Identifying barriers to accessing healthcare for chronic wounds in the Khayelitsha sub-district: A mixed methods study

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DECLARATION

I, Anronel Stofberg, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ACRONYMS

ART	Antiretroviral Therapy
COVID-19	Coronavirus Disease 2019
CW	Chronic Wound
CWC	Chronic Wound Care
DOT	Directly Observed Treatment
EML	Essential Medicines List
ENA	Enrolled Auxiliary Nurse
HIV	Human Immunodeficiency Virus
HPCSA	Health Professions Council of South Africa
KDH	Khayelitsha District Hospital
NCD	Non-Communicable Disease
OPD	Outpatient Department
PACK	Practical Approach to Care Kit
PHC	Primary Healthcare
PN	Professional Nurse
SOPD	Surgical Outpatient Department
STGs	Standard Treatment Guidelines
TB	Tuberculosis
TBH	Tygerberg Hospital
UK	United Kingdom
WHO	World Health Organization

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ABSTRACT

Background: Chronic wounds impose a significant burden on health systems, as delayed access to care contributes to poorer clinical outcomes and increased healthcare costs. These delays are particularly pronounced within resource-constrained systems such as the South African public healthcare system. Identifying barriers to accessing care can contribute to developing interventions to optimise pathways to chronic wound care.

Aim: To map existing services, resources, and referral pathways for chronic wounds at each level of care and identify barriers to accessing care in the Khayelitsha health district.

Methods: A mixed methods study was conducted in the Khayelitsha health district between November 2020 and May 2021. Quantitative data was obtained through surveys in all 12 healthcare facilities offering chronic wound care across three levels of care. Qualitative data was gathered through semi-structured individual interviews with 10 chronic wound care providers and 10 patients. The Four Delays framework (seeking, reaching, receiving, and remaining in care) was utilised to identify and map barriers to accessing care.

Results: Nine overlapping barriers were identified, each contributing to multiple delays across all three levels of care. Seeking care was delayed by personal beliefs and the fear of amputation. Reaching care was delayed by transportation costs and safety concerns. Receiving care was delayed by chronic wound care provider and stock shortages, together with the non-utilisation of treatment and referral protocols. Remaining in care was delayed by deficient health information and lengthy waiting times at healthcare facilities.

Conclusion: This study underscores the complexity of pathways to chronic wound care and emphasises the need for a holistic approach to improve access. Key recommendations include: (1) community health education campaigns, (2) subsidies for transportation to healthcare facilities, (3) increasing the nursing workforce, and (4) ensuring adherence to treatment and referral protocols.

Keywords: chronic wound care, public health, healthcare access, barriers to care, Four Delays framework, mixed methods, Khayelitsha, South Africa

CHAPTER 1 – INTRODUCTION

1.1. Background

Chronic wounds impose a substantial burden on health systems and are defined as wounds that do not heal within three months (1,2). Chronic wounds have profound consequences for patients physically, emotionally, and financially (1,3,4). A systematic review reported that globally, 80% of individuals with chronic leg wounds experienced wound-related pain associated with a diminished quality of life (3,5,6). In severe cases, lower limb amputations were necessary to treat life-threatening complications, leading to disability (6–8). Furthermore, the management of chronic wounds is resource-intensive, placing a major financial burden on health systems (9,10). Chronic wounds accounted for approximately 1-4% of national health expenditures in high-income countries (9,11,12). In addition to these direct costs, they also imposed substantial indirect costs, including, loss of productivity due to sick leave, resignations, and disability (9). Improving access to care through the optimisation of care pathways allows for better clinical outcomes, enhancing patient quality of life, as well as decreasing health system costs.

Global efforts have focused on developing clinical guidelines and strategies aimed at providing a holistic approach to chronic wound care (CWC) (13). However, these guidelines are often tailored to high-income countries and may not account for the specific challenges faced by low- and middle-income countries (LMICs). While guidelines recommend a multidisciplinary approach for optimal treatment, this requires costly resources (14–16). In resource-constrained health systems, such as those in sub-Saharan Africa, delays in accessing CWC are exacerbated by systemic barriers and socio-economic challenges faced by patients (17).

In South Africa, the health system is multi-tiered, with public healthcare facilities categorised into primary, secondary, and tertiary levels of care (18,19). Each level offers distinct CWC services and resources, with referral pathways ensuring that patients reach the facilities they need based on their clinical requirements. However, an effective referral system relies on clear guidelines and smooth execution, which has not always been achieved due to multiple barriers in the South African public healthcare system (20). This often creates delays in accessing definitive care, leading to poor clinical outcomes.

Previously reported barriers to accessing care included financial challenges, resource limitations, and environmental obstacles. Financial constraints, particularly the inability to afford transportation, were consistently reported as significant obstacles to reaching healthcare facilities (21–23). Additionally, long waiting times, overcrowded public healthcare facilities, and shortages of staff, further delayed receiving care (21,24). Safety concerns, such as fear of robbery while traveling to the clinics, deterred patients from timeously seeking care (23). Collectively, these barriers highlighted the multi-faceted challenges that hinder access to care in South Africa.

Cape Town, located in the Western Cape province of South Africa, is divided into eight health districts, of which Khayelitsha is one (25–27). Khayelitsha is characterised by significant socio-economic challenges, with over half of its population (54.5%) living in informal housing (27). The district also faces a high prevalence of health conditions that increase the risk of chronic wound development including human immunodeficiency virus (HIV), tuberculosis (TB), and non-communicable diseases (NCDs) (28–30). While the risk factors for developing chronic wounds are prevalent in Khayelitsha, the socioeconomic challenges and the overburdened public healthcare system further hinder chronic wound healing (27,31–33). Identifying and addressing barriers to accessing care could minimise delays, strengthen pathways to care, and alleviate the chronic wound burden on the health system.

1.2. Research Questions

1. What are the existing services, resources, and referral pathways for chronic wound care available at each level of care in the Khayelitsha health district?

2. What are the barriers to accessing care for persons with chronic wounds living in the Khayelitsha health district?

1.3. Aim

To map existing services, resources, and referral pathways for chronic wound care at each level of care and identify barriers to accessing care for persons with chronic wounds living in the Khayelitsha health district.

1.4. Objectives

The following objectives have been set to fulfil the aim of this study:

1. Map existing services, resources, and referral pathways for chronic wound care available at each level of care in the Khayelitsha health district.
2. Identify barriers to accessing care for persons with chronic wounds living in the Khayelitsha health district.
3. Propose solutions to address barriers identified in Objective 2.

CHAPTER 2 – LITERATURE REVIEW

This literature review examines key issues surrounding access to CWC. It begins by defining chronic wounds and discussing their prevalence, followed by an overview of their management. The review will highlight the impact of chronic wounds, including their detrimental effects on patients and the financial strain placed on the health system. Chronic wound care within the South African public healthcare system will then be explored, with a specific focus on the Khayelitsha health district. The Four Delays framework, which will be used to identify barriers to accessing care, will also be described. Finally, research gaps will be identified, and the study's approach to addressing these shortcomings will be outlined.

2.1. Chronic Wounds

Definitions and Prevalence

A wound is defined as a break in the skin that disrupts normal anatomical structure and function (4). Wounds can result from mechanical, biological, thermal, or chemical trauma and are categorised as acute or chronic based on their duration of healing (34). Wound healing involves an intricate cascade of events, with acute wounds typically repairing within 30 days, depending on the wound depth (35,36). A wound may be considered chronic when it fails to advance through expected stages of healing, within a specific time frame (4). Distinguishing between acute and chronic wounds is important as their differing mechanisms of healing directly influence treatment strategies (37,38). There has been significant debate regarding the duration of healing required to classify a wound as chronic (39,40). Many time frames have been proposed, varying from two weeks to three months (1,4). A panel of chronic wound experts concluded in 2021, that a wound may be considered chronic if its surface area has not decreased by 50% after four weeks of care (13). For this study, a chronic wound was defined as a wound that did not heal within three months (1).

The term 'chronic wound' is often used as an umbrella term for wounds described as non-healing, complex, hard-to-heal, or delayed (41). However, the lack of a universally accepted definition and inconsistent terminology used among researchers and clinicians, make it challenging to determine global chronic wound prevalence (42). Studies have attempted to describe the epidemiology of chronic wounds with varying results. A systematic review and meta-analysis published in 2018 reported the global pooled prevalence of chronic wounds as 0.2% (43). Point prevalence studies from Barcelona and China reported rates of 0.11% and 0.4%, respectively (44,45). Similarly, in South Africa, research on the epidemiology of chronic wounds is limited.

South African studies often focused on specific subcategories rather than chronic wounds as a standalone condition. The most common types of chronic wounds are vascular ulcers, pressure

ulcers, and diabetic foot ulcers (46–48). Although the definitions and prevalence of chronic wounds in South Africa are not well documented, the country faces a high incidence of known risk factors for chronic wound development, including NCDs, HIV, and TB (28). Numerous studies have emphasised the heightened risk of chronic wounds among patients with NCDs such as diabetes, obesity, and hypertension. For example, diabetic patients are particularly prone to developing foot ulcers (29). In South Africa, the prevalence of diabetes is rising rapidly, contributing to a corresponding increase in chronic wound cases (49). Similarly, obesity has been identified as a significant risk factor for venous leg ulcers, as poor circulation associated with the condition impairs wound healing (50). Moreover, HIV hampers wound healing by weakening the immune system (51). Additionally, South Africa ranks among the countries with the highest TB incidence globally, with approximately 427 cases per 100,000 individuals in 2023 (52). TB can lead to the breakdown of tissue, which further contributes to the transition from an acute to a chronic wound (30). This context emphasises the increased risk of chronic wounds in South Africa and underscores the importance of taking into account the underlying causes of chronic wounds when creating a comprehensive management plan.

Chronic Wound Management

The current global CWC guidelines emphasise a holistic approach, focusing on prevention, early diagnosis, personalised treatment based on the underlying cause, appropriate local wound care, and proactive management of complications (53). Both patient-related and wound-related factors are to be considered when designing a treatment plan (54,55). Additionally, studies have shown that a multidisciplinary team approach involving doctors, nurses, allied health practitioners, social workers, and psychologists is vital in optimising care (14–16). Such an approach is important, as it not only focuses on the physical treatment of the wound but also addresses the significant multi-faceted impact that chronic wounds have on patients.

Impact of Chronic Wounds

The overall impact of chronic wounds is profound, affecting patients' physical health, emotional well-being, and financial independence (9,56–58). Chronic wounds are painful and impair mobility, leading to a decreased quality of life (3,59). A systematic review found that 80% of people with venous leg ulcers reported experiencing pain associated with their wounds (3). Wound pain has been shown to disrupt sleep, leading to fatigue, mood disorders, and a weakened immune system (5,6). The pain and restricted mobility caused by chronic wounds hinder patients' ability to perform activities of daily living, ultimately contributing to a diminished quality of life (60,61). In certain extreme cases, lower limb amputations are performed to treat chronic wounds, which lead to disability (5–8). Additionally, the mortality rates associated with chronic wounds are concerning.

A systematic review and meta-analysis reported that globally 50% of individuals with diabetic foot ulcers die within five years (62).

Furthermore, mental health deterioration is a prevalent concern among patients with chronic wounds (63). Research conducted in Brazil found that 30-40% of patients with lower leg ulcers experienced depression or anxiety (64). Comparable findings were reported in England, where 26-27% of patients with chronic wounds faced similar mental health challenges (65). In Syria, 36-39% of patients with diabetic ulcers had depression or anxiety (66). This is markedly higher than the estimated 3.8% of the global population affected by depression, according to the Global Burden of Disease 2019 study (67). Additionally, the prolonged nature of chronic wounds contributes to psychological distress. An American study found that having an unhealed wound for 90 days or more significantly increased the chance of developing mood symptoms (57). This psychological impact is reiterated in a qualitative study from that Ireland explored the lived experiences of patients with chronic wounds and found that malodour was a persistent issue leading to significant emotional distress (68). The psychological burden was described as worse than the physical pain in some cases (68).

Additionally, chronic wounds require long-term treatment, including frequent medical appointments, specialised dressings, medications, and in some cases, surgical interventions (69). The cost of these treatments can be a barrier to healing, especially for individuals without adequate health insurance or financial resources. Studies have indicated that the direct costs associated with CWC can be substantial, leading to financial strain on households (2,9,56,58). Studies reported that patients regularly felt their employment was impacted by their wound, either through altered mobility or pain (56,70). Together with frequent clinic and hospital visits, this resulted in missed days at work, which in turn, led to termination of employment or having to make the decision to resign (70,71).

Chronic wounds not only place a financial strain on patients but also on the health system (58). Treating chronic wounds is resource-intensive, requiring a multidisciplinary team performing frequent follow-ups, wound dressings, and in certain cases surgical procedures and rehabilitation (9,10). Estimating the exact direct costs is challenging due to variations in healthcare reporting across countries. However, several studies provide insights into the financial impact of CWC globally. In 2014, the national health expenditure for chronic wounds in the United States ranged from $28.1 to $96.8 billion (9). This accounted for approximately 0.94-3.23% of that year’s total national health expenditure (9). The United Kingdom (UK) reported that £5.6 billion was allocated to unhealed wounds in 2017, which amounts to approximately 4.59% of the UK's total health expenditure (11). In Singapore, the total cost of illness was estimated to be $350 million in 2017, which is estimated to be 3.14% of the national health expenditure (12,72). This financial strain

was exacerbated by indirect costs associated with loss of productivity due to sick leave, resignations, and disability-related employment loss.

Ultimately, chronic wounds represent a global public health challenge that demands costly resources from health systems. In South Africa, there is a lack of research on the overall impact of chronic wounds on the physical, emotional, and financial well-being of patients, as well as the burden that it places on the health system.

2.2. South Africa's Health System

The South African health system consists of the government-funded public and private sectors (73). The cost of private healthcare in South Africa creates a significant barrier to accessing care, because it is only an option for those who can afford medical aid or pay in cash. This leaves the majority (83%) of South Africans dependent on public healthcare facilities to access medical care (73,74). Government-funded services are free or subsidised depending on income. It has been established that public healthcare facilities struggle with resource constraints, infrastructure limitations, and healthcare provider shortages (73,75,76).

The public healthcare system in South Africa operates within a hierarchical structure (18,19). Different levels of care are connected through referral pathways based on the available services at each level (77). 'Level of care' refers to the categorisation of healthcare facilities according to the services provided. The public healthcare sector is divided into primary, secondary, and tertiary-level facilities (77). For most patients, primary-level facilities are the first point of access to the public healthcare system (18). Most primary-level facilities consist of nurses (78). South Africa has three categories of nurses namely, professional nurse (PN), staff nurse, and enrolled auxiliary nurse (ENA)(78,79). The scope of practice of a PN involves the facilitation of wound healing, the protection of the skin, and the maintenance of sensory functions (78). The scope of practice of a staff nurse encompasses the abovementioned acts under the supervision of a PN. The scope of practice of an ENA does not include wound care. Only a PN may perform level 1 services independently (78).

Level 1 services are available at primary healthcare facilities which include community health centres (CHCs), clinics, and district hospitals (77). District hospitals accept referrals from CHCs and clinics in their specific drainage area. Level 2 services are offered by regional hospitals and include 24-hour primary health services along with at least one of the following on-site specialities: orthopaedic surgery, psychiatry, anaesthetics, or diagnostic radiology (77). The secondary-level facility must also provide trauma and emergency services, short-term ventilation, and access to operating rooms. Outreach services are offered to regional hospitals by tertiary facilities. Referrals are received from district hospitals and other primary-level facilities in an allocated regional drainage area (77). Finally, level 3 services are provided by tertiary-level facilities. A tertiary

hospital provides the same care as above but includes sub-specialist services such as vascular surgery and plastic surgery. Intensive care services and training for healthcare providers are also offered on-site (77).

A multi-level healthcare system requires a functional referral system that ensures patients are transferred to appropriate facilities according to the level of care needed (80). The referral system in South Africa faces many difficulties such as inadequate ambulance services, lack of referral criteria, and poor communication between healthcare facilities. These issues lead to poor continuity of care, poor retention of patients, overcrowded hospitals, and ultimately poor clinical outcomes (75,76).

2.3. Chronic Wound Care in South Africa

Treatment guidelines for chronic wounds in South Africa are based on both local and international best practices (73). However, most international guidelines are often not feasible to implement in low- and middle-income countries (LMICs) as they fail to consider specific challenges of resource-constrained settings. For instance, in resource-constrained health systems, such as those in sub-Saharan Africa, CWC is hindered by systemic barriers, including limited healthcare resources, inadequate infrastructure, and socio-economic challenges faced by patients (17). Additionally, studies have shown that there are discrepancies in the implementation of standardised treatment guidelines across healthcare facilities in South Africa, particularly in areas where health systems are under pressure (75). A lack of trained providers, stock shortages, and inadequate facilities make it challenging to adhere to standardised treatment guidelines, contributing to poor service delivery (75,76). In South Africa, the guidelines available for wound care include the Standard Treatment Guidelines (STGs), Essential Medicines List (EML), Practical Approach to Care Kit (PACK) guidelines, and the 2021 Wound Care Guidelines (81–83).

The Primary Healthcare (PHC) STGs and EML were created by the South African Department of Health to guide the management of patients with relatively common conditions at primary healthcare facilities (82). It also provides referral processes for patients with more complicated conditions. Separate sections discuss three of the most common types of chronic wounds, namely lower leg ulcers, diabetic foot ulcers, and pressure ulcers. Each chapter outlines general treatments and procedures that need to be performed at primary level, as well as specific referral criteria to secondary level of care (84).

According to the PHC STGs, all foot and venous ulcers that are persistently infected and show no improvement after a month must be referred to a secondary-level facility, however, all preceding preventative and curative measures should occur at primary level (84). Diabetic neuropathy and prevention of diabetic foot ulcers are described as a primary level of care responsibility. For the treatment of diabetic foot ulcers, there are general treatments that should

be performed at primary level including glycaemic control, smoking cessation, the treatment of underlying comorbidities, offloading ulcers with correct footwear, weekly callus removal, daily cleansing with sodium chloride 0.9% solution, and the application of a non-adherent dressing, and antibiotic coverage when appropriate. If patient education, foot checks, and analgesia are not adequate to control patient symptoms, then should be discussed for referral. Non-urgent referral should be done in the presence of claudication and ulcers not responding to adequate treatment. Urgent referral is required if the ulcer is associated with a threatened limb presenting as cellulitis, severe hyperglycaemia, abscess formation, surrounding skin changes, or crepitus. Pressure ulcer prevention is also discussed in the PHC STGs, but minimal treatment can be offered at primary level. Zinc and castor oil can be prescribed to apply topically, and the caregivers can be educated on measures to prevent ulcer formation, but beyond that, pressure sores need to be reviewed by a doctor for a management plan to be put in place (84).

The PHC STGs are followed by the Hospital Level (Adult) STGs and EML, as well as a separate Tertiary Level EML (84,85). These guidelines standardise the available services, medications, and referral pathways across secondary and tertiary-level care facilities while highlighting which conditions should be seen at which level of care. It states that complicated leg ulcers and some surgical wound infections should be managed at secondary-level facilities. Diabetic foot ulcers that specifically require arterial revascularisation procedures need to be reviewed by a vascular surgeon at a tertiary facility (81,84,85).

The Western Cape Government Department of Health released the latest Primary Care Guide for adults, also known as the PACK guidelines in 2023 (82). These guidelines are intended for primary-level facilities and differ from the STGs and EML by including visual aids, approach-based flow diagrams, and clear referral pathways. The guidelines are structured either based on the presenting symptom or chronic diagnosis (82).

The Western Cape Government Department of Health also updated the 2005 Metro District Health Services Wound Care Guidelines and released the revised Western Cape Wound Care Guidelines in 2021 (83). It is a comprehensive, user-friendly, approach-based guide that includes practical management and referral guidelines intended for all levels of care, covering both acute and chronic wounds. Various distinguishing features elevate this guide from others. Its format, similar to the PACK guidelines, incorporates numerous flow diagrams and visual aids (83). The guidelines acknowledge the complexity of managing chronic wounds while focusing on continuity of care during the referral process. It promotes a holistic, multidisciplinary approach and includes sections dedicated to preventative care, such as foot care for diabetic patients. At the time of data collection, the 2021 Western Cape Wound Care Guidelines were yet not implemented at the study sites (83). According to the 2021 Western Cape Wound Care Guidelines, all healthcare facilities

within the province should maintain stock of specific wound care consumables to ensure the provision of quality care (see Table 1).

Table 1: Recommended wound care consumables per Western Cape Wound Care Guidelines

Cleaning Products	Adhesive/ Fixative Tapes	Bandages	Moisture Control Products	Antimicrobial Products	Other Products
Normal saline (0.9%)	Microporous paper tape	Non-adherent bandage (Crepe)	Hydrogel (Intrasite®)	Hydrophobic dressing (Sorbact®)	Impregnated tulle (Jelonet®)
0.5-5% pure acetic acid	Zinc oxide adhesive tape	Conforming bandage (Cling)	Hydrocolloid sheets (Comfeel®)	Silver sulfadiazine (Flamazine®)	Occlusive film (Tegaderm®/ Opsite®)
Povidone iodine solution	Elastic adhesive tape	Compression bandage (Ulce3®)	Hydrofibre (Aquacel®)		Zinc oxide
Chlorhexidine solution			Absorbent foams		Acriflavin
Dry gauze			Absorbent dressing (Cutisorb®)		Medicinal honey

While South Africa has established treatment guidelines for CWC, the challenges in implementing these guidelines are particularly pronounced in the Khayelitsha health district. Socio-economic factors, a high prevalence of risk factors for chronic wound development, and strained healthcare resources further complicate wound management (27,32). This context underscores the need for a targeted approach to wound care in Khayelitsha, where the healthcare system faces unique barriers to effective implementation.

2.4. Khayelitsha Health District

Khayelitsha health district, located within the Western Cape province of South Africa, is one of the eight health districts in the City of Cape Town (25). It is located in one of the country's largest townships with more than half of the population (54.5%) living in informal housing (27). Factors that increase the risk of acute wounds transitioning to chronic wounds include HIV, TB, and NCDs such as obesity, hypertension, and diabetes. These conditions are very common in the Khayelitsha health district (31–33,86). Factors hindering the optimal healing of chronic wounds include strained public healthcare systems and challenging socio-economic conditions, such as limited access to sanitation, clean water, and nutritious food, all of which are prevalent in Khayelitsha (27,31–33). The public healthcare facilities that serve the Khayelitsha health district include 10 primary healthcare facilities, one secondary-level hospital, and one tertiary hospital

(25). The primary-level facilities consist of community health centres (CHCs) and clinics. Patients are referred to the secondary-level facility, Khayelitsha District Hospital (KDH), and the tertiary-level facility, Tygerberg Hospital (TBH), as required (32). Khayelitsha District Hospital was established in 2012 as a district hospital, however, as the community's needs increased and the hospital's services expanded, it started to function as a regional hospital (32). For the purposes of this study, KDH will be categorised as a secondary-level facility (77). The hospital is equipped to provide level 2 healthcare services, including emergency care, surgical interventions, and outpatient services. It is staffed by general doctors and general surgeons. However, it is important to note that KDH does not have an on-site vascular or plastic surgeon (32). Consequently, patients requiring level 3 services are referred to the tertiary facility, TBH (87). The three levels of care in Khayelitsha provide a unique opportunity to comprehensively investigate how patients experience the healthcare system and what obstacles they face at different stages in the care pathway.

2.5. Theoretical Framework

Access to timely and appropriate treatment is essential to improve patient outcomes (88). Evidence shows that delayed care leads to morbidity and mortality (89,90). For instance, a global systematic review examining diabetic foot ulcers highlighted that for every day of delay in seeking referral for diabetic foot infections, the risk of major amputation or death increased by 0.6% (90). Access can be defined as the timely use of quality healthcare services ensuring optimal patient outcomes (91). Clear pathways to care should be available and accessible to all. It is important to assess pathways to care to identify barriers causing delays and evaluate the impact of interventions (88,92). Delays in accessing care can be evaluated by using the Four Delays framework, originally developed by Thaddeus and Maine in 1994, as the Three Delays model (93,94). The model highlights delays in seeking, reaching, and receiving care that can impact patient outcomes and quality of care (95–97). The Three Delays model has since been adapted to the Four Delays framework by adding 'remaining in care' as the fourth delay (22,98–100). In the context of addressing chronic conditions, where ongoing engagement with the health system is essential for optimal patient outcomes, including the fourth delay is important for continuity of care (88,101). The Four Delays framework is an easy-to-use tool for identifying site-specific challenges in a structured and stepwise manner (see Figure 1). It can be used to follow the patient's journey through the care pathway while simultaneously identifying barriers related to each of the four delays.

Figure 1: The Four Delays framework

Seeking care (Delay 1) occurs from the onset of symptoms till the decision is made to seek care (88,99). In a recent South African study, the decision to seek care for a traumatic injury was influenced by the expectation of having an unpleasant medical encounter (23). This included being treated disrespectfully by healthcare providers and having to wait many hours to be treated at healthcare facilities. The same study also highlighted the fear of being robbed when walking to the clinic as a barrier to seeking care (23). This mirrors another South African study that reviewed barriers to seeking care for traumatic brain injuries, which highlighted safety concerns as a barrier as well as long waiting times and lack of finances to afford transportation (22).

Reaching care (Delay 2) occurs from the moment the decision is made to seek care, till the point of first contact with the healthcare system (88,99). Studies have indicated that South Africans face significant challenges in accessing public healthcare (102–104). A recurrent barrier has been the inability to afford transport to be able to reach care (21,23). In a study looking at patients with chronic lower back pain in South Africa, the travel costs to healthcare facilities were reported as a barrier to accessing care (21). Similar to chronic wound patients, chronic lower back pain patients attend the clinic frequently and have multiple reasons why it is difficult to reach healthcare facilities, for example, physical limitations and special transportation needs (21). In the abovementioned study on traumatic brain injuries in South Africa, safety concerns impacted the ability of ambulance services to reach patients in high-crime areas, which led to further delays in reaching care (22).

Receiving care (Delay 3) encompasses the period from when a patient arrives at a healthcare facility to when they receive quality healthcare, including interfacility transfers between different levels of care (105). In South Africa, this delay is worsened by long waiting times, overcrowded public healthcare facilities, staff shortages, and a lack of resources (21,24). Additionally, a study done in Soweto, South Africa, showed poor communication between providers across different levels of care that contributed to delays in receiving timely treatment for chronic conditions (24).

Remaining in care (Delay 4) covers the phase from receiving healthcare to optimal recovery (88,99). This phase includes access to follow-up appointments. Lack of health education has been reported as a barrier, making it difficult for patients to remain in care (106). Without adequate

knowledge, patients may struggle to comply with medical advice and follow-up plans which could result in defaulting care and poor health outcomes. Another reason reported for patients not remaining in care was a lack of social support (107).

A key consideration in this study is the limitations of the Four Delays framework, particularly its simplicity and linearity. While the Four Delays framework categorises delays into four distinct stages and assumes a sequential progression through each delay, it does not fully capture the complex and interdependent nature of these barriers in practice. For instance, a delay in seeking care may not stem solely from financial or geographic constraints but also from cultural or societal influences that are difficult to isolate. A study on barriers to surgical care in South Africa highlighted this limitation, demonstrating that barriers and delays often overlap, which the framework does not address (99). Moreover, the framework presents healthcare access as a linear process, from seeking care to remaining in care, however, patients more commonly navigate a fragmented pathway to care. Various factors can lead to interruptions, pauses, or repeated interactions with the healthcare system. This is particularly relevant for chronic conditions such as chronic wounds, where multiple visits are required, and patients are referred between levels of care. By focusing primarily on delays, the Four Delays framework may divert attention from broader systemic challenges, including socioeconomic disparities, quality of care, and political influences, all of which can contribute to delays at every stage. This narrow focus risks providing an incomplete understanding of barriers to accessing healthcare which may hinder the development of effective interventions.

2.6. Summary and Research Gaps

This literature review highlights the significant yet underexplored burden of chronic wounds in South Africa. The country's public healthcare system faces considerable challenges, including resource constraints and socio-economic challenges, which contribute to delays in accessing care and exacerbate the chronic wound burden.

Key research gaps in CWC in South Africa include a lack of studies on available care pathways, referral systems between levels of care, and barriers to access, particularly in resource-constraint settings. Additionally, there is a need for research on innovative, cost-effective interventions to enhance service delivery in these areas.

This study seeks to address these gaps by mapping existing services, resources, and referral pathways across three levels of care, while also identifying barriers to CWC in the Khayelitsha health district. By doing so, it aims to offer targeted interventions to improve access to care, which could enhance clinical outcomes for patients, and reduce health system costs in similar settings.

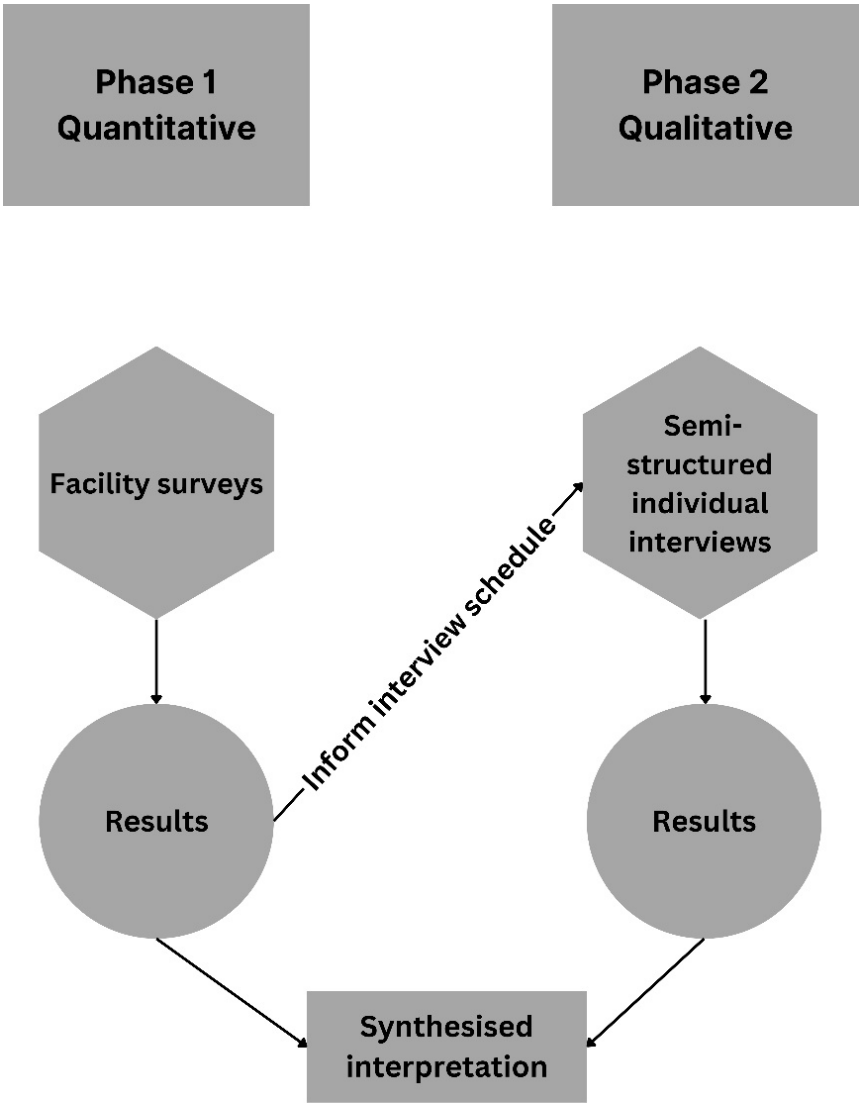
CHAPTER 3 – METHODOLOGY

This chapter describes and justifies the chosen methodology. The study sites, participant sampling, and recruitment processes are described. This is followed by a discussion of the data collection and analytical methods used. Additionally, it also addresses how rigour was ensured, with further comments on positionality and reflexivity. Ethical considerations are addressed, including the influence of the Coronavirus Disease 2019 (COVID-19) pandemic on the study.

3.1. Study Design

For this study, a mixed methods design was implemented over two phases (108,109) (see Figure 2). This approach was utilised to explore the services, resources, and referral pathways for CWC, as well as the barriers to accessing care within the Khayelitsha health district. These methods were carefully selected to ensure that the data collected would comprehensively address the research questions and provide actionable insights.

Figure 2: Summary of study design



In Phase 1, facility surveys were completed to map available chronic wound services, resources, and referral pathways at each level of care in the Khayelitsha health district. The Phase 1 data highlighted specific areas for further investigation and helped shape the interview schedule for Phase 2. In Phase 2, in-depth semi-structured individual interviews were held with CWC providers as well as chronic wound (CW) patients. Both quantitative and qualitative methods were required to provide the foundational information on available pathways to CWC, in order to identify barriers and solutions to accessing CWC in the Khayelitsha health district.

3.2. Phase 1: Facility Surveys

Study Sites

The study sites included all public healthcare facilities that offered CWC services in the Khayelitsha health district. This included 10 primary-level facilities, one secondary-level facility, and one tertiary-level facility (110). One of the reasons for selecting Khayelitsha health district was that the healthcare facilities in the drainage area included three levels of care (19). This allowed for the identification of barriers related to referrals between levels. For chronic conditions that require continuity of care, this is an important aspect to examine. Khayelitsha health district faced many socio-economic challenges, resource constraints and a high burden of diseases such as HIV, TB, and NCDs, all of which contributed to an increased risk of chronic wound development (32). This context created a unique setting to examine the barriers to accessing CWC throughout the entire care pathway.

Data Collection

A combination of facility managers, CWC providers (nurses and doctors), and administrative staff were approached to complete the surveys. This approach allowed for multiple perspectives and insights from different roles within the facilities. Although only one survey was conducted at each study site, multiple respondents participated in completing the survey at each site. Upon receiving the necessary approvals, facility managers were contacted via email to arrange a suitable time for conducting the survey at their facility. The facility managers nominated appropriate individuals to complete the surveys. Consent was obtained for each respondent individually. The survey was administered using a paper-based format (see Appendix A). Depending on the COVID-19 restrictions at the time, the survey was conducted by the researcher over the telephone or in person at the facility. The survey had five sections to capture info on. The first section gathered general information about the facility. The second section focussed on the type and availability of CWC services at the facility. The third section enquired about the existing CWC resources and treatment guidelines. The fourth section gathered information on referral pathways and protocols available. The last section collected data on existing wound care recordkeeping.

Data Analysis

The data were entered into Microsoft Excel to calculate various descriptive statistics, including frequencies, percentages, modes, means, and ranges (111). For categorical data, frequency counts and percentages were reported (112). Means, ranges, and modes were used to describe the socio-demographic characteristics of the participants.

3.3. Phase 2: In-depth Semi-structured Individual Interviews

In-depth semi-structured individual interviews were conducted with two groups of participants. Group A included 10 CWC providers and Group B included 10 CW patients.

Sampling and Recruitment

The interview list consisted of 20 participants, evenly split between 10 CWC providers and 10 CW patients. This sample size proved sufficient, as data saturation was reached (113). Purposive and snowball sampling were used to select both the CWC providers and CW patients for the Phase 2 interviews (114). The aim was to include providers and patients with a broad range of CWC experiences within the Khayelitsha health district. The researcher approached the Phase 1 survey respondents to enquire if they would be interested in taking part in the Phase 2 interviews. Healthcare workers approached potential CW patients to enquire about participating in the interviews. If these patients agreed to participate, they were contacted by the researcher directly. In most cases, the patients were approached on the same day of their clinic visit. To include individuals who received treatment from both a primary and secondary-level facility, patients were recruited from the KDH surgical outpatient department (SOPD). A few other CW patients were recruited from the KDH surgical ward.

All participants were 18 years or older, capable and willing to provide informed consent, and able to be interviewed in isiXhosa, English, or Afrikaans, as these were the three predominant languages spoken in Khayelitsha (27). The first group of participants were CWC providers. Doctors or nurses working at one of the 12 study sites were included in the Phase 2 interviews. Participants were excluded if they were not CWC providers, had two months or less CWC experience, or were not able to communicate in isiXhosa, English, or Afrikaans. The second group comprised of CW patients residing in the Khayelitsha health district, who were actively receiving chronic wound treatment for more than six months at any of the 12 study sites. For this study, a chronic wound was defined as a wound that did not heal after three months. The extended six-month timeframe allowed for accurate identification and diagnosis of chronic wounds, ensuring that the condition met the study's criteria. Additionally, it increased the probability of patients having sufficient experience with CWC services, enabling them to provide detailed and meaningful information during interviews. Those receiving CWC from non-study sites and facilities

outside the Khayelitsha health district, including private healthcare facilities, pharmacies, or traditional healers, were excluded because of the potential influences of these other services on the patient's outcomes and perceptions of barriers to care specific to the Khayelitsha health district.

Data Collection

Initially, the plan was to conduct focus groups with the CWC providers and individual interviews with the CW patients, however, the COVID-19 restrictions did not allow for focus groups at the time of data collection. Therefore, the decision was made to conduct individual interviews with both participant groups. The primary investigator conducted the semi-structured individual interviews in person. A suitable date, time, and place was established once the participant agreed to take part in the study. The interviews were recorded with a voice recorder for the purpose of transcription and data analysis. Consent for the recording of the interviews was obtained from each participant. Interviews lasted approximately 45-60 minutes and were held in a secure, confidential, and private space at the applicable healthcare facility. The services of an interpreter were offered, however, all participants were comfortable speaking in English. To note, two participants did alternate between English and Afrikaans in certain sections, which was acceptable as the researcher was proficient in both languages. The Four Delays framework was used during data collection to structure the qualitative interview questions in a logical manner by focusing on the pathways to care and then focussing on the possible barriers in the process. The interview schedule for Phase 2 was also shaped by the need to clarify certain aspects uncovered in the Phase 1 surveys. Preliminary results from the surveys highlighted gaps and identified delays that needed further exploration in the Phase 2 interviews. For instance, while the surveys included yes or no questions, such as whether the facility had a standardised CWC guideline, the Phase 2 interviews aimed to expand on these responses. Questions were designed to delve deeper into the reasons behind certain answers, such as asking for the name of the guideline, or if these answers were not available, exploring the reasons why. This allowed for a more comprehensive understanding of the wound care practices across different facilities.

Data Analysis

This study implemented Braun and Clarke's six-step approach to thematic analysis, chosen for its organisation and clear structure, making it an ideal tool for novice researchers (115). Qualitative data from the interviews were analysed inductively and later deductively using thematic analysis (116,117). Furthermore, the Four Delays framework was used during the initial coding phase, to synthesise the findings, as well as to present the results in the discussion chapter (88).

Data familiarisation entailed the researcher manually completing the verbatim transcriptions and translations of all 20 recorded interviews. Each interview participant was assigned a pseudonym followed by the designation of either “CWC provider” or “CW patient”. This anonymised the participants while clearly indicating the respective interview groups. The researcher read over the transcripts repeatedly with the goal of thoroughly understanding the content. The transcripts were also re-read while listening to the recordings to confirm accuracy. Notes that were made directly after the interviews were compared to notes made on the day of reading the transcripts to remind the researcher of the impressions and ideas that had surfaced.

Coding was performed manually. Each transcript was analysed line by line to capture nuances. The initial coding process was guided by the research question: What are the barriers to accessing care for persons with chronic wounds living in the Khayelitsha health district? Quotes identifying obstacles to accessing care were highlighted with a specific colour and labelled as barriers. Each quote related to a barrier was given a descriptive label and each quote was coded multiple times and in as many ways as possible to explore all possible themes. The quote below shows how the participant’s line: “Sometimes I have got no money to take the taxi” was highlighted in yellow, labelled as a barrier, and in this instance, given two codes titled “financial constraints” and “lack of affordable transportation to reach clinic.”

> Interviewer: “Is there anything that makes it difficult for you to get to the clinic?”
>
> CW patient: “Sometimes I have got no money to take the taxi.”

In addition to quotes related to barriers, all other quotes were highlighted in blue, coded, and placed in a column with the heading “Other.” For example, the following quote was coded as “negative impact of wound odour” and placed in the “Other” column.

> Interviewer: “Okay, and what has been different in your life since having the wounds?”
>
> CW patient: “Um, what has been different, it makes me feel ashamed like when I am in a crowded place because it smells and that has been different, cause it makes me feel embarrassed so many times and scared of being with many people so, because of it smells and stuff.”

Initial themes were generated by organising all the initial codes in a table, linked with their respective quotes. The generation of two initial themes, through the combination of multiple similar codes, is demonstrated below (see Table 2).

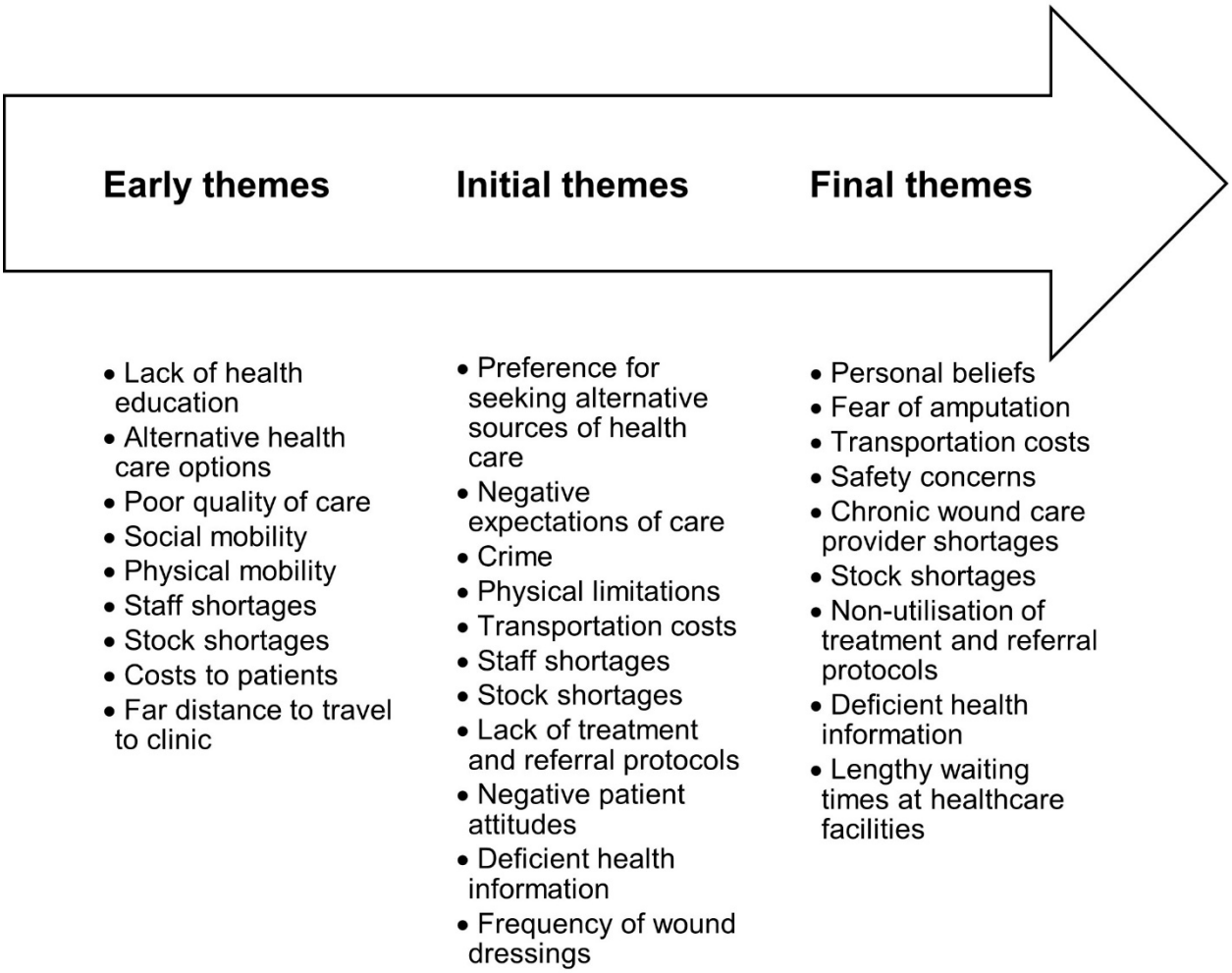
Table 2: Process of generating initial themes

Initial Code	Quote	Initial Themes
Lack of financial means to afford transport	“Yeah, like yesterday I didn’t have the money for transport.”	1. Lack of transportation 2.Cost of transportation
Far distance to travel to clinic	“It is expensive, because I don’t stay near here. It is very far to use taxi.”	
Lack of affordable transportation to reach clinic	“It is expensive, because I don’t stay near here. It is very far to use taxi.”	
Financial constraints	“Sometimes I have got no money to take the taxi.”	
Lack of affordable transportation to reach clinic	“Sometimes I have got no money to take the taxi.”	
Cost of transport	“I missed last time, because I didn’t get transport. Because of money.”	

Reviewing themes involved listing all the initial themes and then refining them through splitting, integrating, and renaming as needed. These themes were repeatedly compared with the dataset to ensure they accurately represented the data and aligned with the research questions. This iterative process required carefully evaluating themes alongside coded extracts, ensuring that patterns were logical and consistent (118). During this phase, the researcher frequently revisited steps two and three to further refine the themes.

Defining and naming themes involved the systematic progression of the data from early, initial, and ultimately final themes (see Figure 3). This approach ensured that the themes were based on the data and directly connected to the research question, providing a clear and comprehensive understanding of the patterns in the data.

Figure 3: Development of themes



In writing the report, the researcher, even at this late stage, went back to initial coding and updated the themes to ensure they represented the data as accurately as possible. All the themes were described in detail and the scope of each theme was outlined to provide clarity and context. In consultation with the study supervisors, the researcher determined it would be helpful to synthesise and report the findings using the Four Delays framework. The four main themes each represented one of the four delays, followed by respective subthemes. Each subtheme represented a barrier to accessing CWC.

3.4. Rigour

In this study, Lincoln and Guba's criteria were used to evaluate the qualitative data (119). It provided practical guidance for establishing credibility, transferability, dependability, and confirmability. This study's credibility was strengthened by spending time with the study participants and engaging in the subject matter to build trust and gain comprehensive perspectives. Person triangulation was used in this study by gathering opinions from multiple sources, including CW patients and CWC providers. Method triangulation was performed using

more than one method of data collection which included both surveys and interviews (120,121). Transferability was demonstrated by providing comprehensive descriptions of participant demographics. To establish the dependability of this study, the researcher offered a detailed account of the research goals, objectives, data collection, analysis, and interpretation. Confirmability of the findings was further supported by directly quoting participants in the results, facilitating transparency and enabling other researchers to verify the interpretations against the original data (119,120).

3.5. Positionality and Reflexivity

The researcher considered the ways in which her professional background, experiences, and preconceptions could have impacted her interactions with participants. The researcher is a medical doctor who practiced part-time during the study period in the KDH Emergency Department. The researcher disclosed to the participants that she was a medical doctor and was working at the hospital. The researcher was aware of the possibility that the participants might have felt uncomfortable talking openly about experiences with a person working in the medical field due to fear of retribution. This situation was discussed with each participant, and it was emphasised that the interview would not affect the participant's medical care or job in any way. The goal of the interview was to hear the participant's story as they are the experts in this subject matter. The researcher was aware that trust and openness were needed for the participants to feel comfortable sharing their experiential knowledge (122).

The interviews were conducted in the healthcare facilities where participants worked or received treatment. Healthcare providers approached patients, without the researcher present to prevent coercion, to enquire about participating in the interviews. The researcher allowed the participants to decide what date and time the interview took place. The researcher hoped that participants would feel they were exercising a measure of control over the interview process. The researcher was flexible with interview times and locations to accommodate the participants. The CWC providers were interviewed in their break rooms. The prevailing sentiment was one of gratitude, as they appreciated the acknowledgment and open discussion of the issue of chronic wounds. Most CW patients were interviewed after they completed their outpatient appointment, and a few were interviewed while admitted to the surgical ward. The researcher was mindful of the long waiting times in the clinic and that the patients were rushing to get home and were already uncomfortable after their wound dressings. However, the researcher experienced all the interviews to have an element of catharsis, with some participants even stating that they never had a healthcare worker ask them how they felt about having a chronic wound. To reduce bias, equal importance was attached to all opinions and experiences shared during the data collection phase. The CWC provider opinions were not deemed 'privileged' or 'more important' in comparison to the CW patient group.

3.6. Ethical Considerations

Ethics Approval

Ethics approval was granted by the Health Research Ethics Committee of the University of Cape Town (Reference: 484/2020), Western Cape Provincial (Reference: WC_202010_014), and the City Department of Health (Reference: 9344).

Privacy and Confidentiality

Discussing the study, obtaining informed consent, completing the survey, and conducting the interviews were done either telephonically or in person depending on the COVID-19 restrictions at the time. All participants were informed that every effort would be made to maintain confidentiality, however, complete assurance could not be guaranteed. Names were replaced with code numbers after informed consent was provided. Participants' personal information was only accessible to the primary investigator who may have needed to know the participants' details if any problem presented itself. Physical documents and recordings with information provided were kept in a secure place, and strict confidentiality was maintained. In any publication, no personal information was used.

Informed Consent

The study design and objectives were explained verbally to potential participants by the researcher. An information sheet and consent sheet (both translated into English and isiXhosa) were sent electronically or physically handed out to the participants to read beforehand. Participants were given the opportunity to ask questions and seek clarification. It was made clear that participation was voluntary, and that consent could be withdrawn at any point. Declining to participate, pulling out of the interview mid-way, or completing the interview would not influence access to healthcare services or care rendered at the relevant healthcare facilities. Consent included having an interpreter present if requested. Each study participant was individually consented. It was made clear to all participants this was student research for a Public Health Master's Degree. Informed consent was obtained by the researcher in person and in writing at the facility on the day of the survey or interview.

Potential Risks and Distress Protocol

Narrating experiences of wound care was mildly upsetting for some participants with chronic wounds. Once a participant appeared to become upset, the interviewer stopped and asked the participant if they would like to take a break. All the participants requested to continue. During the debriefing sessions after the interviews, these participants explained that they felt a sense of relief after being able to express how drastic chronic wounds affected their lives. The distress protocol

stated that if the participant should wish to stop, the interview would be terminated and all the data from that interview would be disregarded. If a participant seemed distressed, provision would be made for referral to a social worker or counsellor at the relevant facility.

Data Storage

All data were handled in confidence and pseudonyms were given to all participants to safeguard their identities. Only the primary investigator and her supervisors had access to the password-protected laptop and secure backup storage.

Compensation

A R150 shopping voucher was given to each participant as a token of appreciation. During the survey and interview sessions, food and beverages were provided. These were minor benefits that did not unduly influence participants in the study.

3.7. Impact of COVID-19 Pandemic

The surveys were completed between November 2020 and May 2021, and the interviews were conducted between February 2021 and May 2021. To note, the COVID-19 infections in the Khayelitsha district surged at the beginning of December 2020 to the end of January 2021 (123). This led to a temporary delay in face-to-face data collection during this period, however, one survey was performed telephonically during this time. The researcher preferred completing the surveys and conducting the interviews in person as this allowed for relationship building with the respondents and interviewees which enhanced the quality of data. Prior to the pandemic, the plan was to conduct focus groups with the CWC providers, however, this was not possible due to the COVID-19 restrictions. The researcher then decided to perform individual interviews with the CWC providers as this was the safest option at the time. The uncertainty and fear associated with the pandemic made the researcher aware of the possible hesitation from potential participants to take part in this study. All precautions were taken to make both the researcher and participants comfortable during the data collection period. Upon reflection, some interviews were slightly rushed by the researcher who, influenced by the empathetic understanding of the demanding nature of a healthcare worker's day in a busy clinic, might have sensed the uncertainty of the participants to engage in discussions about chronic wounds with an unfamiliar interviewer. Despite this, the researcher felt the participants were very enthusiastic and actively took part in the surveys and interviews. The CW patients in the ward were pleasantly surprised to have someone to talk to during their stay as there were no visitors allowed during the pandemic.

CHAPTER 4 – FINDINGS

This chapter presents the findings from Phase 1 and Phase 2 sequentially.

4.1. Phase 1: Facility Surveys

A total of 12 facility surveys were conducted, with one survey completed for each facility. All 12 healthcare facilities providing CWC across all three levels of care in the Khayelitsha health district were included.

Chronic Wound Care Services

Chronic wound care services in the Khayelitsha health district were structured across three levels of care, each offering distinct services and resources (see Table 3). At primary-level facilities, CWC was provided during routine clinic hours on weekdays. New patients did not need appointments and were attended to on a first-come, first-served basis after joining the main queue. Follow-up appointments were scheduled as needed. Emergency CWC was available after hours at one of the primary-level facilities.

The secondary-level facility provided CWC three times a week in the SOPD by referral. Emergency care was available 24 hours a day, seven days a week through the secondary-level facility's emergency department. Additionally, the secondary-level facility was equipped with theatre capabilities and provided in-patient CWC in the surgical ward.

At the tertiary-level facility, CWC was delivered in specialist clinics on designated days, with services strictly available by referral and appointment. Emergency care was accessible through the tertiary-level facility's emergency department. In-patient care was also provided in the wards, along with 24/7 theatre services, ensuring comprehensive management of complex chronic wound cases.

Table 3: Availability of chronic wound care services at each level of care

Level of Care	Primary (n=10)	Secondary (n=1)	Tertiary (n=1)
Chronic Wound Care Clinic	General OPD	Surgical OPD	Vascular SOPD & Plastic SOPD
Available Times	Weekdays 08:00 - 16:00	3 Days per week 08:00 - 16:00	1 Day per week & 3 Days per week
By Referral		✔	✔
After Hours Access	1 Clinic	Emergency Department	Emergency Department
In-patient Facilities		✔	✔
Operating Theatre		✔	✔

Additional Chronic Wound Care Initiatives at Primary-Level Facilities (n=10)

Certain primary-level facilities offered a variety of additional CWC services designed to enhance patient care. The majority of these additional services were not part of the routine standard of care but rather were initiated by the healthcare providers themselves as the need presented. The following innovative interventions were identified at primary level as potential facilitators to accessing care:

Health Information

Informal educational sessions were conducted at seven (70%) clinics. These nurse-led sessions took place either in patient groups in the waiting room or during one-on-one consultations. Common topics included the prevention of diabetic foot ulcers and the importance of timely health-seeking behaviours. However, these sessions varied between clinics and were done sporadically due to time constraints.

Fast-tracking

More than half (60%) of the clinics implemented a fast-tracking system for CW patients. This system allowed for a streamlined registration process by keeping the CW patients' medical records separate or by calling them out of the main queue to a dedicated wound care waiting area.

Home Wound Care Packages

Half (50%) of the clinics offered home wound care packages, which contained basic materials for cleaning and dressing wounds. This service was particularly beneficial for patients unable to attend appointments due to travel constraints, financial limitations, or clinic closures (e.g. during public holidays). A prerequisite for this service was informal training of the patient or caregiver. Additionally, this option was available for patients who preferred less frequent on-site wound dressings, provided they attended the clinic at least every two weeks.

Home-based Care

Home-based nursing services were available through seven (70%) of the clinics, with the goal of reducing the need for patients to attend on-site clinic appointments. These nurses worked in the community and performed basic wound care at the patient's home. Patients needed to apply for home-based care through their primary-level facility.

Chronic Wound Care Resources

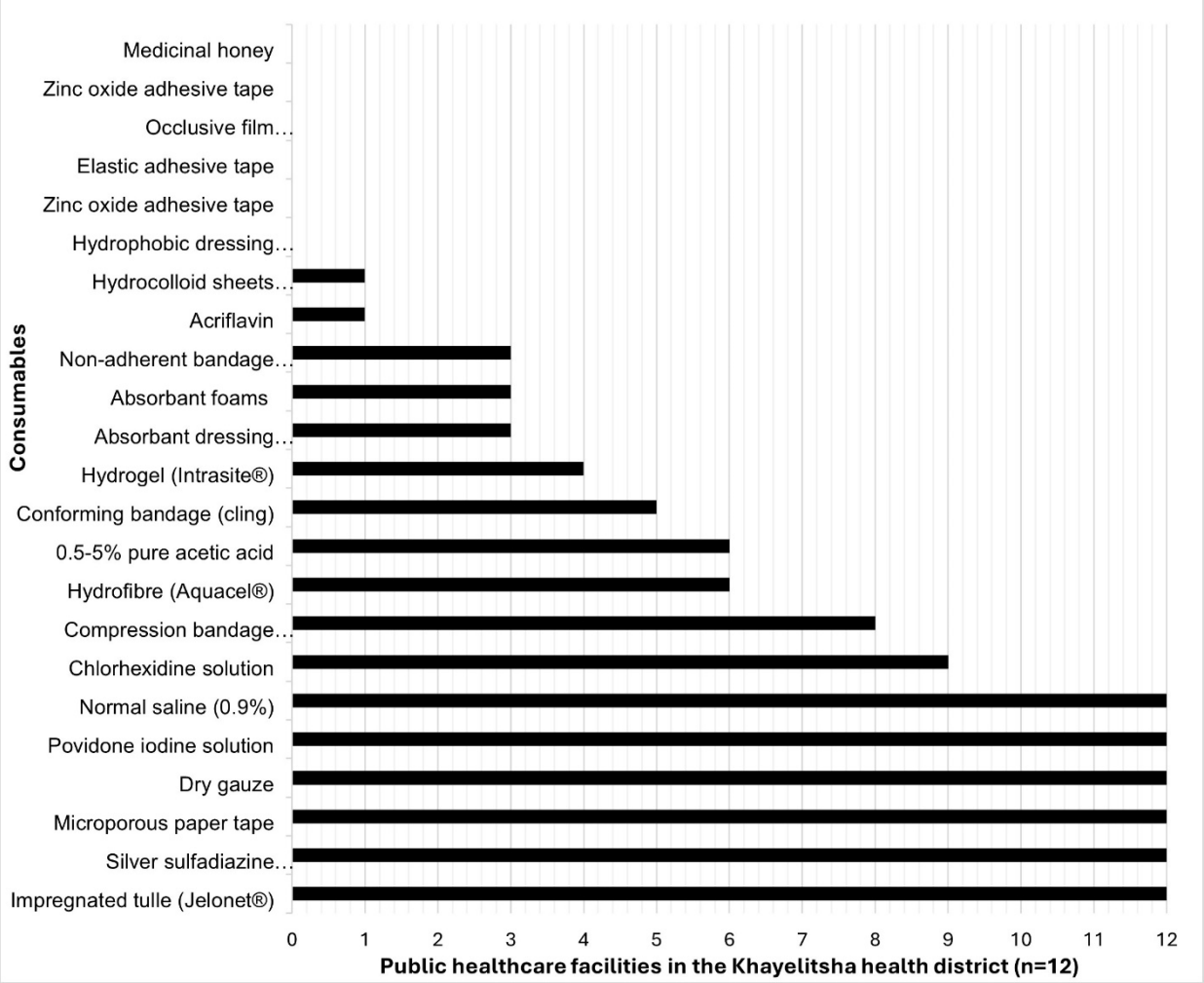
Human Resources

At primary level, either a general doctor or a PN initially evaluated the chronic wound. Consultations were done with secondary or tertiary-level doctors as needed. After this initial assessment, staff nurses did the dressing changes under PN supervision. PNs made the decision whether a doctor needed to be re-consulted in cases of poor healing or any other complications. At the secondary-level facility, patients were seen in SOPD by a general doctor or surgeon on-site who performed the initial wound assessment, as well as subsequent dressing reviews. At tertiary level, each patient was seen by either a plastic or vascular surgeon (see Figure 5).

Wound Care Consumables

The consumables that were commonly available at all the study sites included normal saline, povidone iodine solution, dry gauze, microporous paper tape, silver sulfadiazine, and impregnated tulle (see Figure 4). Hydrophobic dressing (Sorbact®) was out of stock at all the facilities, which correlated with the sites stating that it was also the most highly requested product. Dry gauze, impregnated tulle, and compression bandages (Ulce3®) were usually available at all the facilities, but still highly requested when out of stock. Normal saline, povidone iodine solution, microporous paper tape, and silver sulfadiazine were commonly available at all the facilities, but not highly requested. Cling bandages, acriflavin, hydrocolloid sheets, absorbent dressings, and foams had the lowest availability, but were not specifically identified as highly requested products.

Figure 4: Availability of wound care consumables in the Khayelitsha health district



Treatment Guidelines

The only treatment guideline named by primary-level facilities (n=10) was the PACK guidelines however only four (40%) facilities reported having a hardcopy on-site (82). Secondary and tertiary-level facilities were not aware of any hospital-level guidelines, including the Hospital Level (Adult) STGs, Tertiary Level STG's, and EML (81,85).

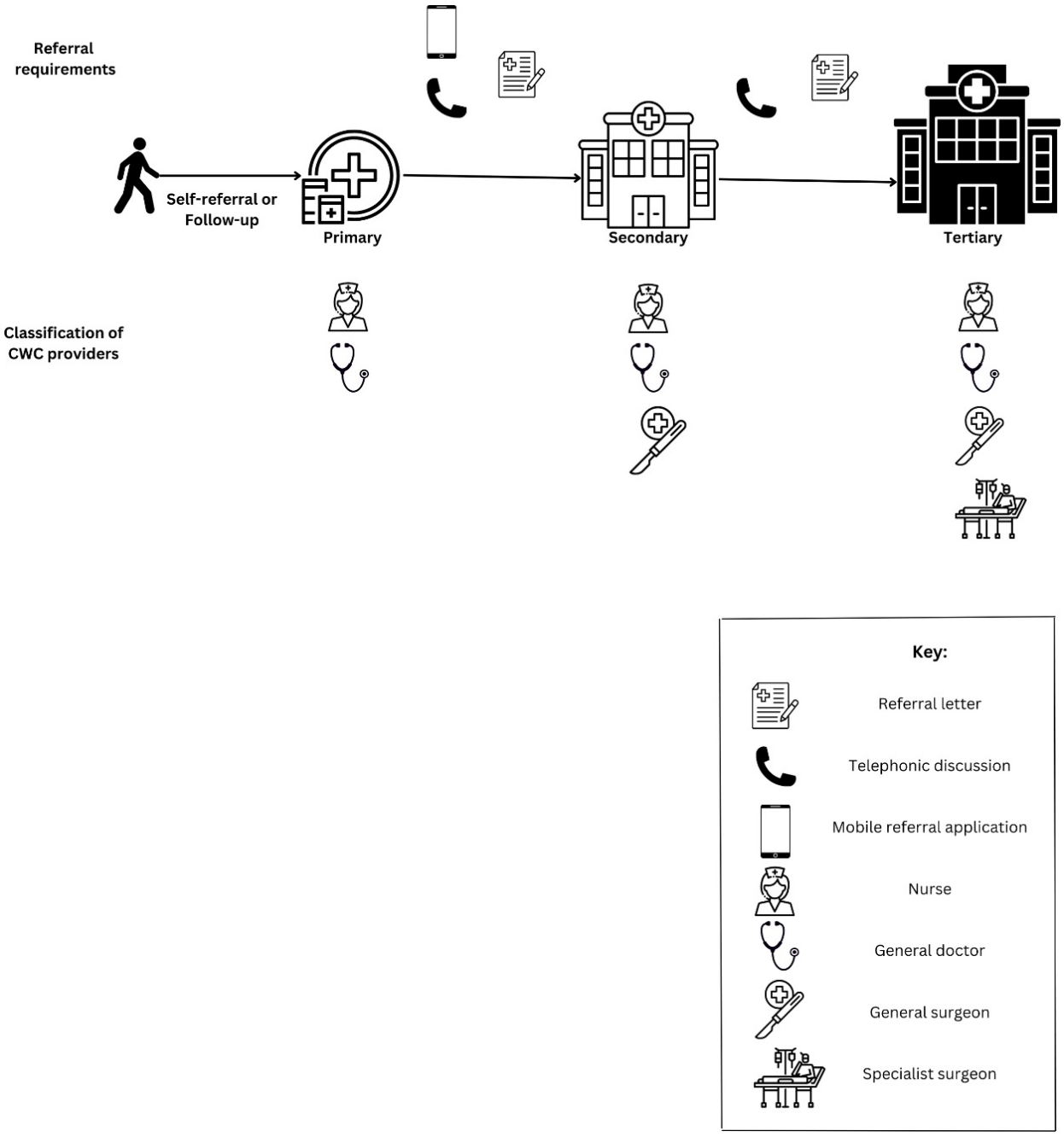
Chronic Wound Care Referral Pathways

Persons with chronic wounds entered the healthcare system at primary level through one of the 10 clinics. As needed, they were referred to KDH for secondary-level care, and to TBH for tertiary-level care (see Figure 5). Certain types of chronic wounds were routinely referred to the secondary-level facility's SOPD for an initial assessment by a doctor. A doctor at the secondary-level facility created a treatment plan to identify any contributing factors that prevented wound

healing. Patients with wound complications, such as local and systemic infection, severe hyperglycemia, and limb ischaemia, were urgently referred to the secondary-level facility's emergency department. Most surgical procedures, including debridements, amputations, and skin grafts, were performed at secondary level. Tertiary-level referrals were rare and only occurred for specific cases, such as when plastic surgery was needed for skin flaps or vascular surgery for arterial revascularisation. Up-referral to secondary or tertiary level of care, required a PN or doctor's referral letter combined with a telephonic discussion or mobile referral application acceptance. Communications through the mobile application called Vula was preferred as wound images could be sent digitally.

After treatment at the secondary-level facility, patients were down-referred to their primary-level facility for follow-up care. In rare cases of down-referral from tertiary to secondary level, this was done through direct communication between the referring and accepting doctors, with the patient being transported via ambulance. Most down-referrals to local clinics were done with a written referral. None of the facilities were aware of an official written inter-facility referral policy for chronic wounds in the Khayelitsha health district. The only protocol referenced by two (17%) of the facilities was the "urgent referral" criteria stated in the PACK guidelines (82). Transportation methods included walking, public or private transport, and in isolated cases own transport. Patients were responsible for reaching primary, secondary, and tertiary facilities on their own at their own cost. Ambulance services were only used for urgent referrals requiring inpatient care.

Figure 5: Mapping chronic wound care human resources and referral pathways across all three levels of care



4.2. Phase 2: In-depth Semi-structured Individual Interviews

This section will describe the perspectives of 20 participants who were individually interviewed between February 2021 and May 2021. The interviewees consisted of 10 CWC providers and 10 CW patients (see Tables 4 and 5).

Table 4: Descriptive socio-demographic characteristics of interview participants (CW patients)

CW Patients (n=10)	
Characteristics	**Frequency (%)**
Age, in years [median (range)]	37.5 (24-67)
Duration of treatment, in months [median (range)]	6 (6-36)
Home language	
isiXhosa	10 (100)
Sex	
Female	6 (60)
Male	4 (40)
Employment status	
Unemployed	6 (60)
Employed	3 (30)
Pensioner	1 (10)
Location of wound	
Lower limbs	8 (80)
Upper limbs	1 (10)
Abdomen	1 (10)

Table 5: Descriptive socio-demographic characteristics of interview participants (CWC providers)

CWC Providers (n=10)	
Characteristics	**Frequency (%)**
Age, in years [median (range)]	43.5 (29-63)
Chronic wound care experience, in years [median (range)]	7 (1-24)
Sex	
Female	8 (80)
Male	2 (20)
Qualification	
Nurse	7 (70)
Doctor	3 (30)

The 10 CW patients ranged in age from 24 to 67 years, with a median age of 37.5 years. Of these, 60% were female. All participants spoke isiXhosa as their first language and either English or Afrikaans as a second language. They had been receiving active treatment for their chronic wounds for between six months to three years, with the most common duration being six months. The majority of wounds were located on the lower limbs. All patients had received care at both primary and secondary-level healthcare facilities, while one (10%) had also attended a tertiary facility.

The 10 CWC providers ranged in age from 29 to 63 years, with a median age of 43.5 years. Of these, 80% were female, and all were fluent in English. The majority (70%) were qualified nurses (see Table 6). Their experience in CWC ranged from one to 24 years, with a median of seven years.

Table 6: Profession of CWC providers by level of care

Profession of CWC Provider (n=10)	**Level of Care**		
	Primary	**Secondary**	**Tertiary**
Nurse	4 (40%)	2 (20%)	1 (10%)
Doctor	0 (0%)	2 (20%)	1 (10%)

The results were arranged into main themes and subthemes using the Four Delays framework (see Table 7). Each main theme represented one of the four delays, followed by respective subthemes. Each subtheme represented one of the nine identified barriers to accessing CWC.

Table 7: Barriers identified using Four Delays framework

Main Theme (Delay)	Subtheme (Barrier)
Seeking (Delay 1)	Personal beliefs
	Fear of amputation
Reaching (Delay 2)	Transportation costs
	Safety concerns
Receiving (Delay 3)	Chronic wound care provider shortages
	Stock shortages
	Non-utilisation of treatment and referral protocols
Remaining (Delay 4)	Deficient health information
	Lengthy waiting times at healthcare facilities

Below are the themes discovered in this analysis. All quotes are presented within double quotation marks to distinguish them as the participants' words, and not those of the researcher. In this chapter, interviewees will be allocated pseudonyms to protect participants' identities.

Main theme 1: Delay in Seeking Care

To access medical care, the decision to seek care needs to be made first. Any delays in seeking treatment can be seen as barriers to accessing care (88). In this study, personal beliefs, together with the fear of amputation, were powerful determinants of health-seeking behaviour.

(a) <u>Personal Beliefs</u>

Personal beliefs, including cultural and religious convictions, negatively influenced health-seeking behaviour. Many CWC providers mentioned that patients frequently turned to traditional healers before seeking treatment at healthcare facilities. According to one CWC provider, one of the reasons for going to a traditional healer was the belief that a person was bewitched, necessitating

traditional treatment before the wound could heal. James, a CWC provider, described that even after successful treatment at a healthcare facility, patients repeatedly returned to traditional healers before seeking care from the clinic.

> "[The patients] always have that hope that the traditional healer will help them even if the patient did have an ulcer before and it was healed at the clinic, but when it develops again she will say I have been bewitched and go back to the traditional and come back when the ulcer is bad." (James, CWC provider)

Another CWC provider, Polly, observed that patients who initially sought treatment from traditional healers, often presented with chronic wound complications.

> "A patient died. One patient was here [at the district hospital] with the bone outside [the leg]. He was busy with the traditional healers." (Polly, CWC provider)

Not only did these patients delay seeking care, but in some cases, the alternative treatments even worsened their wounds according to Marguerite, a CWC provider.

> "We often see patients with cellulitis come to us with little marks from their traditional healers that they went to. And then that obviously causing secondary infection and cellulitis." (Marguerite, CWC provider)

However, amongst the CW patients who were interviewed, all denied going to traditional healers themselves. Even though Themba did not do so herself, she admitted that it was culturally acceptable to consider seeking treatment from a traditional healer.

> "Yeah, [going to a traditional healer] it came to my mind. Cause sometimes we as cultural people yeah, we sometimes resort to that you see. But I haven't gone." (Themba, CW patient)

One CW patient, Buhle, explained that going to the traditional healer would delay receiving appropriate treatment.

> "The sangomas they will delay you. By the time you go to sangomas, the wound is becoming bad." (Buhle, CW patient)

Religion also played a significant role in health-seeking behaviour. One of the CWC providers, Megan, stated that certain churches discouraged patients from making use of healthcare facilities as they stated that believers should rely on prayer to cure their wounds.

> "I think the churches they say no, [the patients] are not allowed to go to the clinics. They have to pray. [The churches] say they are going to pray for their wounds." (Megan, CWC provider)

This theme highlights the need for culturally sensitive interventions aimed at bridging understanding gaps and promoting timely health-seeking behaviour, especially within diverse patient populations.

(b) <u>Fear of Amputation</u>

A fear of amputation was identified as a barrier to seeking timely CWC. This fear was linked to the stigma of going to the hospital with a lower leg wound and ending up with an amputation. CWC providers noted that this fear was shared not only by patients but also extended to family and community members.

> “Some of the younger family members then alluding to the fact of the stigma that exists that if you would come to Khayelitsha hospital that yes definitely losing limbs is something that seems to be in the community.” (Marguerite, CWC provider)

One CWC provider described the belief that patients leave the hospital with an amputation, as a "myth", expressing that, in their experience, this belief was unfounded and was exacerbated by a lack of health information. Another CWC provider, Lilly, pointed out the irony that the fear of amputation often led to a delay in seeking care, which increased the risk of complications that necessitated amputation.

> “Unfortunately, the stigma is paired with a lack of understanding, a lack of knowledge that the amputations in most of the cases that we see are the last resort and last leg of treatment that we can unfortunately offer.” (Lilly, CWC provider)

However, it is important to note that not all individuals shared this belief. Xolani, a CW patient who had undergone an amputation, felt that the decision to amputate was neither unnecessary nor rushed.

> “They decided to amputate, because they say the infection is too much and all that stuff. So, then I made the choice that they must amputate it, because it was so bad.” (Xolani, CW patient)

Despite fear negatively influencing health-seeking behaviour, one CW patient, Esihle, described how family support enabled the decision to seek care.

> “My family says I must go to the clinic.” (Esihle, CW patient)

These differing perspectives raise the importance of personalised and patient-centred approaches to addressing this barrier to seeking care.

Main theme 2: Delay in Reaching Care

After the decision is made to seek care, the following barrier to accessing care is reaching care. Chronic wounds are associated with a spectrum of physical limitations that create difficulties to reaching healthcare facilities (58). In this study, not only did the out-of-pocket transportation costs associated with travelling to healthcare facilities result in delays, but safety concerns also impacted the patient’s ability to reach care.

(a) Transportation Costs

The financial burden associated with reaching healthcare facilities was identified as a significant barrier to accessing CWC. Chronic wounds are known to cause pain, limiting patients' mobility and making it challenging to travel to healthcare facilities for frequent treatments. When patients were unable to walk to their clinics, public or private transportation was often too expensive. In cases where an amputation was performed, the use of crutches or a wheelchair added another layer of complexity to their mobility. Some individuals required specialised transportation services, such as wheelchair-accessible vehicles. Public transportation, a common means of travelling, often lacked the infrastructure to support individuals with mobility challenges. This limitation was pointed out by the following CW patient, Fezeka.

> "Some taxis don't take someone on a wheelchair. [There is] no space in the taxi." (Fezeka, CW patient)

Even when specialised transportation services were available, affordability remained an issue. Esihle, a CW patient, highlighted financial constraints as a decisive factor in missing appointments.

> "[I will] only [miss my appointment] if I don't have transport or money for car." (Esihle, CW patient)

This combination of physical limitations and financial constraints resulted in delayed medical care. While some support was provided through hospital transport services, participants noted that this assistance prioritised elderly patients and those from rural areas, leaving individuals in closer proximity to healthcare facilities, such as Khayelitsha, underserved. However, for patients residing within a short distance of their healthcare facilities, this was a protective factor as it enabled them to walk to their appointments, reducing reliance on costly transportation alternatives. This CW patient, Akhona, expressed a positive sentiment regarding walking to the clinic.

> "I stay close to the clinic, so it is close for me to walk. I might miss an appointment] if it rains maybe, but I have an umbrella." (Akhona, CW patient)

While proximity to healthcare facilities can mitigate some of the transportation barriers, the combination of physical limitations, financial constraints, and inadequate transportation infrastructure continues to pose significant challenges for many CW patients in reaching healthcare facilities.

(b) Safety Concerns

Safety concerns were raised by both a CWC provider and a CW patient, who noted that certain facilities were in high crime areas, making it unsafe for patients to walk to these facilities. If no transport was available, this negatively influenced the decision to seek care. A CWC provider

mentioned that walking to their clinic was not feasible due to the prevalent crime, with some patients even sustaining injuries from assaults and robberies.

> "It's impossible to walk because of crime. Some of [the patients'] wounds are even from being assaulted and robbed." (James, CWC provider)

Although the theme of safety concerns due to high crime rates was not explicitly mentioned frequently by participants, it is crucial to emphasise this as a significant barrier to reaching healthcare facilities. The lack of frequent mention may reflect the normalisation of crime in daily life rather than an indication of its insignificance. Addressing these safety issues is essential for ensuring that all individuals can access the care they need safely. Not only is safe access to facilities a security issue but a fundamental aspect of equitable healthcare access, particularly for vulnerable patients who may already face multiple barriers to care.

Main theme 3: Delay in Receiving Care

Once a patient reaches a healthcare facility, the next barrier to accessing care is receiving care. During this study, three barriers were identified as factors contributing to delays in receiving CWC namely, CWC provider shortages, stock shortages, and non-utilisation of treatment and referral protocols.

(a) <u>Chronic Wound Care Provider Shortages</u>

All participants reported a significant shortage of both doctors and nurses, which caused delays at all levels of care. One CW patient, Bulelani, expressed their frustration with prolonged waiting times at the clinic and attributed this to a shortage of doctors.

> "There must be more doctors, because sometimes we stay here the whole day. You come here early the morning, and you stay the whole day." (Bulelani, CW patient)

At primary-level facilities, where the majority of chronic wounds were managed, daily operations were strained by a limited number of wound care nurses. Recognising this challenge, some providers advocated for establishing additional CWC clinics staffed by trained nursing personnel. This, they argued, would alleviate pressure on secondary and tertiary facilities, allowing them to focus more on managing complications.

> "I would advocate for more nurses with extra wound care training to be the primary care givers for patients with chronic wounds. They should be able to run their own chronic wound care clinics. Then if they feel the wound is not improving they can up-refer." (Tara, CWC provider)

Expanding primary care capacity with specialised CWC clinics, led by PNs, could enhance chronic wound management, potentially easing the burden on secondary and tertiary hospitals.

(b) Stock Shortages

Another critical issue was intermittent shortages of essential CWC materials at specifically primary-level facilities. Patients often experienced delays due to the unavailability of basic supplies, for example, adhesive tape. Cebisa, a CW patient recalled a visit where healthcare providers had to resort to makeshift solutions at the clinic.

> "One time at the clinic, the dressings were out of stock. [The] plaster. Like now, they put Sellotape [on]." (Cebisa, CW patient)

One CWC provider, Katy, attributed shortages to administrative clerks lacking medical training, resulting in incorrect stock orders that further disrupted care.

> "We spoke before about the admin clerks that do not know what the products are that [they] are ordering, so they sometimes cancel ones without realising the impact." (Katy, CWC provider)

(c) Non-utilisation of Treatment and Referral Protocols

Effective CWC requires standardised treatment guidelines, clear referral protocols, and robust communication pathways between all levels of care. However, CWC providers highlighted significant gaps in these areas. Many noted the absence of evidence-based wound care guidelines and referral procedures, which led to inconsistent treatment practices and overall confusion. However, this study showed that there were treatment and referral guidelines available, but that they were not being utilised. Reasons for non-compliance were relying on own experience to treat wounds, and not having a hard copy on hand.

> "I learned from reps and doctors and other nurses. I have years of experience in wound care." (Tim, CWC provider)

District and tertiary facilities said despite efforts to provide clear treatment plans when down-referring a patient, these were often ignored by the clinics.

> "I try and write a relatively intensive letter to the clinic with the diagnosis and exactly what they need to do. For example, what dressings to use and how frequently to change the dressings. The clinics never listen to those letters." (Tara, CWC provider)

Clinics, on the other hand, claimed they lacked the specialised dressings prescribed by secondary and tertiary facilities and had to make do with available resources, which contributed to the perception that they were not following prescribed treatment plans. Opinions among CWC providers varied, with some acknowledging the limited resources and others pointing to inadequate training and a lack of supervision at primary level.

> "I think [at local clinic level] it's supposed to be all the dressings we have here. However, I've been told they have limited dressing options and do not have supervision by doctors all the time. However, I'm honestly unsure." (David, CWC provider)

The clinics felt that the patients didn't trust them, because the ones that were referred to the secondary or tertiary facilities were told by those healthcare providers that certain specialised dressings were needed. However, upon returning to the clinic they were told that the dressings in question were not available. This discrepancy contributed to patient dissatisfaction and the perception of inadequate care. The lack of standardised referral criteria also led to delays and inappropriate referrals. Poor communication between facilities and unawareness of available resources at different levels exacerbated these issues. The tertiary facility reported that clinics often bypassed proper referral protocols, resulting in patients being sent back with new appointments, causing unnecessary frustration and expenses.

> "When the doctors don't discuss and then just send the patients, they get sent back with another date. This makes them go in circles and spend unnecessary funds to reach the hospital. All of this is preventable if the outside doctors just follow the correct procedures. The patients come here and they get mad at us, but I didn't say you must come here. They take out their frustrations on us." (Katy, CWC provider)

The clinics argued that it was often difficult to reach the correct doctor at the tertiary facility to make an appointment as the tertiary specialists were not making use of the mobile referral application, named Vula, as the secondary hospital was (124). These interconnected factors collectively contributed to delays in receiving care. This study highlights the need for regularly updating, distributing, and implementing evidence-based guidelines across all levels of care to ensure continuity of care.

Main theme 4: Delay in Remaining in Care

The final barrier to accessing CWC is a delay in remaining in care. Chronic wounds are associated with an extended healing period which requires frequent visits to the clinic for wound assessments (14). If patients miss appointments or default treatment, this could lead to wound complications. In this study, deficient health information and lengthy waiting times at healthcare facilities contributed to patients being reluctant to return for ongoing care.

(a) <u>Deficient Health Information</u>

Educating and including patients in decision-making processes, allows them to take ownership of their health, and will increase the likelihood of them remaining in care (125). Not only did a lack of health information delay and prevent patients from remaining in care, but all participants agreed that a strong health system required the users to have the knowledge to be able to access and utilise it appropriately. Patients expressed that they were not told basic information regarding their diagnoses, management plans, or prognoses. This created feelings of fear, denial, and distrust in the health system. The CW patients felt that it was the responsibility of the healthcare workers to provide health information and counselling. One CW patient felt the reason for not being able to talk to the doctor was because the doctor was usually busy. The CWC providers differed from the

CW patients, stating that the healthcare workers did their best to educate patients within the limited timeframe they had. Some CWC providers said that they did educate the patients, but that the patients did not adhere to their advice.

> "As far as I know and since I started in nursing, education talks are given in the waiting and reception area regarding different illnesses. When and where to seek help. But the people don't do it." (Katy, CWC provider)

CWC providers did agree that improved communication and health information were vital to creating realistic expectations regarding the wound healing process. When patients did not understand and agree to take part in the long-term plan, it increased the likelihood of that patient defaulting treatment. This CW patient, Themba, expressed how communication made a meaningful difference in his treatment.

> "You know there is no better healing process than communication. Somebody giving you that comfort zone. Telling you exactly what is happening and communicating with you, you see. That's the best thing. If they communicate, they engage you and they make you feel comfortable with whatever that you are going through." (Themba, CW patient)

(b) <u>Lengthy Waiting Times at Healthcare Facilities</u>

A significant barrier to remaining in care was the lengthy waiting times at healthcare facilities. Chronic wound management typically required wound reviews every two to three days. An appointment usually lasted between two to six hours depending on the facility. Nandipha, a CW patient recounted their experience with long wait times.

> "I spend a long time because of the long queue outside, because they call my name after three hours only to be seen. They take long to get the folder. To wait in the queue outside now is hard when it is cold and raining." (Nandipha, CW patient)

Most facilities had extensive queues, causing many patients to spend the majority of their day waiting to be seen by a CWC provider and then waiting once again at the pharmacy.

> "I come [to the clinic] at 06h00 and usually leave at 13h00. [I wait the longest for] pharmacy and the doctors." (Bulelani, CW patient)

These prolonged and frequent clinic visits had an impact on employed patients, exhausting their limited sick leave, eventually resulting in loss of employment and decreased income. This CW patient, Esihle, expressed the difficulty of choosing between attending appointments and going to work.

> "I struggle with money if I have to go to clinic, because I cannot work when I have appointment." (Esihle, CW patient)

The patients who decided to rather go to work, missed their appointments, with some even defaulting completely. David, a CWC provider sympathised with the patients' dilemma.

> “Sitting in long clinic queues for multiple days a week leads to loss of employment. Sometimes patients decide to go to work and miss their appointments.” (David, CWC provider)

At most facilities, CW patients also had to sit in the main queue for follow-up visits before proceeding to the dressing room. However, some facilities implemented a fast-track system to reduce waiting times, where CW patients’ folders were kept separate, and the patients were pulled from the main queue at the start of the day. In a further attempt to decrease the frequency of clinic visits, some clinics offered home wound care kits. CWC providers explained that they provided these kits to certain patients and instructed them on how to change their dressings at home.

> “We [the nurses] advise the patient if the TTO’s are finished somebody who is staying with the patient can go fetch it and we educate that person on how to dress the wounds at home. They come at least once a month to see how the wound looks.” (James, CWC provider)

CW patients had differing opinions on home wound kits. Some found them helpful in reducing clinic visits, while others felt incapable of performing the dressings themselves due to a lack of professional training and the pain involved in cleaning the wounds.

> “I am happy to go to clinic, because I cannot do my own dressings. I cannot see the wound and it is too painful to wash it myself.” (Esihle, CW patient)

All participants agreed that the most helpful service would be a home-based carer who could come to their house to inspect, clean, and dress their wounds. Lengthy waiting times were attributed to several factors, including long queues to enter the facility, the process of opening a folder and waiting for the CWC provider, followed by another long queue at the pharmacy. These factors contributed to a delay in remaining in care, by making patients reluctant to return due to fear of job loss and the inability to spend multiple days at the clinic.

To summarise, this chapter provides an in-depth description of the available pathways to CWC as well as the challenges faced by patients and providers. It offers a foundation for the synthesis and interpretation of the findings explored in subsequent chapters.

CHAPTER 5 – DISCUSSION

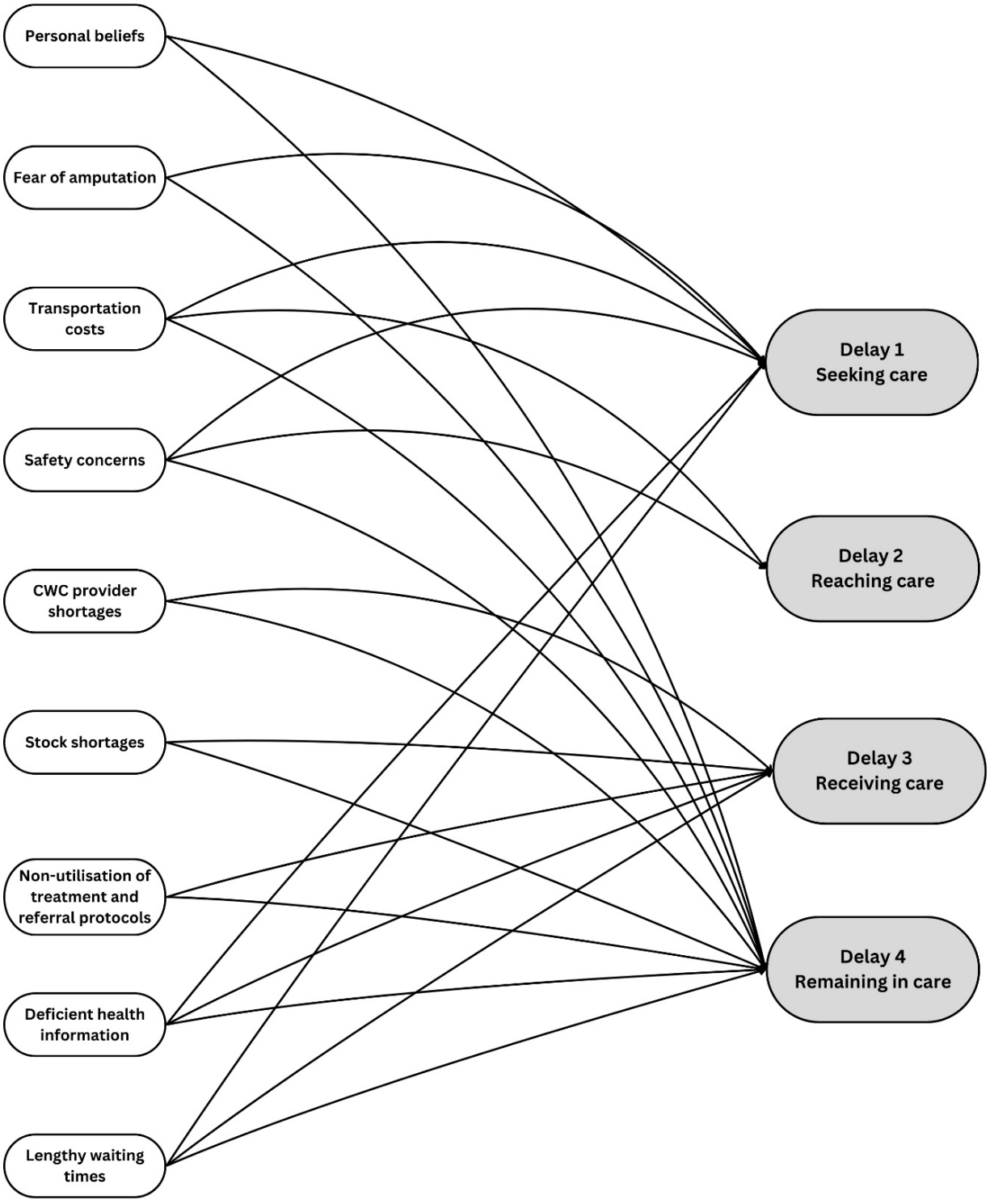
This mixed methods study mapped the complex pathways to accessing CWC across three levels of care in the Khayelitsha health district. Phase 1 was helpful in establishing the foundational knowledge required for developing the interview questions for Phase 2. Phase 2 provided insights into both effective and inadequate aspects of the available pathways to CWC. The Four Delays framework was used to identify nine barriers contributing to delays at various stages of the care pathway (88). The framework helped group each barrier with a primary delay. However, this oversimplified the complex ways in which the barriers and delays overlapped and interacted. The synthesised interpretation of the results showed that each delay was influenced by multiple barriers, with each barrier impacted by more than one delay (see Table 8).

Table 8: Barriers and overlapping delays

Barrier	Delays Influenced	Primary Delay
Personal beliefs	1, 4	1
Fear of amputation	1, 4	1
Transportation costs	1, 2, 4	2
Safety concerns	1, 2, 4	2
Chronic wound care provider shortages	3, 4	3
Stock shortages	3, 4	3
Non-utilisation of treatment and referral protocols	3, 4	3
Deficient health information	1, 3, 4	4
Lengthy waiting times at healthcare facilities	1, 3, 4	4

In order to convey the complexity and implications of overlapping barriers, each delay was reviewed alongside all the barriers influencing it. The visual representation of the barriers shows their overlapping and interconnected nature (see Figure 6).

Figure 6: Overlapping barriers and interconnected nature of delays



Delay 1: Seeking Care

Six barriers contributed to delays in seeking care, including personal beliefs. Cultural beliefs, which fall under personal beliefs, play a significant role in health-seeking behaviour, leading many patients to seek treatment from traditional healers. Both patients and healthcare providers

perceived this practice as delaying formal CWC. Traditional medicine is particularly pronounced in communities, such as Khayelitsha, where traditional healing practices are deeply rooted in cultural beliefs (126). Traditional healers are usually consulted for physical and emotional problems thought to be caused by social violations, supernatural forces, or witchcraft (127,128). One South African study showed that patients underreported traditional medicine use due to fear of discrimination (129,130). This stigma often stems from a lack of scientific understanding and respect for traditional medicine by the formal health system (129). This finding is concerning as it suggests that medical professionals may be unaware of traditional medications or treatments, which could influence formal medical practices and potentially compromise patient safety and treatment efficacy.

In South Africa, traditional healers are not formally recognised as part of the Health Professions Council of South Africa (HPCSA), instead, they are regulated by the Traditional Health Practitioners Act (No. 22 of 2007) (130,131). This act oversees the registration and practice of traditional healers. This council operates separately from the HPCSA (132). A study done in South Africa showed that traditional healers felt the formal health system had negative attitudes towards their work and did not respect their profession (133). To this point, healthcare providers argued that traditional medicine is not based on scientific evidence and that the practice is not regulated (133). However, another South African study found that traditional healers expressed interest in collaborating with the formal medical sector (134). Suggested initiatives included discussions and workshops with the aim of understanding both sectors, outlining referral options, and even sharing knowledge on treating surgical conditions (134,135).

Although significant progress is still needed, collaborating with traditional healers seems to be a viable solution to address delays in seeking care, particularly in resource-constrained health systems. This is supported by the World Health Organization (WHO) which endorsed the integration of traditional healers into formal health systems (135). A study done in Eswatini where traditional healers were trained to conduct HIV and TB testing reported positive feedback from patients and traditional healers, with an increase in health seeking (136). Patients preferred the privacy of seeking HIV and TB testing from traditional healers due to the stigma present at healthcare facilities (136). A study done in Ghana showed that a lack of knowledge surrounding traditional medicine and a discriminatory attitude towards traditional healers, by the formal health sector, were some of the main challenges hindering integration (137). This could be mitigated by conducting more research into the active ingredients of traditional medicine as well as fostering mutual understanding and respect between the traditional and formal health systems.

Another unique barrier identified was the fear of amputation. A community-based fear of receiving an amputation at the hospital made individuals reluctant to seek care. Although fear is inherently subjective, the impact can be profound, especially when fuelled by misinformation. For instance,

during the COVID-19 pandemic, misinformation regarding vaccine safety led many individuals to delay or avoid care (138). In socio-economically challenged areas, educational barriers limit access to reliable health information, making individuals more vulnerable to misinformation (139–141). Lower levels of health literacy and inadequate educational resources are common in underserved communities, which can hinder individuals' ability to critically assess and understand health information (140,141). This increases reliance on second-hand information, which can be more susceptible to inaccuracies and misinterpretations (141). In Khayelitsha, where formal education levels are lower and public health information is often disseminated informally, fear of amputation prevents some patients from seeking timely care, ironically increasing the risk of complications that might necessitate the very intervention feared (27). Alleviating this barrier may be possible through culturally sensitive discussions that address common fears, correct misinformation, and dispel other prevalent myths and stigmas. Incorporating community members, traditional healers, and faith leaders into these health education discussions could improve health-seeking behaviours. For instance, a study in Limpopo on poor male health-seeking behaviour reported that men were more likely to seek medical care when it was suggested by other men, an elder, or a leader in the community (142).

This supports one of this study's positive findings which was the significant role of family support as an enabler to seeking care. Family members often provided encouragement and practical assistance, such as arranging transport or accompanying patients to healthcare facilities. This support not only reduced logistical barriers but also helped patients overcome cultural and religious beliefs that might otherwise hinder them from seeking care. Interventions that strengthen family involvement, such as caregiver support programmes or educational workshops, could further enhance health-seeking behaviours and improve outcomes for patients with chronic wounds (143).

Delay 2: Reaching Care

Two barriers, transportation costs and safety concerns, led to delays in reaching care. Several studies have documented the impact of transportation costs on healthcare access. For instance, a study conducted in Guinea, Madagascar, and the Republic of Congo, found that removing transportation costs, reduced the surgical no-show rate by 45%, suggesting that policies supporting subsidised transport could improve patient retention, which is crucial for continuity of care, especially in CWC (144). Additionally, a study done in KwaZulu-Natal examined the costs incurred by patients accessing free HIV and TB care and identified transport as being a significant contributor to their overall financial burden, especially for HIV and TB patients who required frequent clinic visits, similar to chronic wound patients (145). The study suggested interventions such as transportation vouchers to decrease costs (145). In another South African study, the lack

of access to affordable transport was identified as a predictor of poor ART adherence, suggesting that transportation costs influence health-seeking behaviour (146).

For those able to walk, the risk associated with travelling through unsafe neighbourhoods, such as Khayelitsha, acted as a noteworthy deterrent and prevented patients from reaching care, despite wanting to go (147). These findings align with other South African studies, highlighting how crime-related safety issues contribute to delays in accessing care (99,148). In response to these challenges, strategies to improve access could include hospital-provided transportation, the provision of assistive devices, and enhanced safety measures. For instance, studies indicate that well-lit environments can deter criminal activity and enhance feelings of safety among patients and staff. Improved lighting increases visibility, making navigation easier and encouraging community members to access healthcare services without fear (149). Literature also supports the effectiveness of community collaboration and increased police presence in enhancing safety around healthcare facilities in high-crime areas (150,151). Implementing these strategies in Khayelitsha could significantly improve safety concerns for both patients and staff, facilitating access to care.

Furthermore, two factors noted in this study as facilitators to reaching care, were the distance to the nearest healthcare facility and the provision of assistive devices such as crutches or a wheelchair. This is supported by other South African studies that report that proximity to healthcare facilities is positively associated with healthcare utilisation (152). For example, in the Eastern Cape, pregnant patients who had to travel less than 20km to a healthcare facility, were more likely to seek care (152).

The implications of these findings suggest a need for a collaborative approach to overcome transportation costs and safety concerns as barriers to accessing care. The solutions to these barriers should involve efforts from both healthcare policymakers and patients. Policymakers should consider subsidising transportation and ensuring safety in the community, while patients should be empowered through education and support to navigate the healthcare system more effectively either through locating their nearest healthcare facility or applying for assistive devices. Addressing these barriers requires a multi-faceted approach that includes systemic changes and active community participation.

Delay 3: Receiving Care

A total of five barriers delayed access to receiving care. The shortage of CWC providers, especially PNs, was a significant barrier. At primary-level facilities, most chronic wound patients were initially treated by nursing staff, mainly staff nurses and ENAs. However, only PNs are qualified to independently manage CWC, highlighting a critical gap in human resources (153). Expanding the workforce by deploying more PNs to primary care clinics could allow these facilities

to manage chronic wounds more effectively, potentially reducing the burden on secondary and tertiary hospitals. A systematic review reported that nurse-led wound care initiatives can lead to increased patient satisfaction and improved healing outcomes (5). Furthermore, the establishment of independently run CWC clinics staffed by PNs has been successful in various international contexts, demonstrating that with appropriate training and support, PNs can manage these cases effectively (154). Implementing a similar model in areas such as Khayelitsha could improve access to care and address the gaps in wound management currently faced by patients. A short-term measure would be to assess whether facilities can hire already qualified nurses to fill current gaps. If there is budgetary capacity and available human resources in the system, deploying existing PNs, rather than waiting for new graduates, could rapidly enhance the quality and continuity of CWC. It is important to note that if more PNs were available, more examination and wound dressing rooms would be needed. Overall, capacity building is essential and should encompass the expansion of clinic facilities, the recruitment of more nurses and doctors, and the provision of adequate medical supplies.

Furthermore, a lack of utilisation of treatment and referral protocols contributed to delays and inconsistencies in care. Despite the availability of South African guidelines such as PACK guidelines, PHC STGs, and the Hospital Level (Adult) STGs and EML guidelines, many providers were not using them (82,84,85). From this study, the suggested reasons for lack of adherence included poor communication between levels of care, lack of guideline training, staff shortages causing overburdened providers to not have the time to familiarise themselves with guidelines, and stock shortages often making adherence to guidelines impractical. The reliance on non-standardised practices is concerning. Delayed care due to non-utilisation of guidelines risks worsening patient outcomes, leading to an increased burden on the health system. Additionally, resources wasted from incorrect treatments lead to further delays and unnecessary healthcare expenditure.

This study further demonstrated that stock shortages were prevalent, with many facilities unable to provide the specialised dressings recommended by secondary and tertiary facilities. This problem was exacerbated by the fact that clerks, rather than clinical staff, are responsible for ordering stock. While it is not uncommon for non-clinical staff to manage stock, it raises questions about whether they are adequately trained to understand the specific requirements of wound care. Stock ordering should be based on clinical guidelines to ensure the correct types and quantities of products are available at each level of care (155).

Difficulties in communication between levels of care were highlighted as a related obstacle. Tertiary facilities emphasised the importance of clear and detailed treatment instructions that were often disregarded by primary-level facilities. This was countered by clinics reporting that higher-level facilities were prescribing products that were not available at their level either due to lack of

allocation or poor stock management. This breakdown in communication not only resulted in delays but also created a frustrating loop of patient dissatisfaction and inadequate care, as patients were sent back and forth without receiving the necessary treatment.

An enabling factor in improving communication was the availability and utilisation of mobile referral applications, such as Vula, which streamlined and standardised communication between different levels of care (124). This facilitated communication by enabling healthcare providers to share images of wounds and discuss directly with specialists, significantly enhancing the efficiency and accuracy of referrals and treatment plans (124). To note, this excluded referrals to tertiary level as this was only possible telephonically. Despite this technological intervention, the broader systemic challenges need to be addressed holistically.

Addressing these issues requires targeted interventions including training workshops to disseminate treatment and referral guidelines, stock allocation that aligns with wound care guidelines, robust two-way communication systems between all levels of care, and importantly, expanding the nursing workforce (155,156). These steps can improve care quality, reduce delays, and enhance patient outcomes.

Delay 4: Remaining in Care

All nine barriers led to delays in remaining in care. A key barrier that prevented patients from remaining in care was lengthy waiting times at healthcare facilities. Effective CWC demands frequent interactions with the health system. Chronic wound care is inherently time-consuming for both the patient and health system requiring wound assessments every two to three days (14). In this study, an outpatient visit lasted between two to six hours on average. Time spent at healthcare facilities was divided between waiting outside to enter the facility, waiting in the main queue to open a folder, waiting for a healthcare provider, and waiting to collect medication at the pharmacy. The actual time spent performing CWC was minimal. The negative impact of long waiting times was demonstrated by poor patient retention as patients exhausted their sick leave and could not afford to miss work to attend the clinic for a whole day.

To mitigate this barrier, clinics used innovative interventions to reduce on-site clinic visits and waiting times. These methods included fast-tracking patients and expanding home-based services. Some facilities adopted a system where patients' folders were kept separate, allowing them to be pulled from the queue at the start of the day. This approach has been used to improve patient flow and reduce waiting times in overcrowded clinics. The Fast Queue Strategy, introduced in South Africa in 2001, aimed to reduce waiting times at primary healthcare facilities for adults with chronic conditions, elderly patients, and children (157). Eligibility for this system required prior evaluation at a clinic or hospital. An assessment of its effectiveness was conducted in primary healthcare facilities within the eThekwini Municipality, KwaZulu-Natal (157). Findings

revealed a mix of positive and negative feedback from users, contingent upon the system's effectiveness. Facilities that demonstrated higher user satisfaction typically had sufficient staffing levels and adequate floor space (157). This highlighted how the strategy's efficacy relied on the availability of resources. This implies that at healthcare facilities with more resources, such as providers and adequate infrastructure, the fast-track system could potentially work better. However, this does not diminish the potential benefits that it could have in resource-constrained facilities and should be considered a viable solution (157).

Additionally, another innovative intervention to reduce on-site clinic visits and waiting times was the provision of home-based carers. Both providers and patients suggested this as a viable solution to decrease on-site appointments. Home-based CWC offers significant benefits in LMICs by improving accessibility, reducing costs, and enhancing patient outcomes. It eliminates the need for frequent clinic visits, addressing barriers like transportation and financial constraints. For instance, home-based care can lead to significant cost savings for both patients and health systems by reducing the need for frequent clinic visits and minimising transportation costs and lost wages associated with seeking care (2,158). In South Africa, while home-based care programmes exist for chronic diseases, CWC has not yet been incorporated, primarily due to resource constraints and the complexity of wound management (159). According to South African regulations, only PNs are authorised to perform CWC, which presents challenges in implementing this model as there is already a shortage of PNs (78). Task shifting could be a solution to this challenge (160). This involves training all cadres of nurses, or community health workers to provide specific wound care tasks under the supervision of PNs. An example of successful task shifting in HIV and TB management is highlighted by the WHO, which has supported task shifting for trained lay health workers to provide antiretroviral therapy (ART) and TB directly observed treatment (DOT) (160). Studies in sub-Saharan Africa have demonstrated that these strategies improve access to care without compromising treatment outcomes (160). Additionally, by decreasing waiting times at healthcare facilities, delays in seeking, reaching, receiving, and remaining in care could be alleviated which is especially encouraging.

It is suggested that health education can also play a key role in patients remaining in care. During this study patients reported not being provided with basic information regarding their diagnosis or treatment plan, which limited their ability to participate actively in their wound care. This information gap has been shown to foster feelings of fear, denial, and distrust toward the health system, ultimately increasing the risk of patients defaulting on treatment (161). While healthcare providers state that they strive to educate patients within constrained timeframes, patients observe that overburdened facilities and busy providers hinder communication. Both patients and healthcare providers agree that increased staffing could enhance the quality of interactions, allowing more time for patient education, long-term treatment planning, and potentially improving treatment adherence. Studies indicate that poor communication between healthcare providers

and a lack of patient education contribute to treatment delays and non-compliance in chronic care management (162). By strengthening communication pathways between healthcare facilities and ensuring that patients receive consistent, clear information about their care plan, health systems could better empower patients to manage their health more effectively (163). This, in turn, has the potential to improve adherence to and retention of CWC, ultimately benefiting patients, healthcare providers, and healthcare facilities. It is important to note that safety concerns impact not only initial access to care, but even more so the ability to remain in care, particularly when patients are required to return for multiple follow-up visits. Addressing safety concerns can therefore help to reduce delays related to remaining in care.

During this study, it became evident that by addressing potential obstacles during every clinic visit, it fostered a supportive environment that encouraged consistent patient follow-up. This approach is particularly critical for managing chronic conditions like chronic wounds, where continuity of care and patient empowerment are essential for achieving optimal healing outcomes. Using the Four Delay framework, each delay shows multiple barriers as well as facilitators to accessing CWC (see Figures 7 and 8).

Figure 7: Barriers to accessing chronic wound care using the Four Delays framework

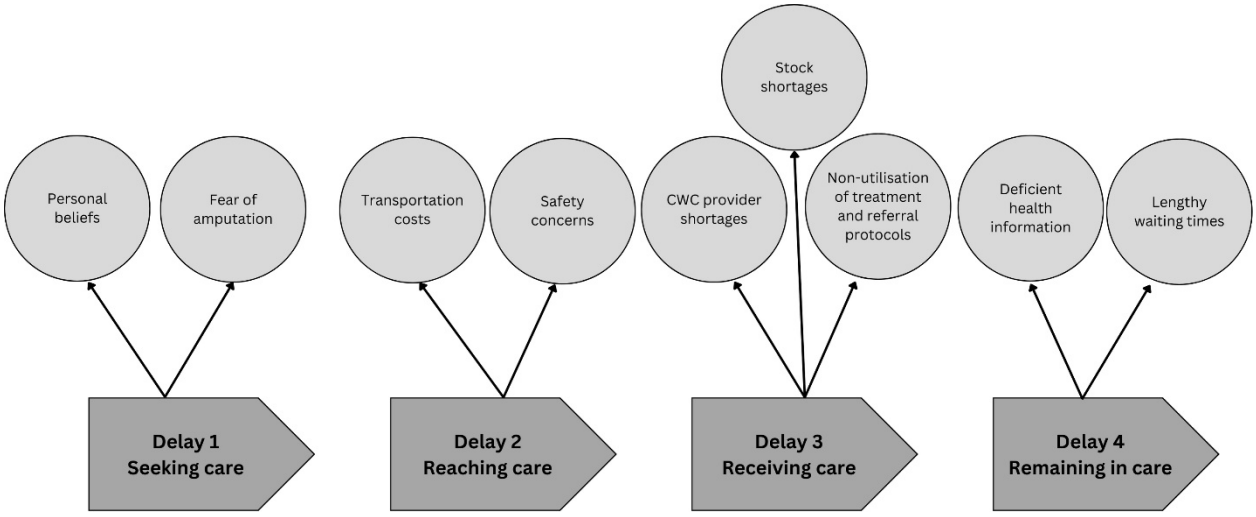
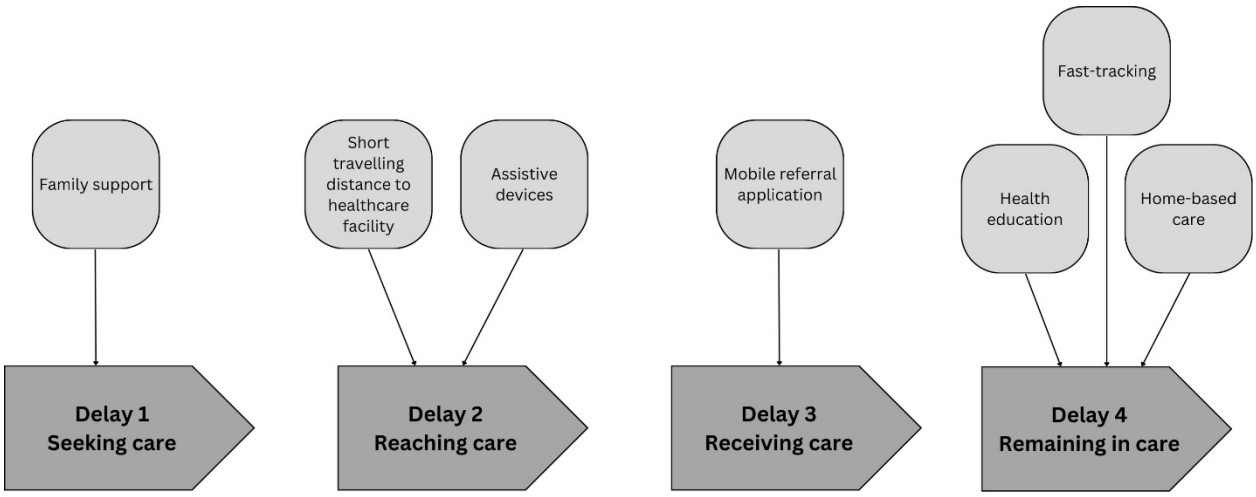


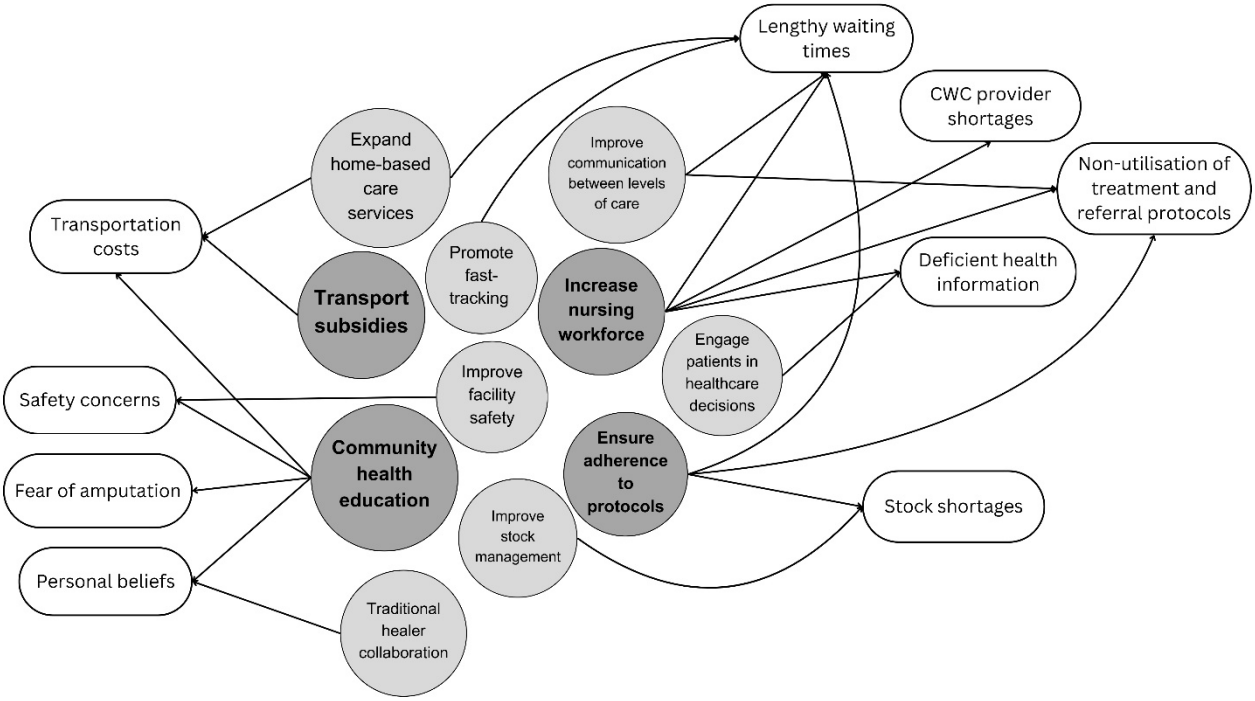
Figure 8: Facilitators to accessing chronic wound care using the Four Delays framework



Recommendations

The findings reveal that barriers to CWC span across multiple delays and require a holistic approach to ensure effective and sustainable solutions. This study offers a total of 11 recommendations to address these barriers. For some barriers, there is more than one suggested solution and some influence multiple barriers and therefore delays (see Figure 9).

Figure 9: Recommendations to address barriers to accessing chronic wound care



This study suggests the following four key recommendations that could potentially address the most barriers and positively influence all delays in the Four Delays framework.

Community Health Education Campaigns

Hosting health education campaigns in the community could target barriers such as personal beliefs and fear of amputation. The goal would be to address myths, stigma, and misunderstandings that deter healthcare engagement. Actionable steps include developing tailored health education initiatives focused on CWC while addressing cultural and religious concerns. Collaborating with traditional, religious, and community leaders is essential to disseminate accurate health information and challenge harmful myths. Additionally, having culturally sensitive, open discussions with diverse population groups can help build trust and bridge understanding gaps. This approach could not only strengthen trust in the healthcare system but also promote timely health-seeking behaviour, reducing delays in both seeking and remaining in care. This recommendation would require many resources and time to execute, however, it could have a lasting impact not only on CWC, but access to care for many other healthcare conditions.

Transport Subsidies

Policies should be updated to support transportation subsidies for patients to reach healthcare facilities. This could address financial and logistical barriers associated with transportation costs. Actionable steps involve introducing transportation subsidies or providing free transportation for patients requiring follow-up wound care. Priority could be given to individuals with disabilities or those living in remote areas far from healthcare facilities. Such an intervention has the potential to significantly reduce delays in reaching care while also encouraging patients to seek and remain engaged with healthcare services. This suggestion is inherently costly, but it could improve the lives of these individuals in a substantial way.

Increasing Nursing Workforce

Increasing the nursing workforce is a long-term strategy that could yield substantial benefits in improving access to care. However, its implementation presents significant challenges as the recruitment, training, and deployment of new nurses require sustained investment in education, infrastructure, and workforce planning. Additionally, establishing nurse-led chronic wound clinics would necessitate policy changes, resource allocation, and ongoing professional development to ensure that nurses can effectively diagnose, manage, and refer patients according to guidelines. Beyond financial constraints, the time required to train new nurses presents a considerable obstacle, as a PN’s training typically takes a minimum of four years (79).

Despite these challenges, the long-term impact of increasing the nursing workforce could be transformative. A higher nurse-to-patient ratio would not only reduce patient waiting times and improve adherence to treatment protocols but also enhance health education efforts, empowering patients with chronic wounds to manage their conditions more effectively. Furthermore, having more nurses available at primary-level facilities could help prevent complications, reducing the burden on secondary and tertiary facilities. While this intervention demands considerable time and financial investment, its potential to create sustainable improvements in CWC access makes it one of the most impactful recommendations.

Ensure Adherence to Treatment and Referral Protocols

Improving adherence to standardised treatment and referral protocols is key to enhancing the consistency and quality of care, strengthening stock management, and improving communication across different levels of care. Actionable steps involve disseminating the latest protocols and providing comprehensive training for healthcare providers at all levels. Adherence should be monitored through regular quality improvement programmes to ensure consistent application. Stock management should be overseen by trained personnel using current wound care guidelines tailored to each level of care. Promoting two-way communication is essential for effective coordination and feedback between primary, secondary, and tertiary facilities, with opportunities to integrate technological solutions such as mobile referral applications. These interventions could improve facility-level efficiency, reducing delays in receiving care and enhancing the quality and continuity of care, which could decrease delays in remaining in care. Due to already existing mobile referral applications, such as Vula, and the 2021 Western Cape Wound Care Guidelines, expanding the use and enforcing adherence to guidelines could be one of the easier solutions to put in place.

These recommendations were prioritised based on their ability to address multiple overlapping barriers. Each recommendation is actionable and scalable, with the potential to bring lasting improvements to CWC in the Khayelitsha health district.

Strengths and Limitations

To the best of our knowledge, this study is the first to identify barriers to accessing CWC in South Africa. Although limited to the Khayelitsha health district, this research addresses systemic challenges that delay CWC that are common nationwide and applicable in other LMICs. However, this study primarily included individuals who successfully accessed care, thereby missing perspectives from those who were unable to obtain care. This limits insights into the barriers faced by individuals who remain outside the health system. Another limitation of this study was that interviews were restricted to only patients who were able to speak isiXhosa, Afrikaans, or English. As a result, individuals who did not speak any of these languages may have been inadvertently

excluded. In this regard, we acknowledge language as a potential barrier to participation in this study, and more broadly, as a barrier to accessing care. Patients who do not speak the dominant local languages may experience challenges in navigating the healthcare system, understanding medical instructions, and effectively communicating their needs.

CHAPTER 6 – CONCLUSION

This mixed methods study mapped existing CWC services, resources, and referral pathways available at each level of care in the Khayelitsha health district. The Four Delays framework was used to identify nine overlapping barriers that led to delays in seeking, reaching, receiving, and remaining in care. Personal beliefs, together with the fear of amputation, were highlighted as deterrents to seeking timely care. Transportation costs and safety concerns emerged as significant barriers to reaching care. Chronic wound care provider and stock shortages, along with non-utilisation of treatment and referral protocols, were identified as systemic obstacles that further delayed receiving care. Lengthy waiting times at healthcare facilities and deficient health information contributed to poor patient retention.

This study demonstrated the complexity of CWC pathways, shaped by available services, resources, and referral systems alongside overlapping barriers and facilitators. This highlighted the need for an approach that addresses barriers holistically rather than in isolation. Positively, facilitators such as family support, shorter travel distances, mobile referral applications, and assistive devices enabled access to CWC. Similarly, innovative interventions including, fast-tracking and home-based care further improved access to care.

This research fills a gap in understanding CWC access in resource-constrained settings, particularly in South Africa. It highlights the interconnected nature of barriers, demonstrating the need for an integrated approach. The study's use of the Four Delays framework in a CWC context offers a novel perspective, providing a foundation for future research and policy development. Furthermore, by identifying practical facilitators and innovative interventions, the research offers actionable insights for improving patient outcomes and alleviating the burden on the healthcare system.

Future research should explore ways to effectively collaborate with traditional healers to address cultural and religious barriers. Additionally, task shifting initiatives should be examined to evaluate the possibility of training community health workers in CWC. Lastly, extending similar research to other districts in South Africa could help identify region-specific barriers and facilitators, potentially enhancing the generalisability of findings.

Addressing CWC barriers holistically requires collaboration between patients, healthcare providers, policymakers, and community leaders. Interventions should prioritise community health education campaigns, policy changes to support transport subsidies, increasing the nursing workforce, and enforcing adherence to standardised treatment and referral protocols. By doing so, health systems can better meet the needs of individuals with chronic wounds, ultimately improving their quality of life and reducing the burden on the health system. This research provides a strong foundation for targeted interventions to enhance access to CWC in Khayelitsha

and similar settings. It calls for continued investment in understanding and addressing barriers to care, with the goal of achieving access to healthcare for all.

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APPENDICES

Appendix A: Data Collection Tool (Facility Survey)

What is a wound?

For the purpose of this study a wound is defined as a breakdown in the protective function of the skin; the loss of continuity of epithelium.

A chronic wound will be defined as:

A "non-healing wound" or a wound that does not complete the reparative process within "three months".

Chronic wound care is NOT:

- Acute wound care (any wound < 3 months)
- Removal of sutures
- Post-operative wound dressings
- Removal of casts for fractures

The most common types of chronic wounds include:

- Diabetes-related
- Vascular ulcers
- Pressure ulcers

1. GENERAL QUESTIONS REGARDING HEALTH FACILITY

1.1. Name of health care facility:	1.2. Date of data collection (dd/mm/yyyy):
1.3. Persons consulted to complete this survey (check all that apply): ☐ Pharmacist ☐ Intern ☐ Community Service Doctor ☐ Medical Officer ☐ Specialist ☐ Clinical/Medical Manager ☐ Staff Nurse ☐ Registered Nurse ☐ Matron	☐ Other:_____
1.4.a. Does this facility offer acute wound care?	☐ Yes ☐ No If No, where are patients referred to? _____
1.4.b. Does this facility offer chronic wound care?	☐ Yes ☐ No If No, where are patients referred to? _____
1.5. When can wound care be accessed?	☐ 24/7 ☐ Routine clinic hours (i.e. M-F 8-4) ☐ Specific wound care times only
1.6. What types of chronic wounds are treated at this facility? (check all that apply)	☐ Diabetes-related ☐ Vascular ulcers ☐ Pressure ulcers ☐ Post-op infection ☐ Malignancy-related ☐ Other:_____
1.7. How do chronic wound patients reach this facility? (check all that apply)	☐ Walking ☐ Public transport ☐ Private transport ☐ E-hailing (Uber/Taxify) ☐ Hospital transportation ☐ Ambulance ☐ NGO transport services ☐ Other:_____

2. SERVICES OFFERED BY HEALTH FACILITY

2.1. What chronic wound care services are available? (circle available services)

☐ Pre-packed wound care packages	☐ Educational services (wound care training for patients and caregivers)
☐ Home-based caregivers or nurses doing home visits	☐ Digital platforms to remind patients of appointments (sms)
☐ Designated clinic queue for chronic wound care visits	☐ Prevention programmes (diabetic foot ulcers)
☐ Other:	

3. RESOURCES AVAILABLE AT HEALTH FACILITY

3.1. Medical staff

3.1.1.1. If a patient has a non-healing wound that has never been assessed at any health facility, who would assess this patient first?

☐ Student nurse	☐ Staff nurse	☐ Registered nurse
☐ Intern doctor	☐ Community Service doctor	☐ Medical Officer
☐ Surgical registrar	☐ Specialist (surgeon)	☐ Nurse with wound care qualification

3.1.1.2. Who would dress this wound referred to in 3.1.1.1?

☐ Student nurse	☐ Staff nurse	☐ Registered nurse
☐ Intern doctor	☐ Community Service doctor	☐ Medical Officer
☐ Surgical registrar	☐ Specialist (surgeon)	☐ Nurse with wound care qualification

3.1.1.3. For patients undergoing ongoing care for wounds, who assesses the wound routinely at each visit?

☐ Student nurse	☐ Staff nurse	☐ Registered nurse
☐ Intern doctor	☐ Community Service doctor	☐ Medical Officer
☐ Surgical registrar	☐ Specialist (surgeon)	☐ Nurse with wound care qualification

3.1.1.4. Who assesses the wound if the first provider thinks there is infection/non-healing/need for up referral?"

☐ Nobody else	☐ Staff nurse	☐ Registered nurse
☐ Intern doctor	☐ Community Service doctor	☐ Medical Officer
☐ Surgical registrar	☐ Specialist (surgeon)	☐ Nurse with wound care qualification

☐ Other: _____

3.1.2. Is there a designated staff member for chronic wound dressings each day?	☐ Yes ☐ No ☐ I don't know
3.1.3.1. Which proportion of the medical staff caring for chronic wounds have extra wound care qualifications/training?	☐ None ☐ Some ☐ All
3.1.3.2. Does this facility offer wound care training for medical staff?	☐ Yes ☐ No ☐ I don't know
3.1.3.3. If Yes, how frequently does training occur?	☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Other:

3.2. Dressings and supplies

3.2.1. Please select products that are never available at this facility for chronic wounds:

☐ EMLA cream ☐ paraffin (jelonet) or petroleum gauze ☐ other non-adherent dressing ☐ hydrogel ☐ foam dressing

☐ acriflavine ☐ alginate dressing ☐ dry gauze ☐ cling bandage ☐ compression bandage ☐ 1-5% pure acetic acid

☐ povidone iodine 10% ☐ silver sulfadiazine (flamazine) ☐ medicinal honey ☐ absorbant dressing ☐ barrier film/paste

☐ hydrocolloid dressing ☐ hydrofiber dressing (aquacel) ☐ sodium chloride 0.9% ☐ chlorhexidine ☐ blades ☐ micropore tape
☐ Other:

3.3. Facilities

3.3.1. Where are chronic wound care patients seen for consultation? ☐ Designated consultation room for wounds ☐ Regular OPD consultation room ☐ Treatment room ☐ Other:
3.3.2. Where are wounds dressed/treated? ☐ Designated treatment room for wounds ☐ Regular OPD treatment room ☐ Regular OPD consultation room ☐ Designated consultation room for wounds ☐ Emergency room ☐ Passageway ☐ Other:
3.4. Protocols
3.4.1. Does this facility have a standardized chronic wound care protocol/guideline? ☐ Yes ☐ No ☐ I don't know If Yes, name:
3.4.2. If Yes, are they being followed? ☐ Yes ☐ No ☐ I don't know

4. REFERRAL PATHWAYS	
4.1. Where are most patients up-referred to? (tick all that apply)	☐ Private hospital ☐ Khayelitsha District Hospital Emergency department ☐ Khayelitsha District Hospital Surgical OPD ☐ Tygerberg Hospital Trauma department ☐ Tygerberg Hospital Plastics OPD ☐ Other:
4.2. Does this facility have an up-referral protocol for chronic wounds?	☐ Yes ☐ No ☐ I don't know
4.3. Up-referring a patient involves (check all that apply):	☐ Phoning the on call nurse/doctor at the relevant facility ☐ Referring the paitient through an MHealth app ☐ Emailing or faxing a referral then waiting for a date/response ☐ Sending with a referral letter only (no prior discussion)

5. AVAILABLE DATA ON WOUND CARE AT FACILITY	
5.1. Does this facility keep a record of wounds treated?	☐ Yes ☐ No ☐ I don't know If Yes select all that apply: ☐ Monthly totals only (no patient details) ☐ Wound types ☐ Consumables used
5.2. How many outpatient visits for wound care are there per month?	_____ (☐ Estimated / ☐ From record book)
5.3. How many outpatient visits are there in total at this facility clinic per month?	_____ (☐ Estimated / ☐ From record book)
5.4. Does this facility keep a record of chronic wound care patients and where they are referred to and from?	☐ Yes ☐ No ☐ I don't know
5.5. What is the number of chronic wound care patients that this facility up-refers on a monthly basis?	_____ (☐ Estimated / ☐ From record book)

Appendix B: Information Sheet for Medical Staff Participating in Survey

INFORMATION SHEET FOR MEDICAL STAFF PARTICIPATING IN SURVEY

FULL TITLE OF THIS STUDY
IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Principal Investigator: Prof Kathryn Chu

You are invited to participate in this research to assist with gathering knowledge regarding the existing services, resources and referral pathways for chronic wound care at each level of care and identifying barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district. You have been selected due to your experience and knowledge regarding chronic wound care in the facility where you work.You are free to accept or to refuse taking part in this study. Please listen to or read this information sheet before making a decision. If you decide to take part in this research, you will be asked to sign the attached consent form to show that you want to take part.

WHY IS THIS STUDY BEING DONE?

This study is being done in order to map existing services, resources and referral pathways for chronic wound care at each level of care and identify barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district.

This study will be done in three phases. The survey is part of phase 1.
The survey will be conducted at all ten primary health facilities in the Khayelitsha sub-district, the Khayelitsha District Hospital (KDH) surgical out-patient department (SOPD) and the Tygerberg Hospital (TBH) plastic surgery clinic. Phase 2 will be conducting focus groups with medical staff at three selected primary health facilities, KDH and TBH. Lastly, phase 3 will include conducting individual semi-structured interviews with persons who have chronic wounds living in the Khayelitsha sub-district.

Chronic wounds are preventable and curable within a robust health care system. This study will attempt to identify barriers to accessing care for chronic wounds in the Khayelitsha sub-district. Hopefully through your participation this study will be able to provide solutions to overcome barriers identified and improve on the existing services, resources and referral pathways. The knowledge gained from this study may serve to support future studies that intend to design an intervention to further strengthen the health care system. You will not gain any direct benefits from participating.

WHAT WILL I BE ASKED TO DO WHEN I AGREE

TO PARTICIPATE IN THIS STUDY?

You will be asked a standard set of questions by the primary investigator. The questions will be about the existing services, resources and referral pathways regarding chronic wound care at the facility where you work. If you are unable to answer certain questions, you will be asked to identify another medical staff member who might be able to answer those specific questions.

WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

There is minimal risk associated with your participation in this study. You can express any concerns you may have, or refuse to reply to questions you don't want to answer. You do not need to give any information that you do not wish to discuss. You can stop the survey at any time without any repercussions.

HOW WILL MY INFORMATION BE PROTECTED?

Your identity will not be revealed in the results of this study. The information about your name will only be accessible to the primary investigator who may need to know who you are if there is a need to deal with any problem. The consent form and information you give will be kept in a secure place and strict confidentiality will be maintained. In any publication, no personal information will be used. The informed consent and survey will be completed in a confidential space.

WHAT WILL HAPPEN AFTER THE RESEARCH IS COMPLETE?

The methodology and findings of this study will be written for scientific presentation and disseminated through peer-review publication. Importantly, the results and the potential impact on the health system will be presented to all local stakeholders at each of the relevant health facilities by December 2021.

WHO APPROVED THIS STUDY?

Ethics approvals was granted by the Health Research Ethics Committee of the University of Cape Town (please see attached documentation).

Permission has been obtained from the Western Cape Provincial Department of Health and the relevant medical managers and head of departments at each primary health facility, KDH and TBH (please see attached documentation).

WHAT SHOULD I DO IF I WANT TO STOP TAKING PART IN THIS STUDY?

Taking part in this research study is up to you. The entire survey should take less than 30 minutes. You can decide not to take part.

If later you change your mind and don't want to be part of the study, you can contact the primary investigator at any time.

If you have questions, concerns or complaints about the research, please call and speak to the researcher Prof Kathryn Chu.

Tel: 021 938 9442

Email: kathryn.chu@uct.ac.za

If you have concerns about the ethical conduct of thi study or any complaints, please contact:

The Human Research Ethics Committee at the University of Cape Town

G50

Old Main Building

Groote Schuur Hospital

Observatory, 7925

Tel: 021 650 1236

Email: hrec-enquiries@uct.ac.za

Thank you very much for your time.

Appendix C: Consent Form for Medical Staff Participating in Survey

INFORMED CONSENT FORM FOR MEDICAL STAFF PARTICIPATING IN SURVEY

PARTICIPANT NO: ☐☐☐☐☐ **INITIALS:** ☐☐☐ **DOB:** ☐☐-☐☐-☐☐☐☐ **(DD-MM-YYYY)**

FULL TITLE OF THIS STUDY

IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Statement of researcher or person obtaining consent:

I have explained the research to the study participant. I have also answered all questions about this research study to the best of my ability. I have included that the study participant can withdraw his/her consent at any time without any repercussions.

_____	_____	_____
Name of person obtaining consent	Date (dd/mm/yyyy)	Signature

Statement of Person Giving Informed Consent and Authorization:

I have read the information sheet or had it read for me. The purpose of the study has been explained to me, including what will be done and risks and possible benefits. I had the opportunity to ask questions and all my questions have been answered. I am aware that I have the right to withdraw my consent at any point.

All the above was explained to me in a language I understand and I had adequate time to consider my participation and discuss it with my family/ friends.

I will receive a copy of this information sheet and consent form.

I hereby voluntarily give my consent to take part in this research study and I agree to:
a) Assist with completing the survey as mentioned above and
b) Allow the information that I give to be used and shared as described above.

_____	_____	_____
Name of participant	Date (dd/mm/yyyy)	Signature

Participant who is unable to read or write:

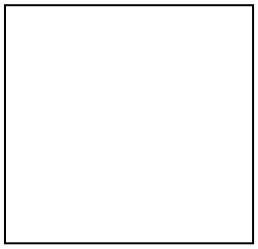
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are unable to read or write should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Witness _____

Signature of Witness _____ **Date** _____
(dd/mm/yyyy)

AND Right Thumb Print of Participant



Appendix D: Information Sheet for Providers Participating in Interviews

INFORMATION SHEET FOR MEDICAL STAFF PARTICIPATING IN FOCUS GROUP

FULL TITLE OF THIS STUDY
IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Principal Investigator: Prof Kathryn Chu

You are invited to participate in this research to assist with gathering knowledge regarding the existing services, resources and referral pathways for chronic wound care at each level of care and identifying barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district. You have been selected due to your experience and knowledge regarding chronic wound care in the facility where you work.

You are free to accept or to refuse taking part in this study. Please listen to or read this information sheet before making a decision. If you decide to take part in this research, you will be asked to sign the attached consent form to show that you want to take part.

WHY IS THIS STUDY BEING DONE?

This study is being done in order to map existing services, resources and referral pathways for chronic wound care at each level of care and identify barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district.

This study will be done in three phases. The focus group is part of phase 2.
A survey will be conducted at all ten primary health facilities in the Khayelitsha sub-district, the Khayelitsha District Hospital (KDH) surgical out-patient department (SOPD) and the Tygerberg Hospital (TBH) plastic surgery clinic. Phase 2 will be conducting focus groups with medical staff at three selected primary health facilities, KDH and TBH. Lastly, phase 3 will include conducting individual semi-structured interviews with persons who have chronic wounds living in the Khayelitsha sub-district.

Chronic wounds are preventable and curable within a robust health care system. This study will attempt to identify barriers to accessing care for chronic wounds in the Khayelitsha sub-district. Hopefully through your participation this study will be able to provide solutions to overcome barriers identified and improve on the existing services, resources and referral pathways. The knowledge gained from this study may serve to support future studies that intend to design an intervention to further strengthen the health care system. You will not gain any direct benefits from participating.

WHAT WILL I BE ASKED TO DO WHEN I AGREE TO PARTICIPATE IN THIS STUDY?

You will be asked to participate in a focus group consisting of a minimum of four other medical staff members, also experienced in chronic wound care at their facilities. The topics that will be discussed will centre around barriers to accessing care for persons with chronic wounds in the Khayelitsha sub-district. The focus group will be conducted by the primary investigator. The interviews will be recorded for the purpose of transcription and data analysis. Each focus group will last approximately one hour and will be conducted either in a private area in the Khayelitsha Community Centre or the Department of Global Surgery conference room at the Tygerberg medical campus.

WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

There is minimal risk associated with your participation in the study. You can express any concerns you may have, or refuse to reply to questions you don't want to answer. You do not need to give any information that you do not wish to discuss. You can stop the focus group at any time without any repercussions.

You may experience some emotional distress in the course of the focus group. Should this occur, the interview will stop and you will be asked if you would like to take a break and continue or if you want to stop all together. Should you wish to stop, the interview will be terminated and all the data from that interview will be disregarded. Should you display significant emotional distress, provision will be made for referral to a social worker or counsellor at a relevant facility.

Each participant will be given a R150 shopping voucher from Shoprite/Checkers as a token of appreciation after completing the focus group. Transportation costs will be reimbursed up to a maximum of R200 per participant.

HOW WILL MY INFORMATION BE PROTECTED?

Your identity will not be revealed in the results of this study. The information about your name will only be accessible to the primary investigator who may need to know who you are if there is a need to deal with any problem. The consent form and information you give will be kept in a secure place and strict confidentiality will be maintained. In any publication, no personal information will be used. The informed consent and interview will be done in a confidential space.

WHAT WILL HAPPEN AFTER THE RESEARCH IS COMPLETE?

The methodology and findings of this study will be written for scientific presentation and disseminated through peer-review publication. Importantly, the results and the potential impact on the health system will be presented to all local stakeholders at each of the relevant health facilities by December 2021.

WHO APPROVED THIS STUDY?

Ethics approvals was granted by the Health Research Ethics Committee of the University of Cape Town (please see attached documentation).

Permission has been obtained from the Western Cape Provincial Department of Health and the relevant medical managers and head of departments at each primary health facility, KDH and TBH (please see attached documentation).

WHAT SHOULD I DO IF I WANT TO STOP TAKING PART IN THIS STUDY?

Taking part in this research study is up to you.
If later you change your mind and don't want to be part of the study, you can contact the primary investigator at any time.
If you have questions, concerns or complaints about the research, please call and speak to the researcher Prof Kathryn Chu.
Tel: 021 938 9442
Email: kathryn.chu@uct.ac.za

If you have concerns about the ethical conduct of the study or any complaints, please contact:
The Human Research Ethics Committee at the University of Cape Town
G50
Old Main Building
Groote Schuur Hospital
Observatory, 7925
Tel: 021 650 1236

Email: hrec-enquiries@uct.ac.za

Thank you very much for your time.

Appendix E: Consent Form for Providers Participating in Interviews

INFORMED CONSENT FORM FOR MEDICAL STAFF PARTICIPATING IN FOCUS GROUP

PARTICIPANT NO: ☐☐☐☐☐ **INITIALS:** ☐☐☐ **DOB:** ☐☐-☐☐-☐☐☐☐ **(DD-MM-YYYY)**

FULL TITLE OF THIS STUDY

IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Statement of researcher or person obtaining consent:

I have explained the research to the study participant. I have also answered all questions about this research study to the best of my ability. I have included that the study participant can withdraw his/her consent at any time without any repercussions.

_____	_____	_____
Name of person obtaining consent	Date (dd/mm/yyyy)	Signature

Statement of Person Giving Informed Consent and Authorization:

I have read the information sheet or had it read for me. The purpose of the study has been explained to me, including what will be done and risks and possible benefits. I had the opportunity to ask questions and all my questions have been answered. I am aware that I have the right to withdraw my consent at any point.

All the above was explained to me in a language I understand and I had adequate time to consider my participation and discuss it with my family/ friends.

I will receive a copy of this information sheet and consent form.

I hereby voluntarily give my consent to take part in this research study and I agree:
a) To be interviewed as part of a focus group
b) For the interview to be audio-recorded
c) For the information that I give to be used and shared as described above.

_____	_____	_____
Name of participant	Date (dd/mm/yyyy)	Signature

Participant who is unable to read or write:

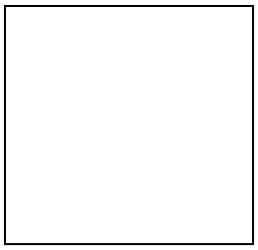
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are unable to read or write should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Witness _____

Signature of Witness _____ **Date** _____
(dd/mm/yyyy)

AND Right Thumb Print of Participant



Appendix F: Information Sheet for Patients Participating in Interviews

INFORMATION SHEET FOR INDIVIDUAL SEMI-STRUCTURED INTERVIEW WITH A PERSON WITH A CHRONIC WOUND

FULL TITLE OF THIS STUDY
IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Principal Investigator: Prof Kathryn Chu

You are invited to participate in this research to assist with gathering knowledge regarding the existing services, resources and referral pathways for chronic wound care at each level of care and identifying barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district. You have been selected due to the inclusion criteria of the study being a person currently being treated for a chronic wound for more than 6 months in the Khayelitsha sub-district.

You are free to accept or to refuse taking part in this study. Please listen to or read this information sheet before making a decision. If you decide to take part in this research, you will be asked to sign the attached consent form to show that you want to take part.

WHY IS THIS STUDY BEING DONE?
This study is being done in order to map existing services, resources and referral pathways for chronic wound care at each level of care and identify barriers to accessing care for persons with chronic wounds living in the Khayelitsha sub-district.

This study will be done in three phases. The individual semi-structured interview is part of phase 3. A survey will be conducted at all ten primary health facilities in the Khayelitsha sub-district, the Khayelitsha District Hospital (KDH) surgical out-patient department (SOPD) and the Tygerberg Hospital (TBH) plastic surgery clinic. Phase 2 will be conducting focus groups with medical staff at three selected primary health facilities, KDH and TBH. Lastly, phase 3 will include conducting individual semi-structured interviews with persons who have chronic wounds living in the Khayelitsha sub-district.

Chronic wounds are preventable and curable within a robust health care system. This study will attempt to identify barriers to accessing care for chronic wounds in the Khayelitsha sub-district. Hopefully through your participation this study will be able to provide solutions to overcome barriers identified and improve on the existing services, resources and referral pathways. The knowledge gained from this study may serve to support future studies that intend to design an intervention to further strengthen the health care system. You will not gain any direct benefits from participating.

WHAT WILL I BE ASKED TO DO WHEN I AGREE TO PARTICIPATE IN THIS STUDY?

You will be asked to participate in an individual semi-structured interview. The topics that will be discussed will centre around your opinions and feelings with regards to your chronic wound care experience in the Khayelitsha health sub-district. The interview will be conducted by the primary investigator, with assistance from a translator fluent in both English and isiXhosa. The interviews will be recorded for the purpose of transcription/translation and data analysis. Each interview will last approximately one hour and will be conducted in a private area at the Khayelitsha Community Centre.

WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

There is minimal risk associated with your participation in the study. You can express any concerns you may have, or refuse to reply to questions you don't want to answer. You do not need to give any information that you do not wish to discuss. You can stop the interview at any time. Participation is voluntary. Declining to participate, pulling out of the interview mid-way or completing the interview will not influence your access to health care services or care rendered at your health care facility.

You may experience some emotional distress in the course of the focus group. Should this occur, the interview will stop and you will be asked if you would like to take a break and continue or if you want to stop all together. Should you wish to stop, the interview will be terminated and all the data from that interview will be disregarded. Should you display significant emotional distress, provision will be made for referral to a social worker or counsellor at a relevant facility.

Each participant will be given a R150 shopping voucher from Shoprite/Checkers as a token of appreciation after completing the focus group. Transportation costs will be reimbursed up to a maximum of R200 per participant.

HOW WILL MY INFORMATION BE PROTECTED?

Your identity will not be revealed in the results of this study. The information about your name will only be accessible to the primary investigator who may need to know who you are if there is a need to deal with any problem. The consent form and information you give will be kept in a secure place and strict confidentiality will be maintained. In any publication, no personal information will be used. The informed consent and interview will be done in a confidential space.

WHAT WILL HAPPEN AFTER THE RESEARCH IS COMPLETE?

The methodology and findings of this study will be written for scientific presentation and disseminated through peer-review publication. Importantly, the results and the potential impact on the health system will be presented to all local stakeholders at each of the relevant health facilities by December 2021.

WHO APPROVED THIS STUDY?

Ethics approvals was granted by the Health Research Ethics Committee of the University of Cape Town (please see attached documentation).

Permission has been obtained from the Western Cape Provincial Department of Health and the relevant medical managers and head of departments at each primary health facility, KDH and TBH (please see attached documentation).

WHAT SHOULD I DO IF I WANT TO STOP TAKING PART IN THIS STUDY?

Taking part in this research study is up to you. You can decide not to take part.

If later you change your mind and don't want to be part of the study, you can contact the primary investigator at any time.

If you have questions, concerns or complaints about the research, please call and speak to the researcher Prof Kathryn Chu.
Tel: 021 938 9442
Email: kathryn.chu@uct.ac.za

If you have concerns about the ethical conduct of the study or any complaints, please contact:
The Human Research Ethics Committee at the University of Cape Town
G50
Old Main Building
Groote Schuur Hospital
Observatory, 7925
Tel: 021 650 1236

Email: hrec-enquiries@uct.ac.za

Thank you very much for your time.

Appendix G: Consent Form for Patients Participating in Interviews

INFORMED CONSENT FORM FOR INDIVIDUAL SEMI-STRUCTURED INTERVIEW WITH A PERSON WITH A CHRONIC WOUND

PARTICIPANT NO: ☐☐☐☐☐ **INITIALS:** ☐☐☐ **DOB:** ☐☐-☐☐-☐☐☐☐ **(DD-MM-YYYY)**

FULL TITLE OF THIS STUDY

IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A mixed methods study

Statement of researcher or person obtaining consent:

I have explained the research to the study participant. I have also answered all questions about this research study to the best of my ability. I have included that the study participant can withdraw his/her consent at any time without any repercussions.

_____	_____	_____
Name of person obtaining consent	Date (dd/mm/yyyy)	Signature

Statement of Person Giving Informed Consent and Authorization:

I have read the information sheet or had it read for me. The purpose of the study has been explained to me, including what will be done and risks and possible benefits. I had the opportunity to ask questions and all my questions have been answered. I am aware that I have the right to withdraw my consent at any point.

All the above was explained to me in a language I understand and I had adequate time to consider my participation and discuss it with my family/ friends. I will receive a copy of this information sheet and consent form.

I hereby voluntarily give my consent to take part in this research study and I agree:

a) That I am 18 years old or older
b) To be interviewed
c) For the interview to be audio-recorded
d) For the information that I give to be used and shared as described above.

_____	_____	_____
Name of participant	Date (dd/mm/yyyy)	Signature

Participant who is unable to read or write:

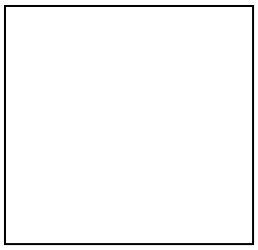
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are unable to read or write should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Witness _____

Signature of Witness _____ **Date** _____
(dd/mm/yyyy)

AND Right Thumb Print of Participant



Appendix H: Approval Documentation

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

06 October 2020

HREC REF: 484/2020

Dr J Githaiga
Division of Social & Behavioural Sciences
Room 3.49, Level 3, Falmouth Building -FHS
Email: jennifer.githaiga@uct.ac.za
Student: STFANR001@myuct.ac.za

Dear Dr Githaiga

PROJECT TITLE: IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A MIXED METHODS STUDY (MMED CANDIDATE: DR. A STOFBERG)

Thank you for your response letter addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 October 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Dr Anronel Stofberg will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30/10/22
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	8/11/2021

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	30 October 2021		
HREC REF Number	484/2020	Current Ethics Approval was granted until	30 Oct 2021
Protocol title	Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?		☐ Yes	X☐ No
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	N/A		
Principal Investigator	Dr Jennifer N. Githaiga		

HUMAN RESEARCH ETHICS COMMITTEE FHS016
08 NOV 2021
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Department / Office Internal Mail Address	School of Public Health and Family Medicine, Division of Social and Behavioural Sciences, FHS, Falmouth Building, Level 3 Room 3.49

1.1 Does this protocol receive US Federal funding?	☐ Yes	X☐ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submission@uct.ac.za)	☐ Yes	X☐ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	X☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7000,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3 710.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R6000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1 500,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 : N/A (student research)

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation for approval

FHS016 form

3. Protocol status (tick ✓)

☐	Open Enrolment
☐✓	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	34
Number of participants enrolled, since last HREC Progress report (continuing review)	34
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	**0**

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

6. Cumulative summary of participants

Total number of participants who provided consent	**34**
Number of participants determined to be ineligible (i.e. after screening)	2
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	34
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
The study has progressed well. The only notable delay was in obtaining Provincial approval for the study sites. However, once approval was received, data collection followed swiftly. The City of Cape Town approval was granted October 2020. Western Cape Provincial approval took five months but was granted in June 2021. Data analysis has been completed and currently the write-up phase of the study is in progress. Special considerations, with regards to the COVID-19 pandemic, did not lead to amendments of the approved HREC protocol. Most data collection was conducted in person according to HREC recommendations and Lockdown Level regulations. The only data collection that was performed telephonically was during a restricted period during level 4 implemented in June 2021 and was for the purpose of completing two surveys. Provisions for this were stated in the approved HREC protocol. Strict adherence to COVID-19 guidelines was maintained including symptom screening prior to interaction, wearing of personal protective equipment (masks), hand hygiene and social distancing practices. Most data collection was conducted outside, depending on the weather. Alternatively, interviews were held indoors with the windows open maintaining social distancing and wearing masks.

8. Protocol violations and exceptions (tick ✓ all that apply)

☐✓	No prior violations or exceptions have occurred since the original approval

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐ ✓	No Prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	✓☐ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	✓☐ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	✓☐ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Agency Name		Report attached	☐ Yes	☐ No	✓☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	✓☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	✓☐ No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
✓☐	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Deterioration of mental health is very common in patients with chronic wounds (1). Factors that influence the development of mood symptoms include wound duration, pain, and immobility (2). Low self-esteem and a negative perception of self is created through repeated episodes of embarrassment secondary to having a malodorous wound that leaks exudate or being physically disabled due to an amputation (3). In a 2003 Australian study, female participants with chronic wounds describe how they had to change their clothes in order to hide their wounds (4). In a study by Hopkins (2004), chronic lower limb wounds had a significant impact on patients' social lives, specifically due to the exudate and odour that it produced. Patients reported that they had difficulty controlling these troubling symptoms and feared reactions from their peers (5). Narrating experiences of wound care was mildly upsetting for some participants with chronic wounds. Once the participant appeared to become upset, the interviewer stopped and asked the participant if they would like to take a break. All of the participants requested to continue. During the debriefing sessions after the interviews, these participants explained that they felt a sense of relief after being able to express how drastic chronic wounds affect their lives. The distress protocol stated that if the participant should wish to stop, the interview would be terminated and all the data from that interview would be disregarded. Should a participant seem distressed, provision would be made for referral to a social worker or counsellor at the relevant facility.

References

1. Palfreyman SP. Assessing the impact of venous ulceration on quality of life. Nurs Times [Internet]. 2008;104(41):34–7. Available from: https://www.nursingtimes.net/clinical-archive/public-health-clinical-archive/assessing-the-impact-of-venous-ulceration-on-quality-of-life-14-10-2008/
2. Renner R, Erfurt-Berge C. Depression and quality of life in patients with chronic wounds: ways to measure their influence and their effect on daily life. Chronic Wound Care Manag Res. 2017;2017(4):143–51.
3. Chase SK, Whittemore R, Crosby N, Freney D, Howes P, Phillips TJ. Living with chronic venous leg ulcers: a descriptive study of knowledge and functional status. J Community Health Nurs. 2000;17(1):1–13.
4. Rich A, McLachlan L. How living with a leg ulcer affects people's daily life: a nurse-led study. J Wound Care. 2003;12(2):51–4.
5. Hopkins A. Disrupted lives: investigating coping strategies for non-healing leg ulcers. Br J Nurs. 2004;13(9):556–63.

13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes		✓☐ No	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	✓☐ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	30th October 2021

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30-10-23
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	

Note: Please email this form and supporting docu
hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	14th October 2022		
HREC REF Number	484/2020	Current Ethics Approval was granted until	30 Oct 2022
Protocol title	Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?		☐ Yes	☒ No
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	N/A		
Principal Investigator	Dr Jennifer N. Githaiga		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Department / Office Internal Mail Address	School of Public Health and Family Medicine, Division of Social and Behavioural Sciences, FHS, Falmouth Building, Level 3 Room 3.49

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submission@uct.ac.za)	☐ Yes	☒ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	☑
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7000,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3 710.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R6000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1 500,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation for approval

FHS016 form

3. Protocol status (tick ✓)

☐	Open Enrolment
☑	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	34
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	**0**

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

6. Cumulative summary of participants

Total number of participants who provided consent	**34**
Number of participants determined to be ineligible (i.e. after screening)	2
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	34
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
The study has progressed well. Data collection and analysis has been completed. The write-up of the literature review, methodology, and results are complete. The write-up of the discussion/conclusions, recommendations, and abstract are currently underway.

8. Protocol violations and exceptions (tick ✓ all that apply)

☑	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☑	No Prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	☒ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	☑ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	☑ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☑ Not applicable
		DSMB report attached	☐ Yes	☐ No	☑ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	☒ No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

If yes, please explain:

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
☑	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

Deterioration of mental health is common in patients with chronic wounds. Multiple studies have shown that depression is the most commonly reported psychological complaint in patients who suffer from chronic wounds (1–3). Factors associated with mood symptoms, such as depression and anxiety, include wound duration of ≥90 days, pain, odorous wounds, and decreased social support (4,5).

Narrating wound care experiences was mildly upsetting for some participants with chronic wounds. Once the participant appeared to become upset, the interviewer stopped and asked if the participant wanted to take a break. All of the participants requested to continue. During the post-interview debriefing sessions, these participants explained that they felt a sense of relief after being able to express how drastic chronic wounds affected their lives. The distress protocol stated that if a participant should wish to stop, the interview would be terminated immediately and all the data from that interview would be disregarded. Should a participant seem distressed, provision was made for referral to a counsellor at the relevant facility.

References:

1. Moffatt CJ, Franks PJ, Doherty DC, Smithdale R, Steptoe A. Psychological factors in leg ulceration: A case-control study. Br J Dermatol. 2009;161(4):750–6.
2. Kouris A, Armyra K, Christodoulou C, Sgontzou T, Karypidis D, Kontochristopoulos G, et al. Quality of life psychosocial characteristics in Greek patients with leg ulcers: A case control study. Int Wound J. 2016 Oct 1;13(5):744–7.
3. Fino P, Di Taranto G, Pierro A, Kacjulite J, Codolini L, Onesti MG, et al. Depression risk among patients with chronic wounds. Eur Rev Med Pharmacol Sci. 2019;23(10):4310–2.
4. Zhou K, Jia P. Depressive symptoms in patients with wounds: A cross-sectional study. Wound Repair Regen. 2016;24(6):1059–65.
5. Yan R, Strandlund K, Ci H, Huang Y, Zhang Y. Analysis of Factors Influencing Anxiety and Depression among Hospitalized Patients with Chronic Wounds. Adv Skin Wound Care. 2021;34(12):638–44.

13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes	☐ No	☑ Not Applicable – N/A	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☑ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	14th October 2022

HUMAN RESEARCH
ETHICS COMMITTEE
- 7 NOV 2023
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.10.2024
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	7/11/23

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown.
Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	06 Nov 2023		
HREC REF Number	484/2020	Current Ethics Approval was granted until	30 Oct 2023
Protocol title	Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?		☐ Yes	☒ No
If yes, could you please provide the HREC Reference number for all sub-studies? **Note**: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Jennifer N. Githaiga		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Department / Office Internal Mail Address	School of Public Health, Division of Social and Behavioural Sciences UCT

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submission@uct.ac.za)	☐ Yes	☒ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	☒
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7000,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3 710.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R6000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1 500,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation for approval

FHS016 form

3. Protocol status (tick ✓)

☐	Open Enrolment
☒	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☐	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	34
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	**0**

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

6. Cumulative summary of participants

Total number of participants who provided consent	**34**
Number of participants determined to be ineligible (i.e. after screening)	2
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	34
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
The study has progressed well. The write-up of the results chapter took longer than anticipated. The write-up of the discussion/conclusions, recommendations, and abstract are currently underway.

8. Protocol violations and exceptions (tick ✓ all that apply)

☒	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☒	No Prior amendments have been made since the original approval

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	☒ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	☒ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	☒ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☒ Not applicable
		DSMB report attached	☐ Yes	☐ No	☒ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	☒ No
If yes, please explain:	

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
☒	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

Deterioration of mental health is common in patients with chronic wounds. Multiple studies have shown that depression is the most commonly reported psychological complaint in patients who suffer from chronic wounds (1–3). Factors associated with mood symptoms, such as depression and anxiety, include wound duration of ≥90 days, pain, odorous wounds, and decreased social support (4,5).

Narrating wound care experiences was mildly upsetting for some participants with chronic wounds. Once the participant appeared to become upset, the interviewer stopped and asked if the participant wanted to take a break. All of the participants requested to continue. During the post-interview debriefing sessions, these participants explained that they felt a sense of relief after being able to express how drastic chronic wounds affected their lives. The distress protocol stated that if a participant should wish to stop, the interview would be terminated immediately and all the data from that interview would be disregarded. Should a participant seem distressed, provision was made for referral to a counsellor at the relevant facility.

References:

1. Moffatt CJ, Franks PJ, Doherty DC, Smithdale R, Steptoe A. Psychological factors in leg ulceration: A case-control study. Br J Dermatol. 2009;161(4):750–6.
2. Kouris A, Armyra K, Christodoulou C, Sgontzou T, Karypidis D, Kontochristopoulos G, et al. Quality of life psychosocial characteristics in Greek patients with leg ulcers: A case control study. Int Wound J. 2016 Oct 1;13(5):744–7.
3. Fino P, Di Taranto G, Pierro A, Kacjulite J, Codolini L, Onesti MG, et al. Depression risk among patients with chronic wounds. Eur Rev Med Pharmacol Sci. 2019;23(10):4310–2.
4. Zhou K, Jia P. Depressive symptoms in patients with wounds: A cross-sectional study. Wound Repair Regen. 2016;24(6):1059–65.
5. Yan R, Strandlund K, Ci H, Huang Y, Zhang Y. Analysis of Factors Influencing Anxiety and Depression among Hospitalized Patients with Chronic Wounds. Adv Skin Wound Care. 2021;34(12):638–44.

13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes	☐ No	☒ Not Applicable – N/A	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☒ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	06 November 2023

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.10.2025
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	25/9/2024

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please use the latest form found on our website:
http://www.health.uct.ac.za/fhs/research/humanethics/forms

HUMAN RESEARCH ETHICS COMMITTEE
25 SEP 2024
HEALTH SCIENCES FACULTY
UNIVERSITY OF CAPE TOWN

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	25 Sep 2024		
HREC REF Number	484/2020	Current Ethics Approval was granted until	30 Oct 2024
Protocol title	Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?	☐ Yes	☒ No	
If yes, could you please provide the HREC Reference number for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Dr Jennifer N. Githaiga		

Department and email address	School of Public Health & Family Medicine, Division of Social and Behavioural Sciences UCT Email: jennifer.githaiga@uct.ac.za

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic combined copy if for full committee review to hrec-submission@uct.ac.za)	☐ Yes	☒ No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please **(tick ✓)**appropriate box for billing purposes:

Submission Type	***Description***	***New fee (Vat Incl.)***	***tick ✓***
Research funded solely from UCT departmental/ divisional/group budget/self-initiated research	Annual evaluation of research progress report for re-certification	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	**R0,00**	☒
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R7700,00**	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	**R3800.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	**R5000.00**	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	**R1650,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	

Vat Number:	
Contact person	
Telephone number	
Email Address	
2. **Internal Journal Billing:**	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation included to support this approval where applicable

FHS016 form

3. Protocol status (tick ✓)

☐	Open Enrolment
☒	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☒	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Publication or thesis submitted and final completion?
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	34
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	**0**

6. Cumulative summary of participants

Total number of participants who provided consent	**34**
Number of participants determined to be ineligible (i.e. after screening)	2
Number of participants currently active on the study	0
Number of participants completed study (without events leading to withdrawal)	34
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
This study is currently in the final stages of write-up. The student is also taking part in an intensive writing curriculum to encourage completion of the dissertation by the end of the academic year.

8. Protocol violations and exceptions (tick ✓ all that apply)

☒	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the original approval and have already been acknowledged or approved If so, did these occur in the last review period

☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☒	No Prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	☒ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	☒ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	☒ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☒ Not applicable
		DSMB report attached	☐ Yes	☐ No	☒ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	☒ No
If yes, please explain:	

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
☒	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

Deterioration of mental health is common in patients with chronic wounds. Multiple studies have shown that depression is the most commonly reported psychological complaint in patients who suffer from chronic wounds (1–3). Factors associated with mood symptoms, such as depression and anxiety, include wound duration of ≥90 days, pain, odorous wounds, and decreased social support (4,5).

Narrating wound care experiences was mildly upsetting for some participants with chronic wounds. Once the participant appeared to become upset, the interviewer stopped and asked if the participant wanted to take a break. All of the participants requested to continue. During the post-interview debriefing sessions, these participants explained that they felt a sense of relief after being able to express how drastic chronic wounds affected their lives. The distress protocol stated that if a participant should wish to stop, the interview would be terminated immediately and all the data from that interview would be disregarded. Should a participant seem distressed, provision was made for referral to a counsellor at the relevant facility.

References:

1. Moffatt CJ, Franks PJ, Doherty DC, Smithdale R, Steptoe A. Psychological factors in leg ulceration: A case-control study. Br J Dermatol. 2009;161(4):750–6.
2. Kouris A, Armyra K, Christodoulou C, Sgontzou T, Karypidis D, Kontochristopoulos G, et al. Quality of life psychosocial characteristics in Greek patients with leg ulcers: A case control study. Int Wound J. 2016 Oct 1;13(5):744–7.
3. Fino P, Di Taranto G, Pierro A, Kacjulite J, Codolini L, Onesti MG, et al. Depression risk among patients with chronic wounds. Eur Rev Med Pharmacol Sci. 2019;23(10):4310–2.
4. Zhou K, Jia P. Depressive symptoms in patients with wounds: A cross-sectional study. Wound Repair Regen. 2016;24(6):1059–65.
5. Yan R, Strandlund K, Ci H, Huang Y, Zhang Y. Analysis of Factors Influencing Anxiety and Depression among Hospitalized Patients with Chronic Wounds. Adv Skin Wound Care. 2021;34(12):638–44.

13. Insurance

Please confirm that valid no fault insurance is still in place? **(tick ✓)**			
☐ Yes		☒ No (Not applicable in this student study)	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☒ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

15. Signature

My required signature certifies that the above is complete and correct.			
Signature of PI		Date	25 September 2024

Western Cape Government
Health

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5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202010_014
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Dr Jennifer Githaiga, Dr Anronel Stofberg, Prof Kathryn Chu

Re: Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Mfuleni CDC	**Mr Mzwamadoda Gaji**	**021 350 0801**
Nolungile CDC	**Sr Bulelwa Gaji-Mbunge**	**021 387 4230**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH INTELLIGENCE
DATE: 22/06/2021
CC

Western Cape Government
Health

TYGERBERG HOSPITAL
REFERENCE:
Research Projects
ENQUIRIES: **Dr GG Marinus**
TELEPHONE:**021 938 5752**

HREC REF: 484/2020

TITLE: **IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A MIXED METHODS STUDY [MMED CANDIDATE: DR A STOFBERG]**

Dear Dr Githalga

PERMISSION TO CONDUCT YOUR RESEARCH AT TYGERBERG HOSPITAL.

1. In accordance with the Provincial Research Policy and Tygerberg Hospital Notice No 40/2009, permission is hereby granted for you to conduct the above-mentioned research here at Tygerberg Hospital.

2. Researchers, in accessing Provincial health facilities, are expressing consent to provide the Department with an electronic copy of the final feedback within six months of completion of research. This can be submitted to the Provincial Research Co-Ordinator (Health.Research@westerncape.gov.za).

DR GG MARINUS
MANAGER: MEDICAL SERVICES

Date: 15/07/22

HREC REF: 484/2020

TITLE: **IDENTIFYING BARRIERS TO ACCESSING HEALTH CARE FOR CHRONIC WOUNDS IN THE KHAYELITSHA SUB-DISTRICT: A MIXED METHODS STUDY [MMED CANDIDATE: DR A STOFBERG]**

NAME GRANVILLE MARINUS

TITLE MANAGER: MEDICAL SERVICES - RESEARCH

DATE 15/01/2021

BY _____ [SIGNATURE]

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REFERENCE: WC_202010_014
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
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Cape Town
7925

For attention: Dr Jennifer Githaiga, Dr Anronel Stofberg, Prof Kathryn Chu

Re: Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Khayelitsha (Site B) CHC	**Dr Leigh Wagner**	**021 360 5228/ 5238**

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Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE:
CC

Dr Melvin Moodley
Director: Health Impact Assessment
21 APR 2021

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

CITY HEALTH

Dr Natacha Berkowitz
Epidemiologist: City Health

T: 021 400 6864 **F**: 021 421 4894
E: Natacha.Berkowitz@capetown.gov.za

Ref: 28032 2020-10-27

RE: Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study.

Dear Jennifer Githaiga

Your research request has been approved as per your protocol. Please refer to the subsequent pages for the approval of any facilities or focus areas requested. Approval comments on any proposed impact on City Health resources are also provided.

Eastern & Khayelitsha:

Contact Person: Prof Vera Scott (Area East Manager)

Tel/Cell: 021 360 1258/082 308 8059

Email: Vera.scott@capetown.gov.za

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinic and its patients must be arranged with the relevant Manager such that normal activities are not disrupted.
3. A copy of the final report must be uploaded to http://web1.capetown.gov.za/web1/mars/ProjectClosure/UploadReport/0/9344, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (9344). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises
6. If this research gives rise to a publication , please submit a draft before publication for City Health comment and include a disclaimer in the publication that "the research findings and recommendations do not represent an official view of the City of Cape Town "

Thank you for your co-operation and please contact me if you require any further information or assistance.

Kind Regards
Dr Natacha Berkowitz Epidemiologist: City Health

Facilities

Area	Subdistrict	Facilities		
Area East	Khayelitsha	**Facility name**	**Interaction start date**	**Interaction end date**
		Kuyasa CDC	2020-11-02	2021-02-28
		Luvuyo CDC	2020-11-02	2021-02-28
		Matthew Goniwe CDC	2020-11-02	2021-02-28
		Mayenzeke Clinic	2020-11-02	2021-02-28
		Nolungile Youth Clinic	2020-11-02	2021-02-28
		Site B Youth Clinic	2020-11-02	2021-02-28
		Town Two CDC	2020-11-02	2021-02-28
		Zakhele Clinic	2020-11-02	2021-02-28
		Nolungile Clinic	2020-11-02	2021-02-28
		Site B Male Clinic	2020-11-02	2021-02-28
		Kuyasa Male clinic	2020-11-02	2021-02-28

Please note

- If a requested facility does not appear in the list above, its interation request has been rejected and the reason for the rejection can be viewed in the link below
- Approval comments for facilities may exist. These comments can be viewed in the link below.

http://web1.capetown.gov.za/web1/mars/ProjectFacility/Read/0/9344

Impacted resources

Impacted resource	Decision	Comment
Additional load on nursing	Approved	approved

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For attention: Dr Jennifer Githaiga, Dr Anronel Stofberg, Prof Kathryn Chu

Re: Identifying barriers to accessing health care for chronic wounds in the Khayelitsha sub-district: A mixed methods study

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Khayelitsha Hospital	**Kitesh Moodley**	**021 360 4500**

Kindly ensure that the following are adhered to:

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Yours sincerely

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 14/01/2021
CC

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Please contact the following people to assist you with any further enquiries in accessing the following sites:

Michael Mapongwana CDC	**Dr Germarie Fouchè**	**021 361 3353**

Kindly ensure that the following are adhered to:

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09 MAR 2021