is necessary in urban population settings, claiming that no significant data has at that stage, demonstrated the evident benefits of PHT in such a setting. Efforts to stabilise the standardisation of PHT outreach programmes in regions with dense urban populations are sometimes criticised (Brieger 2011), suggesting

that these strategies are based on research exaggeration instead of actual clinical evidence (Stephenson *et al*. 2002).

Stephenson *et al*. (2002) acknowledge that a shortened time leading up to the delivery of thrombolysis has been associated with positive outcomes but argue that urban settings demonstrate limited time savings with only marginal benefits in terms of patient outcome. When taking into account associated risk factors of thrombolysis, such as cerebral vascular accidents (CVA) or non-cerebral bleeding, it has been postulated that there is not sufficient evidence to support the application of PHT in the urban setting (Stephenson *et al*. 2002). Implementation barriers, which are reflected by the notion that PHT remains a non-requirement in otherwise urban areas, were evident in the following participant responses:

> *[R]urally, yes, I think it [PHT] would make a great difference, in those sorts of settings, I think, urban, not as much necessarily (Interviewee 6).*
>
> *[B]ecause most people who work in the urban area are very close to a Cath lab [cardiac catheterization laboratory], so I think for them to start thrombolysis is probably not as valuable as those on the periphery (Interviewee 1).*

With respect to the assertion by Stephenson *et al.* (2002), which could be considered circumstantially dependent, the definition of the term 'urban setting' remains open to interpretation, especially in South Africa. The classification of urban and non-urban – or otherwise, rural areas – in South Africa was described by a National Statistics Census (Statistics South Africa 2001), as somewhat fluid, since these terms are mostly indicative of a somewhat integrative society. In addition, the re-demarcation of municipalities in South Africa since 1998 has resulted in the legal definitions of 'urban' and 'non-urban' settings becoming less associated with national district municipalities attempting to move in the direction of an all-inclusive municipal classification.

> *I think that's the main reason why no one has really pushed for it in South Africa, and the big question is, where do we need it?. … Okay, so the place where prehospital thrombolytics is going to make your main difference is in the rural areas (Interviewee 3).*

Arguably, the most important issue when contextualising the urban PHT debate may be the availability of accessible resources, specifically PCI-capable facilities. Challenges in relation to healthcare access bear witness to the historical inequalities in South Africa's healthcare system and which continue to be an encumbrance (Coovadia *et al.* 2009). At present, there are only 62 PCI-capable facilities in South Africa, with almost half of these located in one major centre in the country and 75% in the private healthcare sector (Stassen *el al.* 2017).

In terms of population density and geographical location, the disparity of specialised coronary care in South Africa is evident, with some populations living more than 500 km away from the

nearest PCI facility, and with most of the population having no guaranteed access (Stassen *et al.* 2017). The idea that PHT is not a necessity, or a lack of understanding of its value or potential, which in turn potentially results due to a barrier is highlighted by this participant:

> *I don't think they [leadership or management] see a need for this, because of such a rate of hospitals, in the around, surroundings, that, I don't think they see the need for that. … I think, when they understand the bigger picture, and how it will benefit the patient, I think with proper training and stuff they might start to move in that direction (Interviewee 2).*

- **Scepticism and associated risk perceptions**

A degree of controversy has often surrounded the administration of thrombolysis within the prehospital setting (Fletcher, Stewart and Savage 2013). However, clinical trial data has demonstrated that, when performed by trained prehospital practitioners, PHT is safe, logistically economical and an effective reperfusion strategy (Cannon, Sayah and Walls 1999). Furthermore, while risk perceptions exist within the realm of both in and out of hospital, it needs to be noted that there is no evidence that PHT increases the rate of complications (Benger, Karlsten and Eriksson 2002). This is because, apart from myocardial rupture, which increases with treatment delay, all complications associated with thrombolysis remain static, e.g. they do not increase or decrease due to location of where drug administration occurs. Scepticism and associated risk perceptions as a barrier were made evident in the following comment by one participant:

> *I think there's the whole bleeding risk and, if something goes wrong, it has the potential to go seriously wrong (Interviewee 2).*

Concluding statement on Theme 4: Characteristics of individuals

Sub-theme 4.1: Knowledge and beliefs about the intervention

Behavioural change theories confirm both that the knowledge of or beliefs in an intervention exert a major degree of influence and, that enthusiastic use requires a positive, affective response toward an intervention. It should be noted that the ability and extent to which individuals are able to judge an intervention are directly dependent on their understanding of the principles, which justify the use and application of the intervention. It is, therefore, imperative that the individuals involved be equipped with a sound understanding of or at least a level of familiarity with the facts and truths regarding the intervention.

4.3.3.2 Sub-theme 4.2: Self-efficacy

Defined as an individual's belief in his or her ability to succeed through accomplishing tasks in specific situations (Bandura 1977), self-efficacy is an essential component of behavioural

change theories that examine conduct and demeanour through individual actions (Rimer and Glanz 2012). In terms of the implementation sciences, high levels of self-efficacy enable a readier adaptation to change while lower levels tend to result in difficulties in adjusting to new developments, potentially creating resistance to change (Damschroder *et al.* 2009). Self-efficacy encapsulates multiple factors, almost all of which are present and appear in behavioural change theories, which use environmental and personal characteristics in an attempt to explain scientifically why and how behaviours change (Cunningham *et al.* 2002).

- **Confidence and competency**

Self-efficacy also comprises factors associated with motivation as well as control or situation variables (Dybowski, Sehner and Harendza 2017). In relation to implementation, these factors refer to competence or confidence in respect of mental and/or practical, independent abilities (Herliani, Harun and Ibrahim 2018). Apprehensions around self-efficacy in relation to confidence and/or competence, as the current study highlights, could be considered a cause and effect phenomenon due to the lack of actual clinical practice and experience in PHT administration. However, despite causation, concerns surrounding self-efficacy raise serious questions about whether – at the time of the current study – ECPs possess the cognitive skills or mental capacity required to initiate and practise PHT successfully.

Knowledge and learned experiences are essential elements of clinical practice for healthcare professionals, and any void in practical application or extended periods of non-compliance in terms of skills may result in skill decay (Campbell *et al.* 2015). Referring to a deterioration in proficiency, skill decay may occur as a result of a lack of practice over time, and denotes a lack of ability or adeptness to perform skills due to either retention intervals or non-compliance (Maehle 2017). While there is a paucity of research on advanced life support practitioners' skill retention, evidence suggests that skill decay is likely to occur within six to 12 months after initial training (Yang *et al.* 2012). The issue of skill retention, confidence and competency was attested to by two participants in the following comments:

> *I'm not currently confident that I can perform a thrombolytic case one hundred per cent correctly okay, and I've been qualified as an ECP for seven, no, eight years. … I don't even know if it's confidence, I can be a hundred per cent confident but if I'm competent is another question, and I base that on skill decay. I don't use, I haven't used it. I haven't done it (Interviewee 3).*

> *I think there's a great fear around it, so, I think my reaction is always, thrombolysis, […] I can skip over this part, because I'm actually too scared to do it prehospitally (Interviewee 6).*

Apprehensions about self-efficacy not only generate self-doubt in the cognitive functions of independent practitioners and create the potential for negative patient outcomes but they also

have an effect in the realm of organisational leadership by raising issues around liability, which may potentially damage practitioner–organisation trust or guidance relationships. This issue of relationship trust and self-doubt was reflected in the comments of one of the participants:

> *Look, any practitioner trained well enough and skilled well enough, with enough experience can do it, okay. The issue comes as, who, it falls back on. Us? Who does, where does the responsibility fall? … Okay, so you're an independent practitioner working for us, if you don't do it properly, who gets sued? We will, so this becomes our problem (Interviewee 5).*

- **Education and training**

A significant theme among the research participants related to the perception of a lack of education and a lack of training for the skill or procedure, specifically the administration and/or delivery of PHT. While psychomotor skills may not necessarily be complex themselves, the process of PHT involves a critical level of analysis and clinical decision-making, which elevate the level of difficulty. However, to identify certain issues regarding the lack of training, a breakdown of the actual learning process warranted further discussion, as indicated in the comment of one of the participants:

> *[I]t was the sort of topic we passed over very quickly in fourth year, so, well, discussed, but, the actual implementation prehospitally? We sort of passed over because we don't seem to be doing it yet (Interviewee 6).*

In order to professionalise para-medicine further and to keep up with international trends, the HPCSA has implemented steps to discontinue paramedic short-course training, and now requires higher education at university level (MacFarlene, van Loggerenberg and Kloeck 2005; Sobuwa and Christopher 2019) While tertiary-level paramedic training, specifically the ECP qualification, advances the field of prehospital care and promotes the uptake of activities, such as research, higher education has traditionally been a challenge in South Africa (Beets 2009). South Africa's troubled tertiary educational sector is the result of transformational issues, such as decolonised education, limited resources and a lack of government support or funding (Mouton, Louw and Strydom 2013). The consideration in this regard is whether tertiary institutes can fully support all the learning requirements of ECPs, in terms of both theory and practical skills aspects, or whether some learning criteria are neglected as alluded to in a subsequent response by one participant:

> *I didn't go into much detail about all the thrombolytic stuff, basically, the only experience or exposure I have to thrombolytics is post thrombolytic patients transported to an upgrade facility (Interviewee 2).*

When and if performance issues or concerns regarding competencies arise in the field, education and training should primarily be assessed, although as the current study would

argue, a crucial distinction between academic environments and industry should also be made. Without this distinction, responsibility, as observed by the current study, tends to swing between the academic environment, which includes clinical training, and that of industry, specifically the EMS. Initial assumptions suggest that healthcare professionals should be fully qualified and experienced, thus, fully capable of procedural skills upon graduation. However, upon further supposition, this may not always necessarily be the case, as alluded to above by some participants in the study.

To appreciate this fully, one needs to identify the authenticity of the learning process. Authentic principles of learning address the context and real-world setting, implying that the academic environment and work industry predicate on one another (Herrington and Herrington 2008). Moreover, this area of inter-connectivity between the two environments is related to common healthcare aims or objectives regarding EBPs, known as the knowledge to translation gap (Lang, Wyer and Haynes 2007).

- **Continual professional development**

The responsibility for addressing what Campbell *et al.* (2015) describe as the confidence–competence phenomenon, lies in continuous professional development (CPD). Including factors such as liability, ethics and competency, CPD is an essential component of healthcare practice. The CPD process involves the maintenance of skill competencies through knowledge and experiences acquired beyond the initial education and training (Filipe *et al.* 2014). The HPCSA CPD committee mandates guidelines on CPD, which require healthcare practitioners to update their level of skill and competency (Continuing Professional Development Guidelines for The Health Care Professionals 2014). The committee also postulates that the onus and responsibility to do so lies with the individual practitioners, which some participants acknowledged may be an area of difficultly, at least in terms of facilitating PHT:

> *Okay so, I'll be honest with you, I haven't looked at the evidence in about two years (Interviewee 3).*
>
> *[T]he specifics of it? Not terribly much, but in terms of, you know say, if I had to do it now today, I would have to go and read up about it, sort of, the dosages and things (Interviewee 1).*
>
> *I wouldn't say it's an unsafe sort of skill, but are the practitioners competent? We don't have specialist cardiac response cars where practitioners are continually, all they doing are cardiacs. … So, the drugs safe, practitioners' ability to give it? Keep on top of it? Know when? That's potentially where the issue sits, is that continual medical education related to that. How do you make sure that guy is competent? (Interviewee 5).*

The HPCSA CPD committee stipulates that practitioners are to acquire at least 60 continuous educational units over a 24-month period and reserves the right to conduct mandatory audits on individual practitioners (Continuing Professional Development Guidelines for The Health Care Professionals 2014). However, the guidelines do not refer to any set of specific skill competencies; instead, it instructs a medium of practice or ideal only, with the sole specification being that practitioners are to designate 10 continuous education units to ethical principles. A participant expressed concerns in terms of skill training and retention:

> *Who keeps people upskilled? You know, how many should you do? I don't know. What's the international benchmark in terms of being competent?. … I mean, where do you remain competent? So, fine, you go through your four-year degree, you learn it, you got all the background, perfect, how do you keep updated? (Interviewee 5).*

Although the HPCSA maintains that the responsibility to accumulate continuous education units and maintain evidence of competency rests with individuals registered with the board, this does not take into account nor does it specify any specific set of skill competencies. Pillay (2011) highlighted this issue through a needs analysis of CPD for paramedics in South Arica. Based on his findings, he recommended a national clinical registry, specific to skills, in order to facilitate clinical competence of individualistic skills.

Concluding statement on Theme 4: Characteristics of individuals

Sub-theme 4.2: Self-efficacy

The South African EMS has grown to a level at which qualified and experienced ECPs train and develop undergraduate ECPs although the consideration may be for specialists to offer training in respect of specialist skills, for example those involved in PHT. The recommendation is that prehospital practice be structured around a robust clinical governance programme, capable of identifying errors in clinical judgment and refining practice in a way that improves independent practitioner skills and quality of care.

4.4 An analysis of the implementation of prehospital thrombolysis in South Africa

While the current study aimed to identify reasons why PHT has not become mainstream in South Africa, i.e. engaged by ECPs, and argues that PHT does not qualify as an implemented practice, it does not specifically determine whether PHT has been officially implemented. The study investigated the implementation process associated with PHT and took all possible influential factors into account.

Through the functional stages of implementation, discussed in Chapter 2, namely exploration, installation, initial implementation and full implementation, it was theoretically and objectively determined that PHT has not been implemented fully with success. The notion of whether PHT

has been implemented in South Africa, or not, is paramount, as this provides an indication of its stage of development; thus, which drivers or resources may be necessitated and which implementation strategies might still be lacking. Furthermore, a lack of clarification, or relevant understanding regarding the stages of implementation, could create barriers within the implementation process.

The way in which the implementation of PHT is viewed, could largely determine actions associated with the overall implementation process. The result of perception, discussed in 4.3.2.3 (leadership engagement), refers to knowledge as well as beliefs as influential factors, which could inherently become subversive and affect implementation. Subsequently, if it is conceived, especially by stakeholders, that PHT has already been implemented, this might lead to a decrease in motivation, and disrupt future efforts in actively attempting to reach successful or full implementation.

While current HPCSA guidelines for PHT by ECPs, are reflective of EBP, the consideration in this regard ought to be that expressed guidelines or even policies differ significantly from active guidelines or policies that are at least in use. Subsequently, guidelines or policies that merely exist have no bearing on whether their content is or has been implemented, especially since administration enactment alone has proved to be inadequate in stimulating new practices within healthcare (Watt, Sword and Krueger 2005). Whilst the current HPCSA prehospital guidelines stand as a testament of PHT installation, the absence of PHT in day-to-day practice within South Africa implies that it remains at the stage of installation.

There may be some evidence that PHT is approaching the stage of initial implementation in South Africa, reflecting what Fixen *et al.* (2009) describe as the awkwardness that exists when challenging the status quo. This ‘awkwardness’ can be seen in certain participant responses in 4.3.3.1 (knowledge and beliefs about the intervention), specifically perceptions regarding current (non-reperfusion) practices, such as MONA, as well as scepticism around change associated with the implementation of PHT.

However, there is no evidence to support PHT at the stage of full implementation, with no indication that 50% of intended individuals (ECPs) are actively engaged in its use, this as an indicator of full implementation (Fixen *et al.* 2009). To provide context, this level of engagement, in accordance with the HPCSA statistics of registered practitioners (Statistical Information of Registered Persons 2018), would constitute at least 330 ECPs throughout South Africa, employing PHT in their day-to-day practice. There would also need to also be an appropriate from of clinical governance overseeing the use of PHT in order to be considered a standard practice (Smith *et al*. 2014). Conclusively, PHT within South Africa fails to capture

aspects required in order to constitute a fully implemented practice, i.e. standardised practice, regarding levels of engagement, sustainability and governance.

4.5 Implementation research and gaps in South Africa

While the healthcare initiative in Africa and even sub-Saharan Africa has proved implementation research to be scarce, South Africa has shown potential in this domain, with universities as well as other institutions incentivising implementation research efforts. With projects related to HIV/AIDS, tuberculosis, and other non-communicable diseases, the Centre for Evidence-Based Healthcare focuses on developing programmes intended to strengthen the capacity for implementation research in South Africa (Centre for Evidence-Based Healthcare 2011). Fundamentally, the focus of the Centre for Evidence-Based Healthcare is to inform and promote EBPs by narrowing implementation gaps through systematic reviews, which Bero *et al.* (1998) see as the most effective means of promoting implementation research findings.

While efforts to stabilise and improve implementation research are gaining momentum, South Africa still remains subjective to chronic and even emergent implementation gaps. In contrast to high-income countries, low- and middle-income countries, such as South Africa, face additional challenges in the uptake of evidence-based research in healthcare and any implementation gaps. Haines, Kuruvilla and Borchert (2004) highlight this disparity as a result of inadequate healthcare systems, limited research access, a necessity for professional regulation, and unchecked commercial activity which could neglect or abuse resources.

4.6 Prehospital thrombolysis through the science of implementation

The science of implementation within the field of PHT can be demonstrated by the Grampian region early anistreplase trial (GREAT), which serves to demonstrate an implementation strategy (Rawles 2003). The GREAT initially created an abstract basis for PHT, which began by preparing as well as facilitating the conditions required to accomplish PHT implementation. After determining a needs analysis for PHT, the GREAT was conducted as randomised, double-blind, parallel group trials, which are considered the gold standard in interventional-based studies (Misra 2012). During this period of theoretical testing, and by using improved ventricular function as a predictor of patient outcome in STEMI, the GREAT study demonstrated lower accounts of mortality and morbidity by implementing PHT (Rawles 2003).

CHAPTER 5
CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

The primary purpose of this study was to explore barriers to the implementation of PHT or the lack of PHT for the treatment of STEMI in South Africa. The study also attempted to provide insight into the science of implementation, specifically its purpose and values, including the ability to inform future healthcare practice innovation. The study focused on exploring the perceptions of key role players in the field of prehospital care, those deemed knowledgeable, and those relevant to the environment in which PHT has thus far been implemented unsuccessfully.

The aim of the study was realised through application of the case study design, guided by a conceptual framework. The findings were then analysed using thematic analysis, as reported on in Chapter 3. Discussions on emergent themes represented the fundamental aspect of the study, as presented in Chapter 4 with discussion on the study findings leading to the conclusions and the recommendations. Discussions in this final chapter include recommendations for future practice based on the analysis and summary of the research findings.

5.2 Research limitations

Despite adherence to the case study methodology and verification strategies, the study was subject to some limitations. However, as Price and Murnan (2004) explain, the recognition of the limitations of a study does not resemble a form of weakness, but shows critical thinking and reflection and offers future research opportunities. The current study comprised a single case study, namely a single private EMS organisation, thus its findings may not be able to be fully extrapolated to the entire South African EMS community.

Due to PHT not being available to most, if not all, ECPs at the time of the study, describing experiences or delivering testimony in order to explain potential barriers may to some extent, have been difficult or arguably limited. Therefore, it is possible that the results may have been based on a poor understanding of actual procedure or policies regarding PHT, which in turn might have created a limited basis for conclusions. During the course of the study, new developments took place in emergency medical care, which included moving from protocol-based strategies to clinical practice guidelines for prehospital care. It may be considered that, these developments may subsequently affect existing PHT barriers or improve the systematic uptake of PHT, although such developments have not been evident during the research period.

5.3 Summary of the findings

The study findings are based on an individual case study, specifically one private EMS, although the wide array of knowledge and experiences within the case provided in-depth perspectives into the barriers to the implementation of PHT in South Africa. Semi-structured

interviews were conducted with selected key informants, including operational, managerial, directive and clinical personnel. These interviews underlined several potential barriers to the implementation of PHT.

The barriers were classified primarily as cost, complexity, cosmopolitanism, readiness for implementation, implementation climate, leadership engagement, knowledge and beliefs, and self-efficacy. The findings also highlighted the disconnect in the links between newly adopted policies, effective practices and prevailing clinical systems, which, although not unique to South African healthcare, have traditionally been a problem area for many organisations.

5.3.1 Analysis-based recommendations

Based on analysis of the identified themes, and through application of the CFIR-ERIC tool, this section presents a summary of potential barriers in the implementation of PHT within South Africa, and provides implementation strategies to overcome these barriers. The data and inferences presented in the form of themes were aligned with the constructs of the conceptual framework, as well as the CFIR-ERIC strategy-matching tool. Important to note is that certain recommendations, those in terms of implementation strategies, either overlap or exist on a spectrum of relevancy, implying that some strategies may relate to multiple constructs.

Thus, in order to avoid repetition, suggested implementation strategies were then aligned with the objectives of the study and the most relevant were selected. The diagram below depicts a schematic representation of the implementation strategies from the CFIR-ERIC tool and data points from the thematic analysis methodology, linked to the constructs of the conceptual framework, which is discussed throughout the subsequent section.

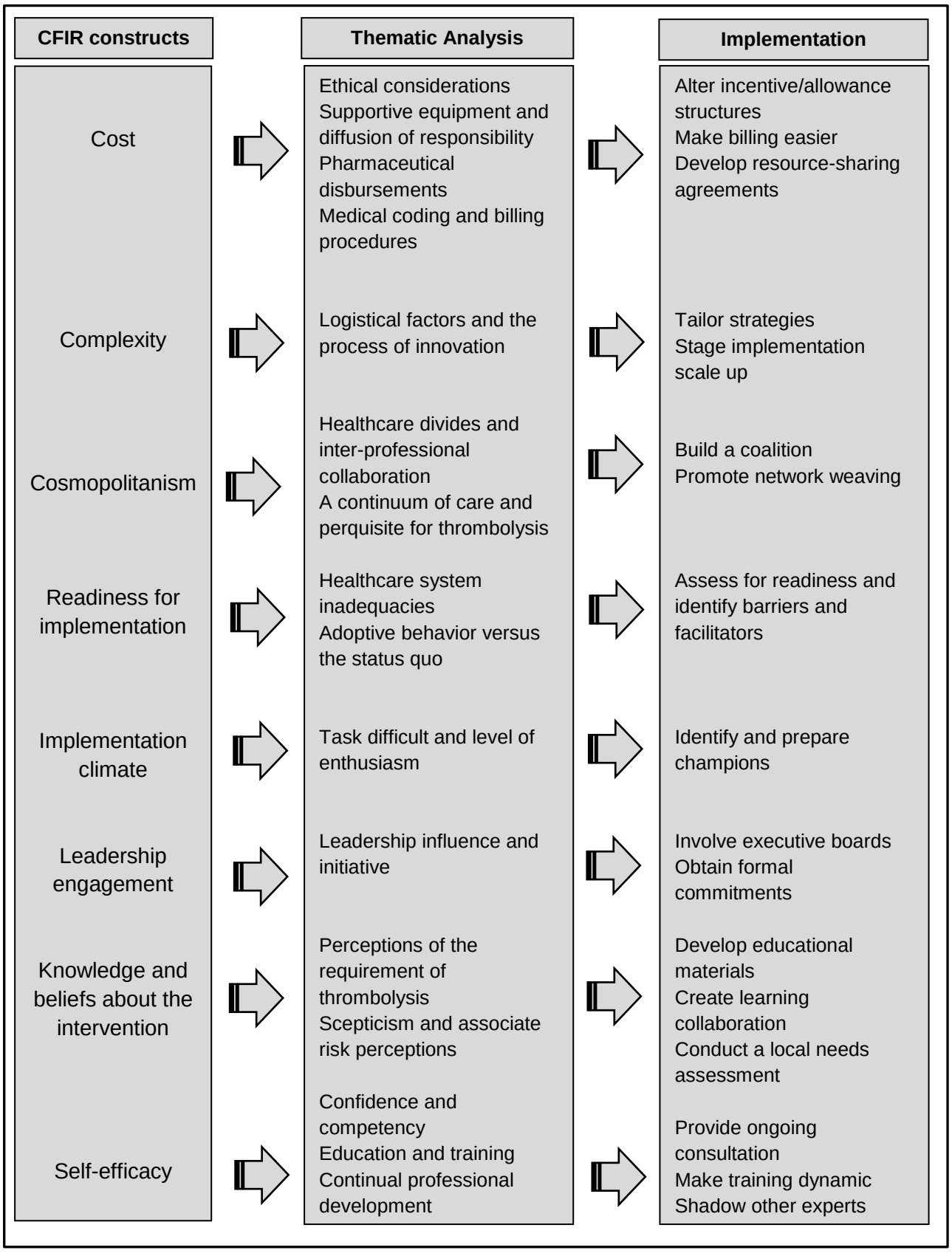

Figure 4.2: Evolved correlation between methodology and conceptual framework

Source: Author's own compilation

5.3.2 Recommendations and discussion

The next section logically follows a series of brief discussions in accordance with the analysis-based findings setting a pattern for implementation strategy recommendations.

5.3.2.1 Cost

In terms of cost as a barrier to PHT, the study highlighted issues associated with medical coding systems, billing and a diffusion of responsibility, specifically regarding supportive equipment. In consideration of these cost-related issues and in line with the CFIR-ERIC tool, the following implementation strategies are suggested:

- **Alter incentive/allowance structures**

In attempts to improve patient care delivery and foster healthcare organisational relationships, there have been a growing number of calls to shift from a service-based approach, which incorporates fees for service, towards a value-based system, which incentivises clinical practice. (Conrad 2015). Currently, South Africa's healthcare system operates and relies largely on a service-based approach, which is arguably inefficient regarding equal healthcare access and long-term sustainability (Delobelle 2013).

- **Make billing easier**

One of the issues highlighted in the study was the inability to bill for PHT as an intervention, specifically in relation to medical coding systems in South Africa, which lack accurate descriptors for medical, surgical and diagnostic services. Local healthcare funders, administrators as well as other stakeholders should consider acquiring guidance from established international coding systems, such as the American Medical Association who establish and maintain medical practice standards (Thorwarth 2008).

- **Develop resource-sharing agreements**

Developing sharing polices or agreements, which consist of internal as well as external resources, pertains to experienced medical personnel and equipment to enable multiple services, within both private and public sectors (Thandani 2014). Service providers should be encouraged to develop plans and identify advantageous resource-sharing opportunities to provide PHT, which would include both needs and cost analysis.

5.3.2.2 Complexity

Logistical factors were deemed one of the major challenges regarding complexity as an encumbrance in terms of fully embracing PHT as an innovation (see 4.3.1.2 Logistical factors and the process of innovation). Specifically, challenges related to complexity comprised technical and/or administrative issues, which represent drug instalment, storage and procedural governance. In consideration of logistical issues and in line with the CFIR-ERIC tool, the following implementation strategies are suggested:

- **Tailor strategies**

One of the reasons tailoring strategies is vital toward successful implementation is that implementers often become fixated on single strategy approaches often as a result of biases based on previous levels of success, which often leads to a one-size-fits-all approach. Powell *et al.* (2017) explain that, in order to tailor an implementation strategy, organisations are required to assess the influential factors fully within the implementation process first and only once this has been done, to focus on the context in which these factors exist.

- **Stage implementation scale up**

Scaling up in terms of healthcare innovation could be seen as the deliberate effort to increase the effect of an EBP such as PHT, one which cannot only be integrated if necessary, but which should also be sustained fully. Strategic planning is vital for this to happen, and implementation research needs to be linked with clinical monitoring and evaluation systems. Like tailoring strategies, for scaling up implementation, there is an emphasis on the requirement to understand fully and contextualise influential factors, which would otherwise facilitate or hinder a successful and sustainable scaling-up process (Barker, Reid and Schall 2016).

5.3.2.3 Cosmopolitanism

In terms of cosmopolitanism, issues regarding healthcare divides, a lack of continuum of care and inter-professional collaboration were at the forefront of charges deemed to be associated with the prohibition of PHT (see 4.3.2.1 A continuum of care and obligation for thrombolysis). In consideration of these issues and in line with the CFIR-ERIC tool, the following implementation strategies are suggested:

- **Build a coalition**

Primarily, patients should not experience care in a vacuum, and establishing partnerships that extend the continuum of care and create synergy along with proper coordination of services is essential. In doing so, organisations can align forces to decrease costs, increase revenue, provide suitable care in the correct environment, and generate value-based care. The fundamental principles of a healthcare coalition are intended to reduce the burden of disease or illness and mitigate against injury or loss of life, as well as achieve a coordinated response or preparedness.

Healthcare coalitions are typically comprised of a network of healthcare services or organisations, which then attempt to share knowledge and resources in order to pursue innovation in an implementation effort. Important to consider is that healthcare originations differ significantly from one another in terms of structure, process, capabilities, response and effectiveness (Evans, Brown, and Baker 2017). Thus, some of the critical steps in building a coalition are determining participants and their jurisdictions, as well as defining the intended function of the coalition, which, as Barbera and Macintyre (2009) explain, require deliberate developmental efforts from healthcare stakeholders.

- **Promote network weaving**

Similar in principle to that of coalition building, although perhaps more specific, network weaving refers to connections and interactions between healthcare communities and organisations, with the intention to build upon existing relationships (Kemper-Koebrugge *et al.* 2016). In terms of implementation, the aim of network weaving is to intensify collaboration through knowledge sharing and shared goals or outcomes. Efforts of healthcare services need to be improved to weave a network in order to strategise reperfusion therapy in South Africa, which would support the successful implementation of PHT.

5.3.2.4 Readiness for implementation

Described by Greenhalgh *et al.* (2004: 609) as the "motivation and receptivity for change", readiness for implementation refers to indicators of organisational commitment towards change. This comprises constructs that contribute to context involving change i.e. organisational setting, resources, and culture. Regarding readiness for implementation, the current study highlighted issues surrounding healthcare system inadequacies, and whether these would facilitate and support the uptake of PHT. The following implementation strategies were suggested to support this in line with the CFIR-ERIC tool:

- **Assess for readiness and identify barriers and facilitators**

In order to initiate change and implement PHT successfully in a climate which may lack readiness, organisations should employ strategies to improve the uptake of PHT, such as adopting an implementation model of diffusion or knowledge to process. Multiple diffusion or knowledge to process models exist, although Bradley *et al.* (2011) explain the problem with most of these is that they are largely theoretical, and thus have limited practical application. Accordingly, in an attempt to move PHT from theory to clinical practice, an all-inclusive diffusion or knowledge process model may be required, one which preferably includes both theory and practical applicability.

5.3.2.5 Implementation climate

Although similar to readiness for implementation in the sense that implementation climate also refers to an organisation's 'absorptive capacity for change', implementation climate exits at the individual level and not at the level of the organisation (Greenhalgh *et al.* 2004). Therefore, implementation climate refers to individuals involved with the change process, and the extent to which they are motivated, supported, and rewarded for new innovations. In accordance with the CFIR-ERIC tool, the following implementation strategies are recommended for implementation climate:

- **Identify and prepare champions**

Identifying and preparing champions refers to locating and supporting individuals who are dedicated to carrying out the innovation, those who have a deep understanding of the application and context of the intervention, as well as the environment to which it is being introduced (Miech *et al.* 2018). The aim of encouraging champions of change is to overcome

resistance that an innovation is likely to provoke and, as Shaw *et al.* (2012) explain, is a critical component to efforts regarding transformational change within an organisation.

5.3.2.6 Leadership engagement

In terms of leadership, barriers hinged mostly on the degree of influence and initiative demonstrated by leaders or those in positions of power. Considering this fact and in accordance with the CFIR-ERIC tool, the following implementation strategies are recommended:

- **Involve executive boards**

Involvement of executive boards is crucial in facilitating the implementation of new healthcare practices, as these often hold power required to change or execute policies, although in order to be effective, executive boards should be appropriately appointed or established (Arnwine 2002). The concept of transformational leadership engagement would favour the transactional approaches typical of healthcare organisations and executive boards, but which, through limited integration, may lead to ineffective implementation (Bass and Avolio 1993). Traditionally, transactional leadership tends to focus on the existing rules and strategies formulated by policymakers, while a transformational approach enables leaders to realign existing rules and policy norms to fit their environment.

Transformational leadership in the healthcare environment calls for leaders who are involved in policy- or decision-making to engage further by exploring, understanding and, ultimately, embracing the culture of a constantly shifting healthcare environment (Al-Sawai 2013). This could facilitate the development of a greater awareness of the accepted management of STEMI, the state and capabilities of prevailing healthcare systems, and the possibilities of alternative strategies. Following this process, leaders may then be able to realign existing rules and policy norms deliberately to fit the environment and create a clinical pathway for the implementation of PHT.

- **Obtain formal commitments**

Leadership engagement should promote a degree of latitude in respect of the risk experimental strategies that are rooted in abstract theory which, incidentally, was the basis for the GREAT study (Rawles 2003). If risk experiments are conducted within a controlled and co-ordinated environment, these could lead to positive outcomes through the prototyping of new ideas or strategies. Using the theoretical underpinnings of implementation theory and raw experimentation, the GREAT study successfully field-tested PHT (Rawles 2003), an example of which leaders, especially those in the prehospital environment, should take note.

5.3.2.7 Knowledge and beliefs about intervention

Under knowledge and beliefs about the intervention and as a potential barrier, perceptions regarding requirements and scepticism of PHT appear to play a major role (see 4.3.3.1

perceptions regarding the requirement for thrombolysis). Based on this fact and in line with the CFIR-ERIC tool, the following implementation strategies were concluded:

- **Develop educational materials**

Factual and accurate information is central to changing beliefs and improving the knowledge of individuals either directly or indirectly involved with an innovation where a lack of such information could influence the implementation of PHT. The current study would advise healthcare organisations, those in support of PHT, and especially EMS, to make efforts to develop and disseminate supporting materials, specifically in a way that will allow clinicians and stakeholders at the individual level to learn objectively about PHT (see 4.3.3.1 knowledge and beliefs about the intervention).

- **Create learning collaboration**

Collaborative learning plays a central role in educational healthcare environments, ensuring that information is disseminated to its intended or target audience and acting as a motivational tactic for individuals to receive information (Wolf *et al.* 2016). Healthcare service providers should always be encouraged to introduce collaborative learning within the realm of implementation in order to facilitate new innovations, specifically PHT.

- **Conduct a local needs assessment**

While Blasé *et al.* (2015) acknowledge that data on its own is not enough to promote or sustain long-term implementation, it remains a necessary component for productive change. Thus, EMS and other relevant stakeholders should be encouraged to collect and, in turn, analyse data specifically related to the requirement of PHT. A local needs assessment would provide invaluable information not only to justify the need for PHT but also to go further to ensure that the implementation of PHT is resolved by remedying the correct issues.

5.3.2.8 Self-efficacy

Several issues acted as potential barriers under the sub-theme 'self-efficacy'. These included concerns around confidence or competency regarding the use of PHT, as well as issues relating to education and ongoing training (see 4.3.3.2 self-efficacy). Primarily, the greater the level of self-efficacy, the more likely it is that individuals will make decisions to engage with new interventions (Damschroder 2009). Therefore, in order for an intervention to be successful, there are a number of key components that should be in place, namely experience, training and confidence. Considering these factors, and again in line with the CFIR-ERIC tool, the following implementation strategies are suggested.

- **Provide ongoing consultation**

Provision of consultation with experts in the field is a way of supporting implementation, at least through developing skills and knowledge of individuals tasked with providing or administering a new intervention (Nadeem, Gleacher and Beidas 2014). It is important to note that expert consultation in this instance, although ideal, does not apply to cardiologists

exclusively. As discussed previously (see 4.3.2.1 healthcare system inadequacies), this is critical within the local context. Healthcare services should be encouraged to acquire guidance from allied or other healthcare experts within the realm of pharmaceutical or coronary care and should develop a consultation model for ECPs expected to engage with PHT.

In terms of medical oversight with regard to prehospital administration safety, several technical solutions already exist (Benger, 2002). These comprise telemetry through modern ECG capabilities, as well as single bolus thrombolytic agents such as r-tPA. However, organisational changes are required to facilitate the administration of PHT and elements surrounding the continuum of care management of STEMI patients in South Africa. Therefore, consensus on what needs to be achieved should involve key role players in the industry, including both prehospital and inter-hospital directorates. A vigorous protocol that is designed and shared by secondary care, in the form of medical consultation or clinical governance, would further be clinically invaluable.

- **Make training dynamic**

The purpose of dynamic training is healthcare to deliver knowledge that is conducive to a working environment or context, and to ensure that training is interactive in order to enhance learning experiences (Bergero, Hargreaves and Nicholas 2012). Since PHT is evidently not fully implemented and therefore, available throughout the EMS within South Africa, training institutes should foster ongoing training programmes or partnerships with clinical facilities that actively engage in thrombolysis. Access to CCU facilities in this regard would be invaluable. This is a short-term solution, until the establishment of ECPs who are suitably trained and confident to manage STEMI with PHT independently.

- **Shadow other experts**

Paramedics already have many skills, which are relevant for STEMI management, although some may require further training in ECG recognition or drug administration (Johnston, Brightwell, and Ziman 2006). This knowledge is essential in becoming confident enough in the clinical decision-making process, specifically regarding the patient's eligibility for thrombolysis. Where possible, training institutes should provide ways in which prehospital undergraduates could observe directly and participate in shared administration skills of thrombolysis, specifically IHT, to be able to relate these experiences to PHT.

5.4 Conclusion

While attempting to answer the research question pertaining to barriers of PHT, the study also highlighted the significance of PHT, and by doing so, identified with what could be perceived or even described as a 'reperfusion dilemma' regarding current reperfusion strategies. Based on merit and risk stratification in terms of clinical outcome, this choice of reperfusion strategy encompasses pharmaco-invasive or mechanical reperfusion, or in some instances, even a combined therapy.

Objectively, however, and, as discussed in this thesis, the verdict of reperfusion strategies evidently resembles less of a dilemma, and more of a Hobson's choice, an orthodox or eponymous term used to explain the appearance of choice in a situation in which none exists. (Shatz 2016; Manas and Curzen 2018). Fundamentally, the incident of CAD and STEMI is dramatically increasing in South Africa (Chetty and Ross 2016), while mortality and morbidity factors as a result, continue to severely impact economically disadvantaged populations (Keates *et al.* 2017).

The treatment approach to STEMI, above all else, remains time-sensitive, and international recommendations for reperfusion strategies (Widimsky *et al.* 2010). have proved themselves to be non-universal, or to some extent, confined. Therefore, international and/or generic reperfusion guidelines should be adapted according to local context, or those environments in which limited clinical resources pose distinctive challenges to the very same guidelines in effect (Armstrong, Westerhout and Welsh 2009; Ibanez *et al.* 2018).

The findings of the current study suggest what is already well known within the realm of the implementation sciences, although, perhaps not what has been understood or at least well recognised within other areas of scientific study. Specifically, implementation is a highly complex phenomenon, one that may in effect hinder or prohibit healthcare innovation without a comprehensive understanding or reasonable sense of appreciation. South African EMS, allied and/or other healthcare organisations need to reach consensus regarding what needs to be done to implement PHT. In doing so, key role players should be afforded a role in the discussion, considering that part of the implementation process may be related to legislation, especially within the domain of cost or medical billing procedures.

One of the first steps towards the successful implementation of PHT should be to raise awareness in terms of reperfusion strategy limitations in South Africa and associated benefits of PHT in order to change education and beliefs, which may be contributing to barriers. Furthermore, research effort is required within the science of implementation. Based on such research, an understanding should be developed on what it would take to implement new healthcare innovations, in this case, PHT. The topic discussed within this study was deemed one of clinical significance; therefore, it is imperative that it receives greater recognition and engagement as well as commitment from leaders or relevant stakeholders.

5.5 Recommendations for future research

This section provides some recommendations to help overcome barriers and to identify additional or other not yet identified barriers to PHT in South Africa.

- Enhance the impact of implementation science within South African healthcare systems, and improve definitions as well as examples of implementation strategies by committing existing strategies to practice. Implementation science is a rapidly growing area of inquiry, and substantiating current implementation strategies will guide future

generations of improved frameworks as well as reform that is outdated or inadequate healthcare practices.

- Encourage in-depth exploration of STEMI pathways and national service frameworks, with the intention of setting patient-centred target times to reperfusion and encourage hospitals to expand their role and expertise in terms of initiating PHT. Increasing awareness of PHT, both in and out of hospitals, has the potential to develop community-driven decision-making teams.
- Create innovation initiative by assigning PHT teams tasked with introducing administration of PHT initially in perhaps more critical, or rural/outlying areas. Determine resources and resistance mechanisms and thereafter develop evaluation criteria.

5.6 Closing statements

The Constitution of the Republic of South Africa, 1996, confirms the right and access to healthcare in South Africa as one of many socioeconomic rights guaranteed. However, unlike certain socioeconomic rights, i.e. the right to basic education or the Bill of Children's Rights, the right to healthcare is subject to an internal limitation. Fundamentally, this refers to the availability of government or state-funded resources, including specialist healthcare and in this instance, PCI, which remains a major challenge in terms of healthcare access for the general population. Section 27 (1) (3) of the Constitution further stipulates that no one may be refused appropriate medical treatment in an emergency, and undeniably, STEMI signifies an absolute emergency.

Described by Goldstein and Wiel (2005) as the prototype of a true emergency, with both efficacy and minutes determining survival outcomes, STEMI is a condition in which timely intervention plays an important role. It is essential that patients diagnosed with STEMI receive immediate reperfusion therapy, especially in cases where direct access to PCI is either delayed or not guaranteed. Based on this premise alone, PHT is not only an attractive option in terms of a plausible reperfusion strategy, but also a valid logistical solution to the CAD epidemic in South Africa.

The benefits of PHT in terms of safety margin and overall clinical effectiveness have been proved and are well documented with the utmost benefits seen with early administration after STEMI symptom onset. If the outcome of patients presenting with AMI and STEMI in South Africa is to be improved, and the national healthcare profile reformed, in terms of lessening the effects of CAD, then PHT and its implementation are undoubtedly an important development.

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List of annexures

Annexure A: Research permission letter

Annexure B: Letter of information and consent

Annexure C: Interview protocol guide and questionnaire tool

Annexure D: Consolidated Framework for Implementation Research (CFIR) constructs

Annexure E: Expert Recommendations for Implementation Change (ERIC) strategy- tool

Annexure F: Screenshot of generated implementation strategy compilation

Annexure G: Consolidated criteria for reporting qualitative research (COREQ)

Annexure H: Institutional Research Ethics Committee Approval

Annexure A
Research permission letter

Dear Sir/ Madam

My name is Andrew Lynch, and I am an emergency care practitioner and post graduate student currently registered at the Durban University of Technology, with the department of Emergency Medical Care and Rescue.

My aim is to complete a Master's Degree in Emergency Medical Care. The research I wish to conduct involves the private emergency medical services in South Africa. This project will be conducted under the supervision of Mr Simpiwe Sobuwa (Acting HOD: Emergency Medical Care and Rescue) and Dr Nicholas Castle (Honorary Research Fellow) of the Durban University of Technology.

I am hereby seeking your consent to access selected participants within your organisation. Potential participants will be selected based on their knowledge, expertise and experiences which will inform the objectives of the study. Participation in the study is voluntary and ethical considerations will, at all times, be adhered to in line with human rights principles.

I have provided you with a letter of information and consent which includes my research proposal, study objectives, as well as the measure and consent assets to be used in the research process. I have also provided a copy of the approval letter which I received from the Durban University of Technology Research Ethics Committee.

Upon completion of the study, I undertake to provide a bound copy of the full research report to your organisation upon request to do so. If you require any further information, please do not hesitate to contact me on 0713770321, email: andylynch01@hotmail.com. Thank you for your time and consideration in this matter.

Yours sincerely,

Andrew Lynch (BHSc Emergency Medical Care)

Annexure B

LETTER OF INFORMATION

Dear potential research participant

This letter serves to invite you to participate in my research study detailed below. I would also like to assure you that all information derived herein will be treated with the utmost confidentiality. I thank you for your participation or, at least, your consideration thereof.

Title of the Research Study:

An exploratory inquiry into the implementation process of prehospital thrombolysis in the treatment of acute myocardial infarction within South Africa: A case study of a private emergency medical service.

Principal Investigator(s)/Researcher:

Andrew Lynch BHSc (Emergency Medical Care)

Co-Investigator(s)/Supervisor/s:

Mr Simpiwe Sobuwa MSc (Med) Emergency Medicine;
Dr Nicholas Castle PhD (Academic) Health Service Research MSc (Dist) Cardiology

Brief introduction and purpose of the study

This study intends to highlight some of the barriers resulting in the challenges associated with the delivery of prehospital thrombolysis in emergency medical care in South Africa. The results of which suggest that these barriers often result in direct consequences to those patients requiring specialist interventional care and, yet, who are unable to receive it, while other applicable treatment strategies appear not to have been implemented. In essence, there are noted deficiencies as well as evident limitations in the management of STEMI patients in South Africa, specifically in respect of prehospital thrombolysis.

Outline of the procedures

You are invited to attend an individual interview which will be conducted exclusively by me, as the primary researcher. The research study is qualitative inquiry with a case study design and semi-structured interviews being used at the data collection method. In order to ensure a neutral location as well as suitable times and dates, interviews will take place either in your work environment or at a place and time which suit you. The duration of the interviews will vary according to constructed conversation but will not inconvenience you or your workplace (approximately 10–15 minutes).

Risks or discomfort to the participants

No form of harm, physical, psychological, emotional, social or financial, will be inflicted on you during the study and you will retain the right to fair and equitable treatment at all times.

Benefits

The potential benefits of the study may include conference presentations and publications. As a participant, you have the opportunity to potentially contribute to the existing body of knowledge and, therefore, also to advances in the medical and health sciences in South Africa.

Reason/s why the participant may withdraw from the study

Participation in the study is on a voluntary basis and you may choose to withdraw from the study at any time with no adverse consequences.

Remuneration

As a participant you will receive no compensation or remuneration for your participation in the study**.**

Costs of the study

As a participant, you will neither incur nor be expected to cover any costs pertaining to the study.

Confidentiality

All the information acquired during the interview process will be secure and protected to ensure full confidentiality. A pseudonym will be allocated to you to protect your identity as a research participant. The use of deductive disclosure methods will further guarantee that all identifying characteristics, such as organisational position, roles or responsibilities will be omitted to ensure that you cannot be identified.

Research-related injury

This study involves no risks of research related injury. However, in the extreme or unlikely event of such, you will not be able to claim or receive compensation.

Persons to contact in the event of any problems or queries

Please contact the researcher on 0713770321 email: andylynch01@hotamil.com, alternatively you may contact my co-researchers and supervisors Mr Simpiwe Sobuwa on 0313735269 email: simpiwes@dut.ac.za, Dr Nicolas Castle email: castle.nicolas@gmail.com, or you may refer to the Institutional Research Ethics Administrator on 031 373 2900. Any issues or complaints may be reported to the Director: Research and Postgraduate Support, Prof. S Moyo on 031 373 2577 or moyos@dut.ac.za

General

Once completed, all the findings of the research project will be made available to your organisation upon request. Please sign the necessary consent form below in order to confirm your willingness to participate in the study. I thank you for both your time and your contribution to this research project.

CONSENT

Statement of Agreement to Participate in the Research Study

Research Ethics Clearance Number: REC 64/16

- I hereby confirm that I have been informed by the researcher, Andrew Lynch, about the nature, benefits, and risks, of this study, and the research procedure to be followed.
- I have also received, read and understood the above written information (participant letter of information) regarding the study.
- I am aware that the results of the study, including personal details regarding my gender, age, date of birth, initials and diagnosis will be anonymously processed in a study report.
- In view of the requirements of research, I agree that the data collected during this study may be processed on a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings which may emerge during the course of this research and which may relate to my participation will be made available to me.

Full Name of Participant **Date** **Time** **Signature/Right Thumbprint**

I, Andrew Lynch, herewith confirm that the above participant has been fully informed about the nature, conduct and risks of this study.

Andrew Lynch

_____ _____ _____

Full Name of Researcher **Date** **Signature**

_____ _____ _____

Full Name of Witness (If applicable) **Date** **Signature**

_____ _____ _____

Full Name of Legal Guardian (If applicable) **Date** **Signature**

Annexure C **Interview protocol guide and questionnaire tool**

(FOR USE BY THE RESEARCHER ONLY)

Introduction

Thank you for participating in this research project. I am currently registered at the Durban University of Technology with the department of Emergency Medical Care and Rescue. My aim is to complete a Master's Degree in Emergency Medical Care. I wish to undertake my research project in the Western Cape Province in the both provincial and the private emergency medical services.

Brief description of the research problem through aims and primary research question

Title

An exploratory inquiry into the implementation process of prehospital thrombolysis in the treatment of acute myocardial infarction within South Africa: A case study of a private Emergency Medical Service.

Study aims

To explore the barriers to the implementation of prehospital thrombolysis in the treatment of acute myocardial infarction in the emergency medical services in South Africa, despite the growing evidence supporting its use and benefits.

Research question

What are the barriers to the implementation of prehospital thrombolysis in the treatment of acute myocardial infarction in the emergency medical services in South Africa?

Confidentiality assurances and agreement (additional conclusion post interview)

In order to ensure participant anonymity and maintain confidentiality, pseudonyms will be allocated to all participants. Furthermore, no names of the companies, organisations or individual participants will be mentioned in the research study without official, written permission.

Certain aspects of the participant data will also be omitted in order to further protect identities. Deductive disclosure will ensure that all identifying characteristics, such as company, organisation and roles or responsibilities of participants will not be identified. Data cleaning will ensure that data containing this information will be stored in a separate, password protected, computer file.

Name of participant/interviewee (insert pseudonym)

E.g. Participant 1

Name of primary researcher (interviewer)

Andrew Lynch

1. **Opening question (interview lead in- icebreaker)**
   Could you tell me a little about yourself and your position in your organisation by briefly describing your roles and responsibilities?

2. **Open ended question (non-specific)**
   Will you tell me what you know about PHT?

   Follow up questions (specific)

   - What type of information or evidence are you aware of regarding the safety and effectiveness of PHT?
   - Do you think that there is a strong need for the use of PHT, and how essential would it be to the needs of your patients?

   Prompts (if required)

   - You mention (*based on participant's response).* Can you elaborate on this?
   - You mention *(based on participant's response.)* Can you tell me how….?
   - In what way *(based on participant's response).* Does that…?
   - In order to clarify, could you tell me more about …? *(based on participant's response)*

3. **Open ended question (non-specific)**
   In your opinion, why are ECPs not currently using PHT?

   Follow up questions (specific)

   - How confident are you that ECPs are able to independently deliver PHT?
   - How do you feel about the prevailing practices that are available for the treatment of acute myocardial infarction and which are related to PHT, such as PPCI?

Prompts (if required)

- You mention (*based on participant's response)* Can you elaborate on this?
- You mention *(based on participant's response)* Can you tell me how …?
- In what way *(based on participant's response)* Does that …?
- In order to clarify, could you tell me more about …? *(based on participant's response)*

4. **Open ended question (non-specific)**

What factors do you think are involved in the implementation of PHT?

Follow up questions (specific)

- What type of local or national policies, regulations or guidelines influence the decision to implement PHT?
- What elements or changes do you think could be implemented in your organisation to facilitate the use and administration of PHT?

Prompts (if required)

- You mention (*based on participant's response)* Can you elaborate on this?
- You mentioned *(based on participant's response)* Can you tell me how …?
- In what way *(based on participant's response)* Does that …?
- In order to clarify, could you tell me more about …? *(based on participant's response)*

5. **Closing question (based on snowball sampling method)**

Is there anyone in your organisation whom you would be able to recommend and who could contribute to this study based on his/her relevant knowledge, expertise and experiences?

6. **Concluding statements**

- Express thanks and acknowledgement to participant.
- Confirm assurances of participant confidentiality.

Annexure D

Consolidated Framework for Implementation Research Constructs
CFIR Website: http://cfirguide.org/constructs.html

Construct		Short Description
I. INTERVENTION CHARACTERISTICS		
A	Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have the desired outcomes.
C	Relative advantage	Stakeholders' perceptions of the advantages of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention may be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organisation, and to be able to reverse the course of the intervention (undo implementation), if warranted.
F	Complexity	Perceived difficulty of implementation reflected in duration, scope, radicalness, disruptiveness, centrality, intricacy and number of implementation steps.
G	Design quality and packaging	Perceived excellence in the way in which the intervention is bundled, presented and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.
II. OUTER SETTING		
A	Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised by the organization.
B	Cosmopolitanism	The degree of the organisation's networks with other external organisations.
C	Peer pressure	Mimetic or competitive pressure to implement an intervention; typically because the majority of or other key peer or competing organisations have already implemented it or are bidding for a competitive edge.
D	External policy and incentives	A broad construct that includes external strategies to disseminate interventions, including policies and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay for performance, collaboratives, and public or benchmark reporting.
III. INNER SETTING		
A	Structural characteristics	The social architecture, age, maturity, and size of an organisation.

B	Networks and communications	The nature and quality of social networks webs and the nature and quality of both formal and informal communications within the organisation.
C	Culture	Norms, values, and basic assumptions of the organisation in question.
D	Implementation climate	The absorptive capacity for change, shared receptivity of individuals involved in an intervention, and the extent to which intervention, once implemented, will be rewarded, supported, and expected within the organization.
1	Tension for change	The degree to which stakeholders perceive the current situation as intolerable or requiring change.
2	Compatibility	The degree of tangible fit between the meaning and values attached to the intervention by the individuals involved, how those align with the individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative priority	Individuals' shared perception of the importance of the implementation within the organisation.
4	Organisational incentives and rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, salary increases, and less tangible incentives such as increased stature or respect.
5	Goals and feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and the alignment of that feedback with the goals.
6	Learning climate	A climate in which: a) leaders express their own fallibility and require team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe enough to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
E	Readiness for implementation	Tangible and immediate indicators of organisational commitment to its decision to implement an intervention.
1	Leadership engagement	Commitment, involvement, and accountability of leaders and managers in respect of the implementation.
2	Available resources	The level of resources dedicated to the implementation and ongoing operations, including funds, training, education, physical space, and time.
3	Access to knowledge and information	Ease of access to comprehensible information and knowledge about the intervention and how to incorporate it into work tasks.
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge and beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individuals' belief in their own capabilities to execute the courses of action required to achieve the implementation goals.
C	Individual stage of change	Characterisation of the phase an individual is in as he/she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual identification with organisation	A broad construct related to how individuals perceive the organisation, and their relationship with and degree of commitment to that organisation.

E	Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.
V. PROCESS		
A	Planning	The degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance, and the quality of such schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities.
1	Opinion leaders	Individuals in an organisation with either formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
2	Formally appointed internal implementation leaders	Individuals from within the organisation who have been formally been assigned the responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	"Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming any indifference or resistance that the intervention may provoke in an organisation.
4	External change agents	Individuals who are affiliated to an outside entity who formally influence or facilitate intervention decisions in the desired direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of the implementation accompanied by regular personal and team debriefing about the progress of the implementation and experience of the intervention.

Annexure E

Expert Recommendations for Implementation Change (ERIC) strategy matching tool https://cfirguide.org/choosing-strategies/	
Access new funding	Access new or existing money to facilitate the implementation
Alter incentive/allowance structures	Work to incentivize the adoption and implementation of the clinical innovation
Alter patient/consumer fees	Create fee structures where patients/consumers pay less for preferred treatments (the clinical innovation) and more for less-preferred treatments
Assess for readiness and identify barriers and facilitators	Assess various aspects of an organization to determine its degree of readiness to implement, barriers that may impede implementation, and strengths that can be used in the implementation effort
Audit and provide feedback	Collect and summarize clinical performance data over a specified time period and give it to clinicians and administrators to monitor, evaluate, and modify provider behavior
Build a coalition	Recruit and cultivate relationships with partners in the implementation effort
Capture and share local knowledge	Capture local knowledge from implementation sites on how implementers and clinicians made something work in their setting and then share it with other sites
Centralize technical assistance	Develop and use a centralized system to deliver technical assistance focused on implementation issues
Change accreditation or membership requirements	Strive to alter accreditation standards so that they require or encourage use of the clinical innovation. Work to alter membership organization requirements so that those who want to affiliate with the organization are encouraged or required to use the clinical innovation
Change liability laws	Participate in liability reform efforts that make clinicians more willing to deliver the clinical innovation
Change physical structure and equipment	Evaluate current configurations and adapt, as needed, the physical structure and/or equipment (e.g., changing the layout of a room, adding equipment) to best accommodate the targeted innovation
Change record systems	Change records systems to allow better assessment of implementation or clinical outcomes
Change service sites	Change the location of clinical service sites to increase access
Conduct cyclical small tests of change	Implement changes in a cyclical fashion using small tests of change before taking changes system-wide. Tests of change benefit from systematic measurement, and results of the tests of change are studied for insights on how to do better. This process continues serially over time, and refinement is added with each cycle
Conduct educational meetings	Hold meetings targeted toward different stakeholder groups (e.g., providers, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to teach them about the clinical innovation
Conduct educational outreach visits	Have a trained person meet with providers in their practice settings to educate providers about the clinical innovation with the intent of changing the provider's practice
Conduct local consensus discussions	Include local providers and other stakeholders in discussions that address whether the chosen problem is important and whether the clinical innovation to address it is appropriate
Conduct local needs assessment	Collect and analyze data related to the need for the innovation
Conduct ongoing training	Plan for and conduct training in the clinical innovation in an ongoing way

Create a learning collaborative	Facilitate the formation of groups of providers or provider organizations and foster a collaborative learning environment to improve implementation of the clinical innovation
Create new clinical teams	Change who serves on the clinical team, adding different disciplines and different skills to make it more likely that the clinical innovation is delivered (or is more successfully delivered)
Create or change credentialing and/or licensure standards	Create an organization that certifies clinicians in the innovation or encourage an existing organization to do so. Change governmental professional certification or licensure requirements to include delivering the innovation. Work to alter continuing education requirements to shape professional practice toward the innovation
Develop a formal implementation blueprint	Develop a formal implementation blueprint that includes all goals and strategies. The blueprint should include the following: 1) aim/purpose of the implementation; 2) scope of the change (e.g., what organizational units are affected); 3) timeframe and milestones; and 4) appropriate performance/progress measures. Use and update this plan to guide the implementation effort over time
Develop academic partnerships	Partner with a university or academic unit for the purposes of shared training and bringing research skills to an implementation project
Develop an implementation glossary	Develop and distribute a list of terms describing the innovation, implementation, and stakeholders in the organizational change
Develop and implement tools for quality monitoring	Develop, test, and introduce into quality-monitoring systems the right input—the appropriate language, protocols, algorithms, standards, and measures (of processes, patient/consumer outcomes, and implementation outcomes) that are often specific to the innovation being implemented
Develop and organize quality monitoring systems	Develop and organize systems and procedures that monitor clinical processes and/or outcomes for the purpose of quality assurance and improvement
Develop disincentives	Provide financial disincentives for failure to implement or use the clinical innovations
Develop educational materials	Develop and format manuals, toolkits, and other supporting materials in ways that make it easier for stakeholders to learn about the innovation and for clinicians to learn how to deliver the clinical innovation
Develop resource sharing agreements	Develop partnerships with organizations that have resources needed to implement the innovation
Distribute educational materials	Distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically
Facilitate relay of clinical data to providers	Provide as close to real-time data as possible about key measures of process/outcomes using integrated modes/channels of communication in a way that promotes use of the targeted innovation
Facilitation	A process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship
Fund and contract for the clinical innovation	Governments and other payers of services issue requests for proposals to deliver the innovation, use contracting processes to motivate providers to deliver the clinical innovation, and develop new funding formulas that make it more likely that providers will deliver the innovation
Identify and prepare champions	Identify and prepare individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization
Identify early adopters	Identify early adopters at the local site to learn from their experiences with the practice innovation

Increase demand	Attempt to influence the market for the clinical innovation to increase competition intensity and to increase the maturity of the market for the clinical innovation
Inform local opinion leaders	Inform providers identified by colleagues as opinion leaders or "educationally influential" about the clinical innovation in the hopes that they will influence colleagues to adopt it
Intervene with patients/consumers to enhance uptake and adherence	Develop strategies with patients to encourage and problem solve around adherence
Involve executive boards	Involve existing governing structures (e.g., boards of directors, medical staff boards of governance) in the implementation effort, including the review of data on implementation processes
Involve patients/consumers and family members	Engage or include patients/consumers and families in the implementation effort
Make billing easier	Make it easier to bill for the clinical innovation
Make training dynamic	Vary the information delivery methods to cater to different learning styles and work contexts, and shape the training in the innovation to be interactive
Mandate change	Have leadership declare the priority of the innovation and their determination to have it implemented
Model and simulate change	Model or simulate the change that will be implemented prior to implementation
Obtain and use patients/consumers and family feedback	Develop strategies to increase patient/consumer and family feedback on the implementation effort
Obtain formal commitments	Obtain written commitments from key partners that state what they will do to implement the innovation
Organize clinician implementation team meetings	Develop and support teams of clinicians who are implementing the innovation and give them protected time to reflect on the implementation effort, share lessons learned, and support one another's learning
Place innovation on fee for service lists/formularies	Work to place the clinical innovation on lists of actions for which providers can be reimbursed (e.g., a drug is placed on a formulary, a procedure is now reimbursable)
Prepare patients/consumers to be active participants	Prepare patients/consumers to be active in their care, to ask questions, and specifically to inquire about care guidelines, the evidence behind clinical decisions, or about available evidence-supported treatments
Promote adaptability	Identify the ways a clinical innovation can be tailored to meet local needs and clarify which elements of the innovation must be maintained to preserve fidelity
Promote network weaving	Identify and build on existing high-quality working relationships and networks within and outside the organization, organizational units, teams, etc. to promote information sharing, collaborative problem-solving, and a shared vision/goal related to implementing the innovation
Provide clinical supervision	Provide clinicians with ongoing supervision focusing on the innovation. Provide training for clinical supervisors who will supervise clinicians who provide the innovation
Provide local technical assistance	Develop and use a system to deliver technical assistance focused on implementation issues using local personnel
Provide ongoing consultation	Provide ongoing consultation with one or more experts in the strategies used to support implementing the innovation
Purposely reexamine the implementation	Monitor progress and adjust clinical practices and implementation strategies to continuously improve the quality of care
Recruit, designate, and train for leadership	Recruit, designate, and train leaders for the change effort
Remind clinicians	Develop reminder systems designed to help clinicians to recall information and/or prompt them to use the clinical innovation

Revise professional roles	Shift and revise roles among professionals who provide care, and redesign job characteristics
Shadow other experts	Provide ways for key individuals to directly observe experienced people engage with or use the targeted practice change/innovation
Stage implementation scale up	Phase implementation efforts by starting with small pilots or demonstration projects and gradually move to a system wide rollout
Start a dissemination organization	Identify or start a separate organization that is responsible for disseminating the clinical innovation. It could be a for-profit or non-profit organization
Tailor strategies	Tailor the implementation strategies to address barriers and leverage facilitators that were identified through earlier data collection
Use advisory boards and workgroups	Create and engage a formal group of multiple kinds of stakeholders to provide input and advice on implementation efforts and to elicit recommendations for improvements
Use an implementation advisor	Seek guidance from experts in implementation
Use capitated payments	Pay providers or care systems a set amount per patient/consumer for delivering clinical care
Use data experts	Involve, hire, and/or consult experts to inform management on the use of data generated by implementation efforts
Use data warehousing techniques	Integrate clinical records across facilities and organizations to facilitate implementation across systems
Use mass media	Use media to reach large numbers of people to spread the word about the clinical innovation
Use other payment schemes	Introduce payment approaches (in a catch-all category)
Use train-the-trainer strategies	Train designated clinicians or organizations to train others in the clinical innovation
Visit other sites	Visit sites where a similar implementation effort has been considered successful
Work with educational institutions	Encourage educational institutions to train clinicians in the innovation

Annexure F

Generated implementation strategy compilation (screenshot)

	A	B	C	D	E	F	G	H	I	J
1	ERIC Strategies	Cumulative Percent	Complexity	Cost	Cosmopolitanism	Implementation Climate	Readiness for Implementation	Leadership Engagement	Knowledge & Beliefs about the Intervention	Self-efficacy
2	Assess for readiness and identify barriers and facilitators	239%	30%	16%	15%	52%	81%	14%	20%	11%
3	Identify and prepare champions	224%	30%	12%	15%	37%	19%	41%	40%	30%
4	Alter incentive/allowance structures	170%	7%	44%	0%	44%	23%	32%	16%	4%
5	Create a learning collaborative	156%	33%	8%	31%	19%	15%	5%	16%	30%
6	Conduct educational meetings	155%	13%	12%	12%	15%	23%	9%	56%	15%
7	Build a coalition	153%	0%	4%	62%	19%	35%	18%	16%	0%
8	Facilitation	141%	20%	8%	12%	22%	19%	18%	20%	22%
9	Capture and share local knowledge	136%	27%	4%	23%	15%	15%	9%	24%	19%
10	Model and simulate change	128%	27%	20%	8%	19%	4%	14%	4%	33%
11	Promote adaptability	122%	40%	16%	0%	15%	15%	9%	16%	11%
12	Identify early adopters	121%	20%	8%	4%	30%	12%	9%	20%	19%
13	Involve executive boards	115%	0%	20%	23%	11%	15%	45%	0%	0%
14	Inform local opinion leaders	113%	13%	12%	15%	7%	15%	18%	28%	4%
15	Conduct local needs assessment	113%	3%	4%	12%	26%	31%	14%	24%	0%
16	Develop a formal implementation blueprint	112%	43%	8%	4%	7%	12%	23%	4%	11%
17	Conduct local consensus discussions	111%	7%	4%	15%	19%	27%	27%	12%	0%
18	Conduct ongoing training	108%	37%	0%	0%	11%	8%	0%	12%	41%
19	Conduct educational outreach visits	108%	7%	4%	23%	7%	8%	9%	28%	22%
20	Conduct cyclical small tests of change	105%	37%	8%	0%	11%	12%	0%	12%	26%
21	Visit other sites	104%	3%	16%	38%	15%	0%	5%	12%	15%
22	Provide ongoing consultation	101%	20%	0%	0%	15%	8%	14%	4%	41%
23	Access new funding	100%	3%	72%	4%	0%	4%	9%	8%	0%
24	Tailor strategies	96%	27%	12%	0%	19%	12%	5%	12%	11%
25	Use advisory boards and workgroups	95%	0%	0%	35%	11%	15%	18%	8%	7%
26	Recruit, designate and train for leadership	94%	7%	4%	15%	26%	12%	23%	4%	4%
27	Stage implementation scale up	92%	30%	8%	0%	4%	15%	0%	20%	15%
28	Promote network weaving	86%	0%	0%	50%	7%	4%	9%	12%	4%
29	Develop educational materials	83%	13%	0%	4%	0%	12%	0%	36%	19%
30	Increase demand	78%	3%	12%	0%	7%	8%	27%	20%	0%
31	Develop academic partnerships	77%	0%	4%	50%	4%	0%	0%	12%	7%
32	Obtain formal commitments	73%	0%	0%	19%	4%	23%	27%	0%	0%
33	Develop resource sharing agreements	70%	0%	32%	31%	0%	4%	0%	0%	4%
34	Fund and contract for clinical innovation	68%	3%	28%	0%	7%	4%	18%	4%	4%
35	Make training dynamic	64%	10%	0%	0%	4%	0%	9%	0%	41%
36	Use an implementation adviser	59%	10%	4%	8%	7%	4%	18%	0%	7%
37	Audit and provide feedback	57%	3%	8%	0%	11%	4%	5%	4%	22%
38	Mandate change	55%	7%	8%	0%	15%	4%	14%	4%	4%
39	Organize clinician implementation team meetings	54%	20%	0%	0%	11%	8%	0%	4%	11%
40	Shadow other experts	52%	7%	0%	4%	4%	0%	0%	4%	33%
41	Provide local technical assistance	51%	17%	4%	4%	0%	0%	5%	0%	22%
42	Purposely reexamine the implementation	45%	17%	0%	4%	4%	8%	9%	4%	0%
43	Use train the trainer strategies	45%	7%	0%	8%	4%	8%	0%	4%	15%
44	Make billing easier	44%	3%	32%	0%	4%	0%	5%	0%	0%
45	Develop disincentives	42%	0%	16%	0%	4%	0%	23%	0%	0%
46	Develop and organize quality monitoring systems	41%	10%	4%	0%	7%	8%	5%	0%	7%
47	Obtain and use patients/consumers and family feedback	40%	0%	4%	0%	7%	8%	14%	4%	4%
48	Involve patients/consumers and family members	39%	0%	0%	4%	15%	8%	9%	0%	4%
49	Develop and implement tools for quality monitoring	39%	7%	0%	0%	4%	15%	9%	0%	4%
50	Facilitate relay of clinical data to providers	39%	3%	0%	0%	7%	4%	5%	12%	7%
51	Distribute educational materials	38%	3%	0%	0%	0%	15%	0%	16%	4%
52	Place innovation on fee for service lists/formularies	38%	0%	24%	0%	0%	0%	14%	0%	0%
53	Work with educational institutions	35%	0%	4%	19%	0%	8%	0%	4%	0%
54	Use data experts	34%	3%	12%	4%	4%	4%	0%	4%	4%
55	Centralize technical assistance	33%	10%	0%	4%	0%	4%	5%	0%	11%
56	Intervene with patients/consumers to enhance uptake & adherenc	29%	3%	4%	0%	4%	4%	14%	0%	0%
57	Use other payment schemes	25%	0%	20%	0%	0%	0%	5%	0%	0%
58	Alter patient/consumer fees	24%	0%	20%	0%	4%	0%	0%	0%	0%
59	Develop an implementation glossary	24%	3%	4%	4%	0%	4%	5%	4%	0%
60	Use mass media	23%	0%	4%	8%	4%	0%	0%	8%	0%
61	Provide clinical supervision	21%	7%	0%	0%	4%	0%	0%	0%	11%
62	Use capitated payments	21%	0%	16%	0%	0%	0%	5%	0%	0%
63	Change accreditation or membership reqs	16%	0%	4%	8%	0%	0%	5%	0%	0%
64	Prepare patients/consumers to be active participants	16%	0%	0%	0%	7%	4%	5%	0%	0%
65	Revise professional roles	15%	3%	0%	0%	7%	0%	5%	0%	0%
66	Change physical structure and equipment	15%	3%	4%	0%	4%	4%	0%	0%	0%
67	Start a dissemination organization	12%	0%	0%	8%	0%	0%	0%	4%	0%
68	Create or change credentialing and/or licensure standards	12%	0%	4%	4%	4%	0%	0%	0%	0%
69	Create new clinical teams	11%	3%	0%	0%	0%	0%	0%	0%	7%
70	Use data warehousing techniques	8%	0%	0%	0%	0%	4%	5%	0%	0%
71	Change record system	8%	0%	0%	4%	0%	0%	0%	0%	4%
72	Change liability laws	7%	0%	0%	0%	7%	0%	0%	0%	0%
73	Remind clinicians	5%	0%	0%	0%	0%	0%	5%	0%	0%
74	Change service sites	0%	0%	0%	0%	0%	0%	0%	0%	0%

Annexure G

Consolidated criteria for reporting qualitative research (COREQ)

No. Item	Guide questions/ Description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal characteristics		
1. Interviewer/ Facilitator	Which author/s conducted the interviews?	32
2. Credential	What were the researcher's credentials?	45
3. Occupation	What was their occupation at the time of the study?	45
4. Gender	Was the researcher male or female?	Declaration page
5. Experience and training	What experience or training did the researcher have?	45
Relationship with participants		
6. Relationship with participants established	Was a relationship established prior to study commencement?	32-33
7. Participant knowledge of the interviewer	What did the participants know about the researcher?	118-122
8. Interviewer characteristics	What characteristics were reported about the interviewer/ facilitator?	44-47
Domain 2: Study Design		
Theoretical framework		
9. Methodology orientation and Theory	What methodological orientation was stated to underpin the study?	27-29; 34-39
Participant selection		
10. Sampling	How were participants selected?	29-31
11. Method and approach	How were participants approached?	29-31
12. Sample Size	How many participants were in the study?	30
13. Non-participation	How many people refused to participate or dropped out? Reasons?	29-30
Setting		
14. Setting of data collection	Where was the data collected?	28-32
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	33
16. Description of sample	What are the important characteristics of the sample?	29-31
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors?	33
18. Repeat interviews	Were repeat interviews carried out?	33
19. Audio/ visual recording	Did the research use audio or visual recording to collect the data?	33
20. Field notes	Were field notes made during and/ or after interviews?	32
21. Duration	What was the duration of the interviews?	33
22. Data saturation	Was data saturation discussed?	30
23. Transcripts returned	Were transcripts returned to participants for comment and/ or correction?	33
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	35

25. Description of the coding tree	Did authors provide a description of the coding tree?	35-39
26. Derivation of themes	Were themes identified in advance or derived from the data?	35-40
27. Software	What software, if applicable, was used to manage the data?	35
28. Participant checking	Did participants provide feedback on the findings?	33
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified?	54-79
30. Data and findings consistent	Was there consistency between the data presented and the findings?	80-82
31. Clarity of major themes	Were major themes clearly presented in the findings?	53-80
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	53-80

Annexure H

Institutional Research Ethics Committee Approval

DUT DURBAN UNIVERSITY OF TECHNOLOGY

Institutional Research Ethics Committee
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30 March 2017

IREC Reference Number: **REC 64/16**

Mr A C Lynch
10 Park Road
Malvern
Queensburgh
Durban
4093

Dear Mr Lynch

An exploratory inquiry into the implementation process of prehospital thrombolysis in the treatment of acute myocardial infarction within South Africa- A case study of a private Emergency Medical Service

The Institutional Research Ethics Committee acknowledges receipt of your notification regarding the piloting of your data collection tool.

Kindly ensure that participants used for the pilot study are not part of the main study.

In addition, the IREC acknowledges receipt of your gatekeeper permission letter.

Please note that FULL APPROVAL is granted to your research proposal. You may proceed with data collection.

Yours sincerely,

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2017 -03- 30
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
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