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A survey of venous ulcer care in wound care practices in Gauteng

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Declaration

I, Fébé Antoinette Bruwer, declare that the research report in this dissertation titled “A survey of venous ulcer care in wound care practices in Gauteng” is my original work.

This dissertation is hereby submitted to the University of the Free State for the master’s degree qualification, Magister Societatis Scientiae. I declare that it is my independent work, and that I have not previously submitted it for a qualification at any other institution of higher education. The dissertation is my own work in design and execution, and all material contained therein has duly been acknowledged in the text and list of references.

_____ _____

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Dedication

I would like to dedicate this research to all nurses who strive to make a difference in someone else's life on a daily basis, as there is no greater reward than doing something for someone who can never repay you.

This research is especially dedicated to those nurses who, regardless of not being recognized, still strive to do better every day.

Abstract

Background: Venous leg ulcers are the most common type of leg ulceration, and prevalence seems to be increasing as the population ages and co-morbidities increase. Venous lower leg ulcers seem to be an underestimated and misdiagnosed chronic disease that has a significant socio-economic impact on the individual, as well as on the community and the health care system. Evidence-based care improves outcomes for patients suffering from this debilitating disease.

Objective: The objective was to describe the current level of care within wound care practices in Gauteng according to the Donabedian structure-process-outcome quality improvement model.

Method: Forty-eight facilities were selected randomly from wound care practices (both public and private) in Gauteng. Trained fieldworkers conducted structured interviews with care providers to assess infrastructure, human recourses, level of education, equipment available, policies and protocols. Within these facilities, patient files were randomly selected from patients who had previously presented with venous lower leg ulcers. One hundred and sixty files were audited by using a checklist to assess processes implemented and outcomes reached.

Results: A lack of proper record-keeping made data collection challenging. A few important findings were deduced from this study. The facilities lack the necessary equipment to perform vital assessments. Hand-held Dopplers were available in 60% (n=48) of the facilities. Patients were attended to by clinicians with no formal wound care training, as 61% (n=48) of the personnel at the facilities indicated no formal wound care training. Although the majority of files (92%, n=160) indicated that an assessment tool was used, many of the elements thereof were not comprehensively done according to best available evidence. Pain, presence of varicose veins, previous treatment, and functioning of the calf muscle were assessed in more than 70% of the files. However, aspects such as smoking, body mass index and anaemia, which all play a major role in wound healing, were assessed in fewer than 30% of files. Distinguishing between superficial infection and deep infection seems to be a challenge, together with the overutilization of antimicrobials and antibiotics. Furthermore, 71% received compression therapy while the Ankle Brachial Pressure

Index (ABPI) of only 30% was known. Outcomes were recorded fairly well at three weeks but declined towards completion of treatment.

Conclusion: Quality of care could be measured by measuring structures, processes and outcomes. Accurate record-keeping is vital to obtain a view of the processes being followed and the outcomes being reached. From this survey, it was evident that clinicians providing wound care are not all trained in wound care, that best practice guidelines are not being fully implemented, and that the consequences may be detrimental to the patients, as a high number of amputations were reported.

Keywords: Venous ulcer; Lower leg ulcer; Venous insufficiency; Ankle Brachial Pressure Index (ABPI); Hand-held Doppler; Compression therapy; Best Practice Guidelines

List of abbreviations

ABPI – Ankle brachial pressure index
AWCP – Advanced wound care practitioner
BPGs – Best practice guidelines
CVD – Cardio vascular disease
CEO – Chief Executive Officer
DoH – Department of Health
DVT – Deep vein thrombosis
GCP – Good clinical practice
GP – General Practitioner
IOM – Institute of Medicine
MMP – Matrix metalloproteases
NEI – National Educational Institutions
NERDS – Non-healing, Exudate, Red friable granulation, Debris, Smell (Malodour)
NPWT – Negative pressure wound therapy
PAD – Peripheral arterial disease
RN – Registered nurse
SPNP – Society of Private Nursing Practitioners
STONEES – Size bigger, Temperature increase, Os (probe to bone), New Breakdown, Erythema, Oedema, Smell (Malodour)
WHASA – Wound Healing Association of Southern Africa
WHO – World Health Organization

Table of Contents

List of tables

List of figures

Chapter 1: Rationale and overview of the research

1.1 Background information

Chronic wounds, specifically lower leg ulcers of venous aetiology, are often complex and hard to heal. In addition, they place a significant socio-economic burden on the patients, and the health care system (Woo, 2013, p. 538). This burden, emphasized by Augustin, Brocatti, Rustenbach, Schäfer and Herberger (2012: 238), constitutes a mean value of €9 060 (R151 845) per patient per year, of which €8 288 (R137 901) constitutes direct and €772 (R12 938,72) indirect cost. Inappropriate indirect costs can be ascribed to the lack of knowledge and skill of the practitioner delivering the care (O'Brien, Lawton, Conn & Ganley, 2011: 145).

Chronic venous disease is listed as the seventh most common chronic disease worldwide and is the underlying cause of between 40-80% of leg ulcers (Harding & Dowsett *et al.*, 2015: 3). According to the European Wound Management Association (Probst & Seppanen *et al*., 2014: 2), the average cost per episode of leg ulcers could be up to €6 650 (about R106 400), which accounts for 2-4% of the health care budget in European countries (Hellström & Nilsson *et al.*, 2016: 240).

Data seem to be lacking on the prevalence of lower extremity ulcerations of venous aetiology in South Africa. In contrast, the prevalence in both the USA and UK can be indicated as being between 1% and 22% of the population over the age of 60 years (Agale, 2013: 1; Sieggreen & Kline, 2012: 360).

Woo (2013: 540) highlights several areas in wound management that need attention. The first area is the need for a “systematic and holistic approach to wound management”. Sibbald, Goodman and Reneeka (2013: S13) reiterate that treating the cause of the wound involves a holistic assessment of all intrinsic and extrinsic factors that might influence wound healing outcomes. Wound management is explained under the principles of the “wound bed preparation paradigm” of Sibbald, Goodman, Woo, Krasner, Smart, Tariq, Ayello, Burrell, Keast, Mayer, Norton and Salcido (2011: 415), which views wound management as treating the cause and addressing patient-centred concerns before attending to the local wound care issues. In this paradigm, “local wound care” refers to the attention paid to the wound bed itself including debridement of devitalized tissue, treatment of infection or reduction of bioburden, maintenance of

moisture balance and, finally, treatment of non-viable or unhealthy wound edges (Sibbald, Goodmam & Reneeka, 2013: 347).

The second area of concern raised by Woo (2013: 540) is the general deficit in the level of advanced wound care education. Ylönen, Stolt, Leino-Kilpi & Suhonen (2013: 200) found that nurses seem to lack knowledge about the physiology and underlying causes of lower leg ulcers which, in turn, contributes to sub-standard care and non-evidence-based treatment. Woo (2013: 540) indicates that nurses play an invaluable part in the delivery of wound care and are essential to the quality of the care delivered. Zarchi, Latif, Haugaard, Hjalger and Jemec (2014: 23) concur by stating that the quality of care delivered is affected by the knowledge of members of multidisciplinary teams in which wound care nurses are the key health care providers. Therefore, it is vital to improve nurses' knowledge of wound management to ensure a high quality of care. Woo (2013: 541) emphasizes that nurses who possess adequate knowledge and perceive wound care as rewarding are more likely to provide evidence-based care. When care is standardized, quality can be measured (Anderson, 2012: 33).

The third area raised by Woo (2013: 540) is the rise in the number of patients with chronic diseases and conditions, such as diabetes mellitus. This increases the need for better quality wound care, as wounds are often complications of chronic diseases and conditions. According to the International Diabetes Federation (IDF), the number of people with diabetes will increase from 382 million, or 8,3% globally in 2013, to 592 million, or 10%, by 2035. Two to three per cent of people with diabetes develop a foot ulcer annually, which demands more efficient wound care due to the increasing financial burden (IDF, 2013: 14).

Donabedian (1966: 166; 1988: 1745) developed the structure-process-outcome model to measure quality of care. In this model, the first concept, namely "structure", focuses on the qualifications of the care providers, their tools and resources, as well as the physical/organizational setting of the facility. Ahgren (2007) and Øvretveit (1998) (cited by Willumsen, Ahgren and Ødegård (2012:199) indicate that structural qualities also include managerial ability, the staff's range of competence and experience, and "user empowerment". According to the original work of Donabedian (1966: 166), the second concept, "process", refers to the interpersonal and technical aspects of the treatment process, best practice guidelines (BPGs) and how they are implemented.

Ahgren (2007) and Øvretveit (1998) (cited by Willumsen *et al*., 2012: 199) add that "process quality" involves how the work is carried out, i.e., work routines and communication among staff. The third concept, "outcomes", measures change in patient symptoms and functioning (Donabedian, 1966: 166). Ahgren (2007) and Øvretveit (1998) (cited by Willumsen *et al*., 2012: 199) include an improved management system, professional results and the end-user's quality of life and well-being as outcome measures.

1.2 Problem statement

Implementing standardized care would not only improve quality of care, but also patient outcomes. Several studies have documented issues regarding knowledge transfer and variation in clinical practice (Das, 2011: 1; Tomson & Van der Veer, 2013: 19). Both Das (2011: 1) and Tomson and Van der Veer (2013: 19) mention the inevitable variations in clinical practice caused by a lack of standardization, which supports the idea that standardized care could contribute to an improvement in quality of care. Similarly, Hensen, Ma, Luger, Roeder & Steinhoff (2005:104) advocate the use of "care pathways" to define local standards based on Best Practice Guidelines (BPGs) and, ultimately, increase efficiency by optimizing the care delivery process.

Bolton, McNees, Rijswijk and De Leon (2004: 65) also support the idea of implementing and applying standardized protocols to improve outcomes of wound care. They reiterate the fact that nurses who are certified in wound care have a better understanding of wound care and deliver more consistent evidence-based care with improved outcomes, i.e., reduced healing times and number of wound care rounds, which ultimately has a cost implication. Bolton *et al*. (2004: 67) conclude that standardized care is not only a cost-saving measure, but also a time-saving one.

Access to high quality, effective care inevitably contributes to the timely healing of venous leg ulcers (Anderson, 2012: 32). Regulation 258 of the Regulations Relating to the Scope of Practice of Persons who are Registered or Enrolled Under the Nursing Act, No. 50 of 1978 (South Africa, 1978) (hereafter "the Nursing Act"), states that nurses are responsible for "the facilitation of the healing of wounds". However, as Andrews and Langley (2015: 59) point out, there are no standards of care for wound management in South Africa, and tissue viability is not seen as a specialty in South

Africa. Thus, with no standards in place against which care could be measured, the evaluation of wound management is unachievable (Andrews & Langley, 2015: 59). The need for a wound care management system that is both evidence-based, and cost effective has been documented by Regmi and Regmi (2012: 56).

The researcher has found very little data on care delivered to patients presenting with lower leg ulcerations of venous aetiology in wound care facilities in Gauteng, South Africa. Leg ulcers are common problems that could be difficult to treat, very costly to manage and often disabling to the patient. As mentioned above, quality of care can be measured through the Donabedian structure-process-outcome model (Donabedian, 1966: 166; 1988: 1745).

Mainz and Bartels (2006: 79) contend that performance and outcome indicators might be the only way to obtain quantitative data on quality of care with the aim of improving the quality. Campbell, Roland and Buetow (2000: 1612) argue that, when defining "quality of care", it is critical to recognize the differences between the structure, the process, which they describe as the actual care given, and the outcome, or the "consequences of the interactions between individuals and a health care system". Campbell *et al*. (2000: 1612) also state that both structure and process could be measured by their capacity to result in a favourable outcome.

The researcher is unaware of any research in South Africa that has measured the current standard of lower leg ulcer care according to the Donabedian system. Therefore, the research question was formulated as follows: "What is the current level of care provided to patients with lower leg venous ulcers in the Gauteng Province?"

1.3 Aim

The aim of the study was to describe the current management of venous leg ulcer care according to the Donabedian model in wound care practices in Gauteng to determine whether evidence-based guidelines are being followed to aid management.

1.4 Objectives

The objectives of the study were to describe the:

- Structures available in the facility;
- Processes being implemented at the facility; and
- Outcomes being reached at the facility.

1.5 Conceptual framework

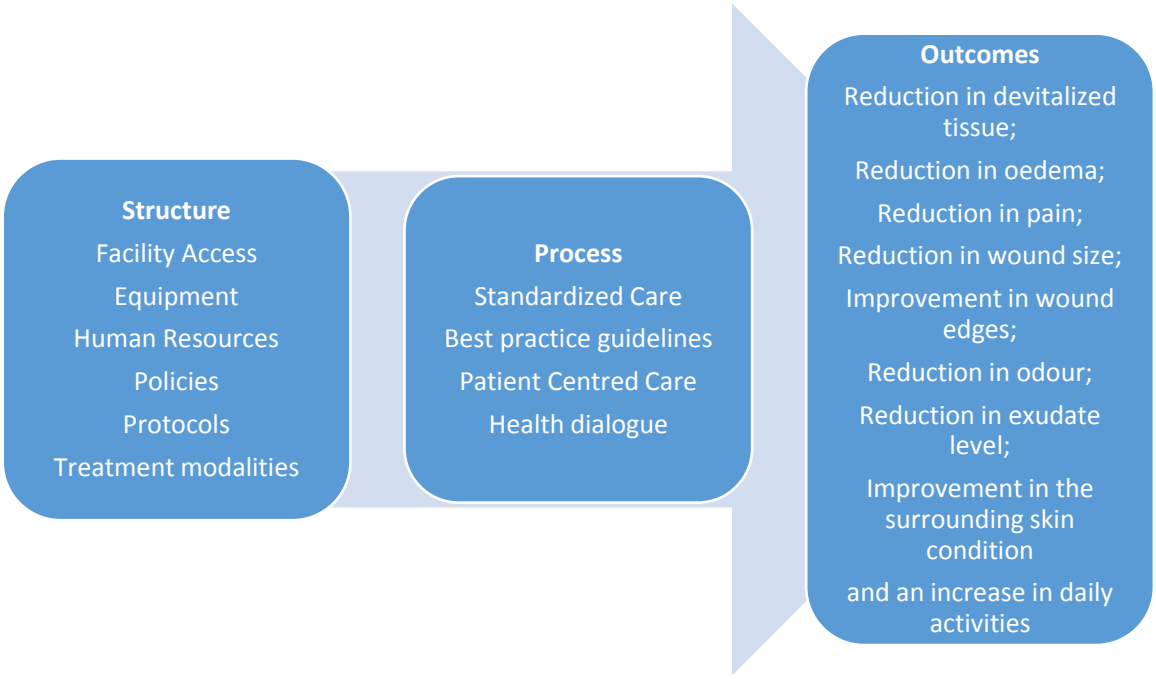


Figure 1.1 Schematic summary of the Donabedian model

Donabedian (1966: 166) proposed that the level of quality of care could be assessed by investigating the **structure** of the setting in which care is being provided, measuring the **process** of care and assessing the **outcome** of the care. Considering the Donabedian structure-process-outcome model, which forms the framework for this study, the following concepts are defined:

Structure refers to the characteristics of the setting in which the care is being provided and can include organizational characteristics, e.g., the physical setting (building or other form of structure, e.g., mobile clinic), human resources, educational level of personnel, equipment available, and policies and protocols related to care delivery.

Process refers to an assessment of whether the patient did, in fact, receive "good care" with reference to the BPGs; thus, were the BPGs implemented? It also refers to an evaluation of the interpersonal process such as providing information and emotional support and involving the patients in decisions regarding their care. According to the Donabedian model, by assessing the process, the appropriateness and efficacy of the therapy or care are being measured.

The notion of **outcomes** refers to a change in health status because of the care received. Cleary and O'Kane (2009: online) mention that the use of outcome data as a measure of health care dates back more than 150 years. The outcome could provide a measure of the effectiveness of the medical intervention. According to the Donabedian model, when using outcome as a quality indicator, both the relevance and measurability of the outcome should be determined.

1.6 Concept clarification

Quality of care

The concept of "quality of care", as indicated by the work of Donabedian (1966: 166), is fundamentally difficult to define. Thus, it seems to be quite complex to determine one definition, as there are several aspects that could qualify as a "measurement" of quality, and different groups might have different reasons for measuring quality, as mentioned by Cleary and O'Kane (2009: online), hence the different measurement criteria and emphases.

The Institute of Medicine (IOM, 2001: 3) defines "quality of care" as follows: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". The IOM specifies six aims of high quality medical care systems, namely to be:

i. Safe – avoiding injury to patients from the care that is supposed to help them.
ii. Effective – providing services based on scientific knowledge to all who could benefit (avoiding overuse and underuse).
iii. Patient-centred – providing care that is respectful of and responsive to individual patient preference, needs and values, ensuring that patient values guide all clinical decisions.
iv. Timely – reducing waits and sometimes harmful delays for both those who receive and those who give care.

v. Efficient – avoiding waste, in particular, waste of equipment, supplies, ideas and energy.

vi. Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socio-economic status (IOM, 2001: 3).

An operational definition would indicate how we intend to measure this concept. Thus, for operational purposes, “quality of care” is defined as providing patients, who are presenting with lower leg ulcers, with wound care that is:

- Based on scientific knowledge (current BPGs);
- Patient centred (patients are involved in their care and educated accordingly);
- Efficient (the most appropriate application according to current guidelines);
- Safe (no harm is done); and
- Equitable (available to all), to increase the likelihood of desired outcomes.

Desired outcomes would be measured by:

- Reduction in wound size through advancing of the wound edges (Sibbald, *et al*., 2011: 437);
- A reduction in oedema by measuring the leg circumference;
- The management of exudate and infection (if applicable);
- A reduction in devitalized tissue;
- A reduction in malodour;
- An improvement in the surrounding skin;
- A reduction in pain according to a pain scale (Sibbald, *et al.,* 2011: 432); and
- An increase in activities of daily living.

Appendix D and F contain the measurement tools that will be applied in the study to incorporate the concepts of “structure”, “process” and “outcome” into the measuring tools.

Best Practice Guidelines/Evidence-based practice

Best practice is what guides practice, according to O'Brien *et al.*(2011: 145). With regard to best practice wound care, O'Brien *et al*. (2011:145) also point out that the absence of a coordinated approach seems to be contributing to clinical diversity, inconsistency and the frequent use of outdated methods. In this study, best practice was not measured, but instead described as being implemented or not.

Lower leg venous ulcer

Sieggreen and Kline (2012: 363) describe venous ulcers as chronic skin and subcutaneous lesions that are commonly found on the lower extremity, especially in the pretibial and medial supra-malleolar areas of the ankle where the perforator veins are located. Venous hypertension is both the cause and the reason why these ulcers are hard to heal (Carmel & Bryant, 2016: 432).

For operational purposes, the lower leg ulcers included in the study were chronic open wounds around the gaiter area, as confirmed by an ankle brachial pressure index (ABPI) of between 0,8 and 1,3. In addition, the wounds presented with typical symptoms of venous hypertension, i.e., oedema, that were measured by measuring leg circumference or the reduction thereof (Flanagan, 2013: 53).

Wound care practice

A wound care practice is generally seen as any facility that offers wound care as a service, whether a separate facility or part of a hospital, a facility in a public-sector hospital or clinic, or home-based care.

1.7 Research design

A randomized, descriptive quantitative design was followed to evaluate venous leg ulcer care with regard to BPGs in wound care practices in Gauteng. The main aim of descriptive research is to accurately portray the characteristics of individuals, situations or groups and the frequency with which certain phenomena occur using statistics to describe and summarize the data (Polit & Beck, 2012: 379). The study was conducted in two parts:

- Part 1 – Structured interviews were conducted using a questionnaire (Appendix D) to gather data on the structure; and
- Part 2 – File audit conducted utilizing a checklist (Appendix F) to gather data on the process and outcomes.

1.8 Data collection techniques

Table 1.1 provides an overview of the research objective, data collection techniques and sample applicable to the study.

Table 1.1 Research objective, data-collecting techniques and sampling

Objective	Data-gathering techniques	Sample
Structure	Structured interview by means of a questionnaire	Randomly selected sites from the population of wound care practices or clinics, General practitioner practices, pharmacy clinics, private nursing practitioners providing home-based care and public-sector clinics rendering wound care as a service
Process	File audit by means of a checklist	Randomly selected files of patients treated for venous ulcer from sample sites
Outcome	File audit by means of a checklist	Randomly selected files of patients treated for venous ulcer from sample sites

1.8.1 Structured interview

A structured interview refers to a formal written instrument that consists of a set of questions (Polit & Beck, 2012: 297). In this study, structured interviews were conducted by means of a questionnaire containing mostly closed-ended questions (Appendix D). Data collected from these interviews were used to assess the structures. A structured interview using a questionnaire has the advantage that the fieldworker has much better control of the response rate since interviews are usually conducted with one respondent at a time (De Vos, Strydom, Fouche & Delport., 2011: 196). However, structured interviews are time consuming, and respondents might be reluctant to answer due to the presence of the interviewer (De Vos *et al*., 2011: 186). Although time consumption can be reduced by using closed-ended questions, omissions could occur when respondents misinterpret or fail to understand a question (Polit & Beck, 2012: 298). In this study, trained fieldworkers conducted the interviews at the facilities with the selected participants.

1.8.2 Checklist

In this study, a file audit was conducted using a checklist (Appendix F) to measure process and outcome. Checklists indicate whether a characteristic being measured is present or not (De Vos *et al*., 2011: 202). According to Botma, Greeff, Mulaudzi and Wright (2010: 143), checklists are instruments designed to record a phenomenon by means of direct observation of participants. Tally marks are placed on the checklist when the specific behaviour or characteristic being observed has occurred – any other behaviour or characteristics are disregarded. The advantage of using a checklist is that it aids in collecting data correctly and consistently. The disadvantage of a checklist is, that when it is incomplete it is not useful. It is vital to make sure that the checklist is suitable, complete and accurate (Gallagher, 2012: online). In this study, the fieldworkers completed the checklists while collecting data from the depersonalized files at the facilities.

A clinical audit measures practice against set standards, as described by Dilnawaz, Mazhar and Shaikh (2012: 358). The file audit to be conducted in this study measured practice against standards that are based on national and international guidelines. Because of its high degree of reliability and validity, a clinical audit has the advantage of being able to contribute to change in clinical behaviour (Holmboe, 2008: 65).

While obtaining patient records might not be a problem, extracting specific data could pose a challenge. The disadvantages of a clinical audit could include the quality of the documentation and the fact that causation for patient outcome could be limited. Criteria need to be defined accurately to avoid low reliability and reduced validity. In addition, a clinical audit is very time consuming. These disadvantages could, however, be addressed using more than one fieldworker to speed up data collection and adapting checklist according to results from pilot study to aid in streamlining data collection.

1.9 Study population

The study population comprised randomly selected facilities within a 75 km radius from the researcher's base in the following strata:

- All private wound clinics in Gauteng (approximately 15 known);
- Pharmacies in Gauteng that have a wound care service (approximately 50);
- General practitioners who have a wound clinic in their practices (managed by a registered nurse) (approximately 12 known) within Gauteng;
- Private nurse practitioners who work from home or provide home-based care in Gauteng (approximately 30); and
- Wound clinics in public-sector facilities (hospital or clinic, approximately seven (7) known).

All the selected facilities would need to attend to patients with lower leg ulcers of venous origin, and consent from all would be needed before participation. The size of the study population was estimated at 81 facilities.

1.10 Sampling

Stratified random sampling was employed, which means that the groups were proportionally randomized. According to Polit and Beck (2012: 206), "random" indicates that every individual in the study population has an equal chance of being assigned to any group. Five subgroups, also referred to as strata, were identified, namely wound clinics (private), General Practitioner (GP) practices, pharmacies, home-based care, and public-sector wound clinics. Strata are used mainly to ensure that the groups are sufficiently represented in the sample (De Vos *et al.*, 2011: 226). Facilities were listed alphabetically and numbered per stratum. Fifty per cent of the facilities were selected randomly by selecting numbers from five (5) containers

representing the strata and containing all the numbers on each of the lists. This constituted a total sample of 48 facilities.

Clinics or practitioners who wished to withdraw from the study were replaced randomly using the same technique. For conducting the file audit, the fieldworkers requested the facility managers to identify patient files that fit the inclusion criteria as per 1.10.3. From these files, the fieldworkers drew a systematic random sample, in other words, the first file was selected randomly from the files supplied by the facility manager, and then every third file in the pile until a 20% sample was drawn from the files provided (De Vos *et al*., 2011: 230). Sampling is discussed in more detail in Chapter 3.

1.10.1 Inclusion criteria for facilities

The following facilities were eligible for inclusion in the study:

- Facilities where patients presenting with lower leg ulcers of venous origin are treated and which fall in any one of the mentioned strata; and
- Facilities located within a radius of a maximum of 75 km from where the researcher is based in Gauteng (Germiston).

1.10.2 Exclusion criteria for facilities

- Facilities that decline to participate in the survey; and
- Facilities located more than 75 km from where the researcher is based (Germiston, Gauteng).

1.10.3 Inclusion criteria for the file audit

The following files were eligible for inclusion in the file audit:

- Files of adult patients over the age of 18 who have been treated for a confirmed venous leg ulcer, either at the facility or by a private nurse, within the last six months; and
- Files of patients who have completed treatment in the last six months.

1.10.4 Exclusion criteria for the file audit

- Files of children or young adults under the age of 18;
- Files of patients being treated for any other type of wound;
- Files of patients on active treatment;

- Patients identified as being non-compliant to treatment, as well as wounds classified as “maintenance wounds”.

1.11 Pilot study

A pilot study was conducted on a small number of facilities (five) that met the inclusion criteria and represented the five strata identified (Botma *et al*., 2010: 275). The facilities were selected by means of convenient sampling. The aim of the pilot study was to identify possible logistical problems in data collection. Registration with associations such as the Wound Healing Association of Southern Africa (WHASA) or the Society of Private Nursing Practitioners (SPNP) is not compulsory for any private nursing practitioner; thus, tracking down potential participants might be a challenge initially, but their member lists might be a valuable starting point, as members are those who have a special interest in wound care. The second aim of the pilot study was to determine the validity of the checklist and to give an indication as to the feasibility of the study.

The training of fieldworkers was completed before the pilot study commenced. Four fieldworkers were recruited from nurses with previous wound care training or special interest in wound care and who were unemployed at the time and willing to take part in the study. The fieldworkers were trained on basic principles of lower leg ulcer care. They were briefed regarding all aspects of the questionnaire and checklist, as well as the appropriate way, according to GCP (good clinical practice) guidelines, in which to obtain informed consent. They were also required to sign a non-disclosure agreement to ensure all information is kept in confidence. Once the participants in the pilot study have completed the initial questionnaires, the researcher under the supervision of the biostatistician, will analyse and evaluate consistency and interpretability of the results, as these aspects relate to the validity and reliability of an instrument. A post-pilot debriefing session was held to discuss and address any issues that might arise regarding the questionnaire and checklist. Fieldworkers were re-trained to ensure they understood the changes made to the measuring tools (De Vos *et al*., 2011: 244).

1.12 Data collection

Figure 1.2 is an overview of the data collection method.

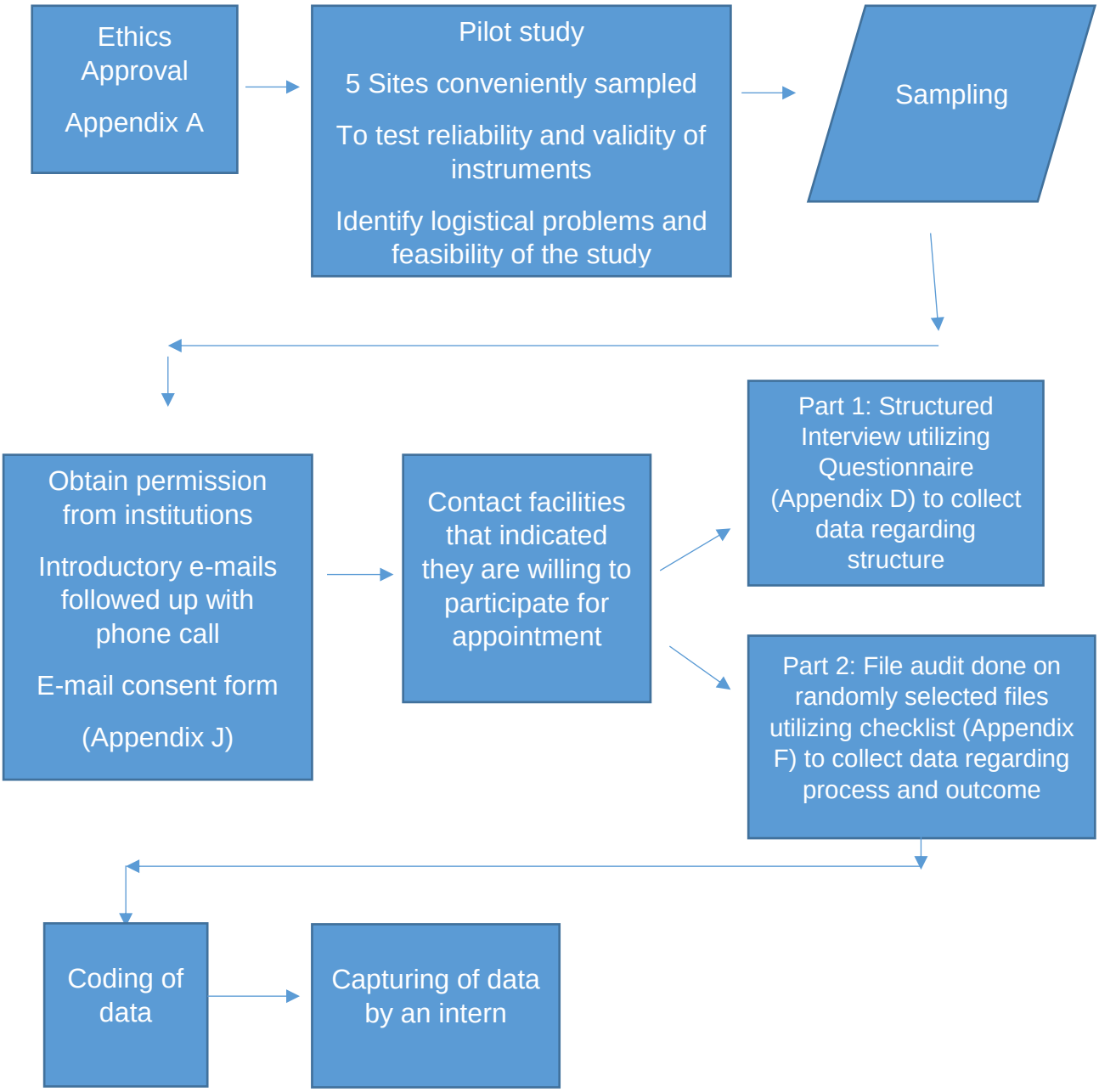


Figure 1.2 Overview of method of data collection

After a list of all the possible participants were compiled and divided into the five strata, randomization was done as explained in Section 1.10.

1.12.1 Recruitment

After randomization, the facilities' contact details were sourced by the researcher and an introductory email with information regarding the study was sent to all selected facilities. The fieldworkers, supplied with a list of facilities and their contact details, followed-up the email with a phone call to the manager of the facility to ascertain willingness to participate and provide information regarding the format of the questionnaire, the approximate length of the interview and the method of retrieving files. The facility manager was requested to respond via email. When a positive written response was received, a fieldworker contacted the facility manager to set up an appointment for the interview at their convenience. In the case of facilities that are part of a hospital or clinic, an email was sent to the relevant manager to obtain consent to enter the facility. This document was signed at the facility during the interview.

To recruit wound care facilities within the Department of Health in Gauteng the researcher needed to supply the following:

1. A request for conducting research in the Gauteng Provincial Department of Health;
2. A motivation letter for conducting such a study and how the study will benefit the Department of Health;
3. The full study protocol with consent form;
4. The study questionnaire;
5. Ethical approval of the proposal by the Research Ethics Committee/Clearance Certificate; and
6. A list of facilities/clinics in Gauteng where the study was to be conducted.

These steps needed to be followed to obtain authorization to recruit clinics within the Department of Health.

1.12.2 Interview

After appointments were set up, the fieldworkers received copies of the questionnaire, checklist, informed consent form and access to facility form to take to the interview (appendices attached). The fieldworkers introduced themselves to the facility manager and discussed the informed consent with them. The manager was given ample time to read through the consent form and respond accordingly.

The relevant manager or head of department also need to sign the access to facility form for the fieldworker to gain access to the facility. When the response was positive, and the informed consent was signed, the fieldworkers initiated the structured interview using the questionnaire. The fieldworker completed the checklist (Appendix F) while conducting the interview.

1.12.3 File audit

After the interview, the fieldworkers requested the facility manager to identify patients who fit the study criteria, namely patients who have been treated at the facility within the last six months but not actively receiving treatment at that time and make their files available. The period of six months was determined by the date of site initiation. For example, when a site was interviewed and audited in October 2016, the files of patients who had been treated between April 2016 and October 2016 were included in the audit. Files of patients who were actively receiving treatment at the time of the interview were excluded from the study. In the case of facilities that fall under the Department of Health, the head of the department also needed to sign the consent form for data extraction (see updated version of Access to Facility form (Appendix L).

The fieldworkers then randomly selected a 20% sample from the files supplied. No identifying data was collected. A file audit was conducted by the fieldworkers using the checklist (Appendix F).

The researcher had provided fieldworkers with an envelope in which to seal the completed questionnaire and checklist. Only the facilities' randomized number and strata were indicated on the envelope. Members of staff were thanked for their participation and the sealed envelopes were delivered to the researcher.

1.13 Data analysis

Data analysis involved the interpretation of the structured interviews and checklists and conversion of the data into a format (numerical form) by which the researcher could answer the research question (De Vos *et al*., 2011: 249). Coding and data capturing were done by the researcher. Data were analysed by the Department of Biostatistics of the University of the Free State (UFS).

Descriptive statistics was used. Ordinal measurement was done by ranking the objects based on their relative standing on an attribute (Polit & Beck, 2012: 402). Frequency distributions were computed by ordering numerical values from lowest to highest, accompanied by a count of the number or percentages of times each value occurred (Polit & Beck, 2012: 402).

1.14 Ethical considerations

Approval of the research proposal was obtained from the Health Sciences Research Ethics Committee of the UFS (Appendix A). Permission to gain entry to any of the facilities was obtained from management at the facility, as well as the practitioner in charge of the facility. In the case of public-sector clinics, permission was obtained from the Department of Health and the study registered online with the department of health. Permission was obtained in writing for conducting the study as well as for gaining access to the facilities and patient files.

Individual informed consent was obtained from the facility manager to participate in the research. Ethical principals were adhered to throughout the study and a detailed discussion thereof follows in Chapter 3.

1.15 Value of the study

Venous leg ulcers are a common problem that is often misdiagnosed. In addition to their negative impact on the quality of patients' lives, they have huge financial implications (Harding *et al.*, 2015: 67). Implementing standardized care would improve the quality of care delivered (Regmi & Regmi, 2012: 56). This study could contribute to determining the level of care that patients are receiving and identifying shortcomings in either structure, process or outcome. The literature indicates clearly that quality of care could be determined by describing the structure, process and outcome achieved (Donabedian, 1966: 166).

Armed with this information, one can assess the association between the outcome and process, or the correlation between the effects of the care and how the care is delivered. Therefore, the aim of this study was not to point fingers or find fault. Instead, the study sought to "create a general picture of conditions", in the words of De Vos *et al*. (2011: 96). More specifically, the study aimed to describe quality of care through structure, process and outcome and, in this way, determine how the quality of

specifically lower leg ulcer care could be improved through standardization and implementation of BPGs.

In the South African health care system, the financial burden of covering the costs of these ongoing treatments falls on private funders such as Discovery Health, Medscheme, Medical Services Organisation (MSO) and Metropolitan Health Group (MHG). Once the level of quality of care is determined, the possibilities of further studies regarding quality improvement through implementation of standardized care could be fundamental in contributing to better outcomes and reduced financial burden on not only the funders, but the patients themselves.

The researcher believes that “knowing is not enough, we must apply; willing is not enough, we must do”, as stated by Johann Wolfgang von Goethe (1749-1832). Therefore, by gaining knowledge about current wound practices in Gauteng and the quality of care provided in these practices, critical shortcomings could be identified. With new knowledge, organizations such as WHASA and the SPNP could develop outcome-oriented training programmes to address these shortcomings and help improve the quality of care. Exploring quality of care could be instrumental in the standardization of care and improvement of outcomes. Richmond, Manderal & Vivas (2013: 187), as well as Barker and Weller (2010: 63), state that the development of standard care practices leads to improved outcomes. Regarding standardized care, Regmi and Regmi (2012: 56) emphasize the importance of developing an appropriate management plan to improve patient outcomes. Thus, patients are sure to benefit, because the literature shows that appropriate, effective and standardized care can contribute to an improved quality of life. Furthermore, improved care could also contribute to speeding up healing time and reducing costs, a vital aspect for individuals and funders paying for costly and often inappropriate treatments.

1.16 Layout of the report

Chapter 1: Rationale and overview of the research

Chapter 2: Literature review

Chapter 3: Research methodology

Chapter 4: Data analysis of structure

Chapter 5: Data analysis of process and outcome

Chapter 6: Conclusions, recommendations and limitations

1.17 Conclusion

In this chapter the reader was orientated regarding the study. A background of the problem was sketched, the aim and objectives outlined. Operational definitions of concepts were provided. The research design described according to data collection techniques, sampling of the study population and pilot study. Method of data analysis was described. Ethical considerations and value of the study outlined. The next chapter is a review of the literature.

Chapter 2: Literature review

2.1 Introduction

Chronic venous leg ulcers can be viewed as a common, worldwide problem (Agale, 2013: 2; Folguera-Álvarez *et al*., 2016: 2; Gordon, Widener & Heffline, 2015: 54; Goto, Tami, Nakagami, Kitamura *et al*., 2016:1). Unfortunately, data from the South African context seem to be lacking. In general, the problem is often overlooked and its impact underrated, as the cost of venous disease is carried by all stakeholders, including the individual, the health care system and the community as a whole (Eberhardt & Raffetto, 2014: 333). Pethericka, Pickett & Cullum (2015: 347) estimate the financial burden of treating these ulcers at approximately £400 million per annum in the UK which amounts to about eight billion south African Rand (R8 000 000 000). This correlates with the one billion dollars and two million workdays lost annually in the USA due to loss of function (Muldoon, 2013: 153).

Chronic venous leg ulcers are the result of chronic venous insufficiency (Ligi, Mosti, Croce, Raffetto & Mannello, 2016: 1964). Several authors emphasize the importance of treating the underlying cause of lower leg ulceration by following BPGs (Regmi & Regmi, 2012: 56; Kolluri, 2014: 136; Kelechi, Johnson & Yates, 2015: 36). Lazarus, Valle, Malas, Qazi, Mauthur, Doggett, Fawole, Bass and Zenilman (2014: 34) conclude that present and future therapeutic modalities need to be based on high quality evidence so that appropriate treatment can be delivered and costs can be decreased as a consequence.

2.2 Venous leg ulcers

The complexity and magnitude of venous lower leg ulcers are associated with an increased mortality rate and substantial morbidity due to infection, pain, limitations on activities of daily living, quality of health, and psychosocial consequences (Kirsner & Vivas, 2015: 379). The 6-28% recurrence rate of ulcers within 12 months not only complicates the problem, but could also be attributed to inadequate diagnosis and management of the underlying disease (Carmel & Bryant, 2016: 167). Peripheral vascular disease is the principal leg ulcer aetiology (Sieggreen & Kline, 2012: 360).

2.2.1 Definition of venous lower leg ulcers

A “venous lower leg ulcer” can be defined as an injury to the skin and subcutaneous tissue on the gaiter area which does not heal spontaneously and is sustained by chronic venous insufficiency (Agale, 2013: 3; Kistner & Eklof, 2017: 2836; Ligi, Mosti, Croce, Rafetto & Mannello, 2016: 1946; Sieggreen & Kline, 2012: 363).

The “gaiter area” refers to the inner ankle region, more specifically the pretibial and the medial supra-malleolar area of the ankle where the perforator veins are located (Pannier & Rabe, 2013: 55; Sieggreen & Kline, 2012: 363), as well as the lower lateral fibula area (Lin, Hseih, Huang, Lui, Chang & Lin, 2017: 3).

2.2.2 Chronicity of venous lower leg ulcers

Chronic ulcers, like venous lower leg ulcers, fail to progress through a normal, orderly and timely sequence of tissue-repair events and, consequently, take much longer to restore anatomical and functional integrity (Kirsner & Vivas, 2015: 379). This stands in contrast to “acute healing” which is described as healing that progresses in a timely and uncomplicated manner (Kirsner & Vivas, 2015: 379). The body initiates a series of continuous and overlapping events to re-establish protective function once an injury has occurred. These events are: initial haemostasis, followed by inflammation, then proliferation, ending in remodelling or maturation (Zhao, Liang, Clarke, Jackson & Xue., 2016: 2). Factors contributing to the chronicity of wounds are ageing, hypoxia, ischaemic reperfusion injury, bacterial contamination, and foreign bodies that create a “rogue” inflammatory response and prolong healing (Zhao *et al.*, 2016: 1). The average healing time for venous lower leg ulcers could be 5,9 months (Harding, Dowsett *et al.*, 2015:1), but up to 93% of venous lower leg ulcers could take up to 12 months to heal (Franks, Barker & Collier., 2016:7).

2.2.3 Prevalence of venous lower leg ulcers

Pannier and Rabe (2015:95) and Sieggreen and Kline (2012: 360) state that varicose veins are present in 10-35% of the general adult population. Epidemiological data largely come from Europe and the United Kingdom (Muldoon, 2013: 6078; Sibbald, Woo & Ayello, 2007: 426). The prevalence of chronic venous insufficiency could be as high as 17% in patients over the age of 60 years in Western countries (Pannier & Rabe, 2015: 95). According to Agale (2013: 2), chronic lower leg ulcers affect between 0,6% and 3% of the population over the age of 60 years. Similarly, Sieggreen and Kline (2012:360) note that 1-22% of the population over the age of 60 suffers from lower

extremity ulcers, which could increase to up to 5% of the population over the age of 80 years (Harding et al., 2015:1). Rabe and Pannier (2017: 6371) conclude that the results of epidemiological studies vary from region to region due to different methods of evaluation, as well as differences in geographical regions; nevertheless, chronic venous disease remains the most common cause of venous ulceration, worldwide.

South African statistics indicates an increase in life expectancy from 55,2 to 64,4 years between 2002 and 2016, and the population over 60 has increased from 6,61% to 8,01% in 2016 (Statistics South Africa, 2016: online). With an increasing number of people over 60, a rise in the incidence of lower leg ulcers could be expected (Franks *et al.*, 2016: 6).

2.2.4 Normal structure and function of lower leg venous circulation

The lower extremity venous system is divided into three components based on its positioning with regard to the muscles and fascia (Sieggreen & Kline, 2012: 361). The venous system comprises deep, superficial and perforator veins and begins at post-capillary level (Sieggreen & Kline, 2012: 363; Carmel & Bryant, 2016: 168). The posterior and anterior tibial veins, as well as peroneal veins, extend form the deep system in the lower leg and form the popliteal vein that becomes the femoral vein. These veins are located in close proximity to, or within, the calf muscle (Carmel & Bryant, 2016: 191).

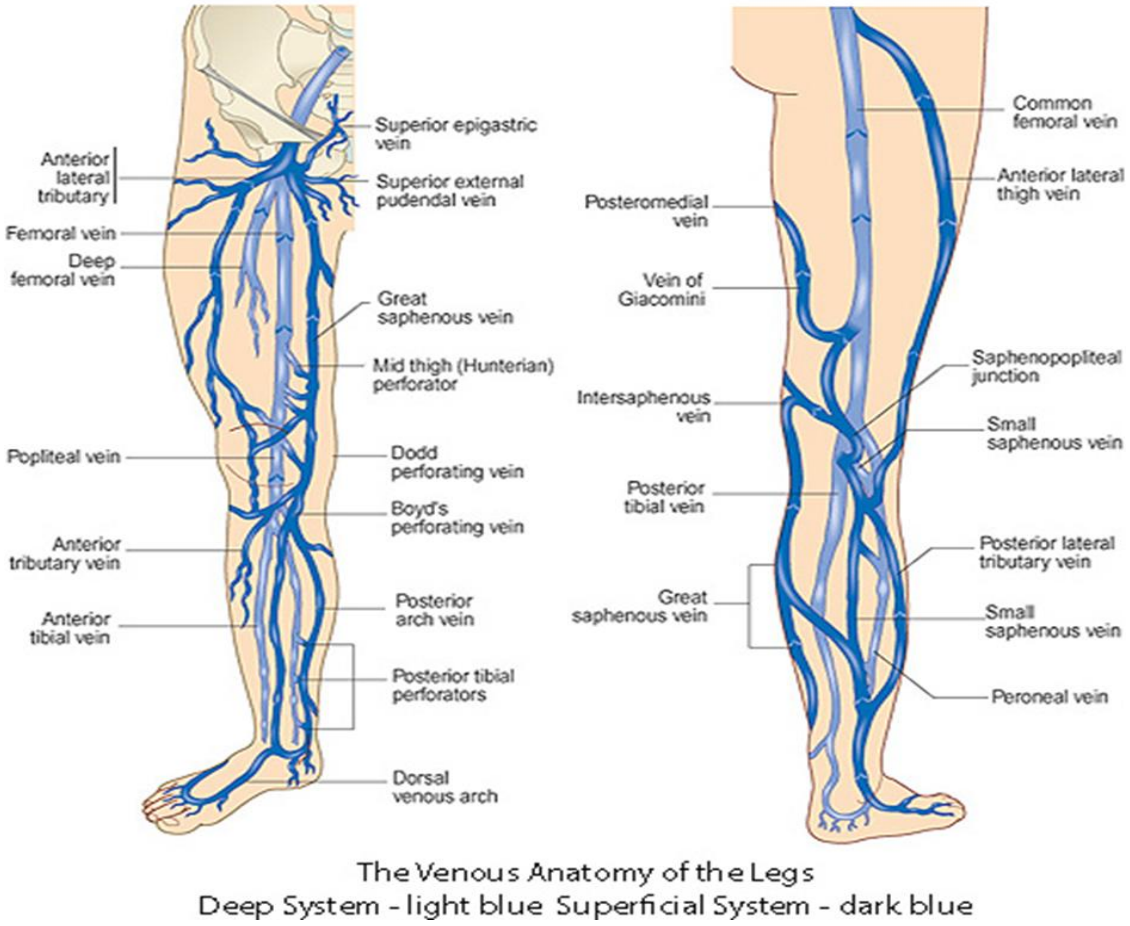


Figure 2.1 Venous anatomy (adopted from Padberg, 2017: 2019)

The superficial venous system comprises the greater and lesser saphenous veins. These veins lie above the fascia and are located within the subcutaneous tissues. They travel up from the dorsum of the foot to the groin and drain the cutaneous circulation (Mamou, 2017: online). The lesser saphenous vein drains the posterior aspect of the calf muscle (Sieggreen & Kline, 2012:362).

The third component of the venous system is the perforator veins that join the saphenous system to the deep system by crossing through the fascia (Sieggreen & Kline, 2012: 362). The perforator's function is to shunt the blood from the superficial system to the deep system (Mamou, 2017: online). This "shunting mechanism" depends on calf muscle contraction during ambulation; the system then empties from the superficial system or saphenous system through the perforators to the deep system and back to the heart (Hess, 2013: 1394).

Bicuspid one-way valves are located throughout the system. They prevent retrograde blood flow by aiding the blood flow from distal to proximal, as the deep venous system has a much higher pressure than the superficial venous system (Bryant & Nix, 2016: 191; Sieggreen & Kline, 2012: 363).

In a standing position the hydrostatic pressure at the ankle is approximately 90mmHg. The smooth muscle tone in the venous walls, the contraction of the calf muscle pump and negative intrathoracic pressure created with inspiration are the three mechanisms, together with the bicuspid valves, that aid the return of blood to the heart (Bryant & Nix, 2016: 191).

The vein wall, which includes three smooth muscle layers (the outer adventitia, the media and the inner intima), also consists of a collagen matrix which provides strength and elastin fibres, which, in turn, compliance (Padberg, 2017: 2147). Venous hypertension disrupts the muscle layer and causes loss of contractility and vessel dilation (Sieggreen & Kline, 2012: 362). It is generally accepted that venous pathophysiology is primarily caused by valvular incompetence. However, as early as 1940 it was conceptualized that wall weakness could contribute to valve dysfunction (Abdel-Naby, Duran, Lal, Padberg & Pappas., 2017: 63), whereas Keijsers, Leguy, Huberts, Narracott, Rittweger & Van de Vosse (2016: 2851) argue that valve dynamics are determined by the vein radius, as well as the valve opening and closing pressures.

The negative thoracic pump, encompassing the thoracic cavity, lungs, heart and diaphragm, supports venous return together with the calf muscle pump. With deep breathing the intra-thoracic pressure becomes negative and stimulates venous return. Effective venous return depends on positive intra-abdominal and negative intrathoracic pressures (Padberg, 2017: 2190).

2.2.5 Risk factors for the development of venous lower leg ulcers

Risk factors are “any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury” (WHO, 2017: online). Both Parker, Finlayson, Shuter and Edwards (2015:969) and Kirsner and Vivas (2015:380) identify risk factors specifically for ulceration and the accompanying delayed healing. Table 2.1 is an amalgamation of the identified risk factors.

Table 2.1 Risk factors for the development of chronic venous ulcers (Kirsner & Vivas, 2015: 380; Parker *et al.*, 2015: 969)

Denominator	Risk factor
Age	>65 years
Gender	Female
Pathophysiological changes	Presence of reflux in deep and perforator veins, deep obstruction and combination of reflux and obstruction
History	History of superficial/deep vein thrombosis (DVT) and pulmonary embolism Previous ulcer history Parental history of ankle ulcers and family history of venous insufficiency Number of pregnancies (for women)
Skin changes	Severe lipodermatosclerosis Oedema
Duration of ulcer	Time since first ulcer episode ≥2 years
Obesity	Body mass index of more than 30 Physical inactivity Diabetes coupled with reduced mobility or lack of mobility
Occupation	Standing for long periods

The population in general is aging; thus, with an increased number of people over the age of 65, as well as the increase in prevalence of atherosclerotic occlusion caused by smoking, obesity and diabetes, the incidence of lower leg ulcers could be expected to rise (Franks & Barker., 2016: S6). Delayed wound healing is exacerbated in the population over 60 years due to reduced inflammatory response, coupled with compromised proliferation, which is known to impair wound healing (Zhao, Liang, Clarke, Jackson & Xe., 2016: 6). Advanced age has been associated with delayed or impaired healing rates, and although the rate of healing might be within normal parameters, underlying diseases, which are more prevalent in the elderly, could contribute to delayed healing (Franks & Barker, 2016: 1).

Peripheral vascular disease is not only seen in patients with advanced age, but also in patients who smoke; suffer from diabetes, hypertension or hyperlipidaemia; or have a family history of vascular disease (Kirsner & Vivas, 2015: 173). Abdel-Naby *et al*. (2017: 61) add that both genetics and a history of DVT are predisposing factors for varicose veins.

While the risk of developing a venous ulcer seems to increase with age, gender does not seem to play a significant role, as both sexes are equally effected (Motowidlo *et al*., 2011: 56). Although age has a noteworthy effect on the risk for developing venous ulceration, no significant difference seems to have been found between the sexes (Finlayson, Wu & Edwards, 2015: 1045). However, in a survey conducted in both Sweden and the UK, female predominance was as high as 62% (Stotts, Wipke-Tevis, & Hopf, 2007: 215). Furthermore, Finlayson *et al.* (2015: 1047) reported a slightly higher recurrence rate of venous ulceration among men, with 51% of male participants having a recurrent venous ulcer. These findings, thus, contradict the view that all sexes are equally at risk, together with the fact that the prevalence of varicose veins and chronic venous insufficiency seems to be much higher in women (73%) than in men (56%) due to pregnancies, which is the physiological basis for venous changes (Lohr & Bush, 2013: 37S). Pregnancy, and specifically multiple pregnancies which cause mechanical obstruction, an increase in blood volume and smooth muscle dilation due to hormonal changes, causes females to present with varicose veins and associated changes at a much earlier age (Dijkstra , Kin, Coroneos, Hazelton & Lane., 2014: 88). According to Abdel-Naby *et al*. (2017: 61), females have a higher risk of developing varicose veins and accompanying chronic venous insufficiency.

Venous abnormalities such as deep vein insufficiency, a history of DVT and popliteal vein reflux contribute to an increased risk for venous ulcer development (Parker *et al.*, 2015: 46). According to Pannier and Rabe (2017: 6460), venous reflux is the consequence of valvular dysfunction and wall dilation. Finlayson *et al*. (2015: 1049) adds a history of previous ulceration and the total duration of the previous ulcer (more than two years) as significant risk factors. Similarly, Sieggreen and Kline (2012: 363) states that DVT could precede venous ulceration and that both symptomatic and asymptomatic thrombi could lead to scarring. Valve incompetence, with or without obstruction, is a direct cause of venous hypertension and venous disease (Keijsers *et al.*, 2016: 2846).

Lipodermatosclerosis is a type of panniculitis or inflammation of the subcutaneous tissue associated with venous insufficiency (Sieggreen & Kline, 2012: 367). This condition is characterized by skin induration (hardening), increased pigmentation, oedema, erythema and “inverted champagne bottle” or “bowling pin” appearance (Sieggreen & Kline, 2012: 366). Typically, Lipodermatosclerosis results in trophic skin changes associated with the “white cell trapping theory”, which posits that venous insufficiency and venous ulceration are caused by neutrophil aggregation in the capillaries (Sieggreen & Kline, 2012: 367).

Venous lower leg ulcers typically have a high recurrence rate, prolonged healing rate and a repetitive cycle (Finlayson *et al.*, 2015: 1043). The average time of recurrence seems to be 42 weeks and, according to Finlayson et al. (2015: 1044), recurrence could be as high as 73% within two years, with an increase in recurrence of up to 78% at three years. Recurrence is defined as “a breakdown of skin over the same lower leg as the previous ulcer” (Finlayson *et al*., 2015: 1043). A duration of more than one year is also associated with a recurrence rate of up to 70% (Vasudevan, 2014: 366).

Obesity leads to decreased mobility and reduced calf muscle function, which could contribute to venous ulceration (Parker *et al.*, 2015: 47). Obesity is also associated with delayed healing (Finlayson *et al*., 2015: 970). According to the WHO (2015: online), more than a third of the world’s adult population has a body mass index of more than 30 and thus classified as obese. Davies, Popplewell, Singhal, Smith and Bradbury (2016: 1) use the term “phlebesity” to describe to correlation between obesity and venous disease.

The underlying pathophysiology, i.e., an increase in femoral vein pressure and diameter, failure of venous valve function, immobility and the increased incidence of diabetes in obese patients, supports the conclusion that there is a very high correlation between the development of chronic venous insufficiency and obesity (Engelberger *et al.*, 2014: 804; Davies *et al.*, 2016: 2).

Calf muscle inactivity increases hydrostatic pressure produced by gravity, causing increased filtration of fluid into the interstitial space which ultimately produces oedema (Padberg, 2017: 2217). Oedema could lead to skin breakdown and ulceration.

Furthermore, oedema contributes to a decrease in oxygenation and the supply of nutrients to the tissues, which could be a contributing factor in delayed healing (Gordon *et al.,* 2015: 56). It is important to control oedema to prevent skin breakdown and ulceration (Gordon *et al*., 2015:56). In jobs that require periods of long standing or sitting, the increased hydrostatic pressure raises the outward wall tension and causes distention of the vessel, with subsequent valve dysfunction and increased venous hypertension (Blebea, 2017: 50).

2.3 Physiology of wound healing

To understand chronic wound healing mechanisms, it is necessary to describe the process of normal wound healing, or acute wound healing. Wound healing is an intricate sequence of four distinct, yet overlapping, phases (Young & McNaught, 2014: 475). These phases include haemostasis, inflammation, proliferation, and maturation or remodelling (Flanagan, 2013: 31). When injury occurs, there is a loss of continuity in the skin. The body's immediate response is to limit the damage by preventing exsanguination, restoring tissue integrity and re-establishing barrier function (Flanagan, 2013: 31). Wounds that extend down to the dermis heal by tissue repair and not by regeneration, because deep dermal structures, such as hair follicles, sebaceous glands, sweat glands, subcutaneous tissue, and other structures such as muscle, bone and ligaments are not able to regenerate (Daughty & Sparks, 2016: 63). The tissue is replaced, but the structure and function of the original tissue, i.e., appendages, nerves, blood and lymph vessels, are lost (Flanagan, 2013: 32). Acute wounds are wounds that proceed through the phases of wound healing in an orderly and timely manner as expected to establish anatomical and functional integrity, whereas chronic wounds fail to proceed through these phases as expected (Young & McNaught, 2014: 475).

Because of the amount of connective tissue needed to fill the deficit in chronic wounds, one characteristic of these wounds is its pattern of healing, which alternates between normal healing, recurrent breakdowns and delayed healing (Daughty & Sparks, 2016:63; Martin, 2013: 44).

After initial injury, the first response of the body is haemostasis, i.e., the attempt of the body to limit blood loss by vasoconstriction and initiating the clotting cascade. Further blood loss is managed by initiating the intrinsic and extrinsic clotting cascades in which the platelets play a vital role. Shortly after the reduction in blood flow due to vasoconstriction, a release of vasoactive metabolites causes reflex vasodilation (Young & McNaught, 2014: 476).

The inflammatory phase of wound healing entails a vascular response and a cellular response (Young & McNaught, 2014: 475). The mast cells concurrently release histamine to increase vasodilation. This results in an increase in vascular permeability to facilitate the movement of cells into the interstitial space which, in turn, causes the typical signs and symptoms of inflammation, namely redness (erythema), swelling (oedema), pain, heat and loss of function (Martin, 2013: 35). Platelets are key to the healing process, as they produce multiple growth factors and cytokines which regulate the healing cascade (Young & McNaught, 2014: 476). The initial priority is to prevent infection, clean the wound and optimize the wound environment so that healing can take place (Martin, 2013: 36). After initial haemostasis and clot formation, fibrinolysis or breakdown of the clot occurs as a result of platelets rupturing and the subsequent release of the growth factors and cytokines that are required to begin the repair process (Daughty & Sparks, 2016: 66).

Mast cells and platelets release chemotactic agents which attract neutrophils to the damaged tissue. Neutrophils are present in the wound within an hour after injury; they are seen as the “first responders” in that their function is to kill bacteria and remove debris (Holloway, Harding, Stechmiller & Schultz, 2012: 88; Young & McNaught, 2014: 477). The second cell to join in the fight against infection is the macrophages, but they only arrive from about 48 hours after injury (Holloway *et al.*, 2012: 89). Macrophages not only remove debris from the wound bed through phagocytosis, but also regulate cytokines, growth factors and proteolytic enzymes (Holloway *et al.*, 2012: 89; Young & McNaught, 2014: 475).

In acute wounds the inflammatory phase is usually short and occurs within an expected time frame, whereas in chronic wounds this phase could be prolonged due to infection, the presence of devitalized tissue, or underlying diseases such as diabetes where leukocyte migration is impaired (Bryant & Nix, 2016: 68; Daughty & Sparks, 2016:73).

Macrophages are responsible for the release of growth factors that accelerate angiogenesis, fibroblast migration and proliferation, as well as the synthesis of connective tissue (Daughty & Sparks, 2016: 73).

Another important cell in this wound healing cascade is the T lymphocyte that releases cytokines and terminate viral organisms and foreign cells. A deficiency in both T lymphocytes and macrophages could delay wound healing. Following the “fighting infection and clean-up phase”, the wound bed is ready for the proliferative phase. This phase encompasses an array of complex processes which include angiogenesis, fibroplasia that results in the formulation of granulation tissue, as well as collagen depositions, epithelization and, ultimately, wound retraction (Young & McNaught, 2014: 477).

Angiogenesis is the formation of a new network of capillaries that is triggered directly post haemostasis (Young & McNaught, 2014: 477; Daughty & Sparks, 2016: 74). In response to hypoxia, vascular endothelial growth factor is released to trigger neovascularization and the repair of damaged blood vessels (Young & McNaught, 2014: 477). As a consequence of growth factor release, fibroblast proliferates and migrates to the wound, an extra-cellular matrix is laid down, and collagen and fibronectin are produced. The fibrinous tissue that fills the wound is known as granulation tissue (Young & McNaught, 2014: 477). Once the deficit has been filled, the fibroblasts change into myofibroblasts, which enables them to connect to surrounding tissue, namely fibronectin and collagen, and aid wound contraction (Young & McNaught, 2014: 478).

The ultimate outcome is a wound bed that is covered by epithelial tissue. Epithelization is the migration of cells from the edge of the wound. This motility is caused by epithelial-mesenchymal transition (EMT) which allows the epithelial cells to travel across the wound bed (Young & McNaught, 2014: 476; Daughty & Sparks, 2016: 73).

The final phase of wound healing is remodelling or maturation. In this phase collagen and other proteins are re-organized, and the scar matures (Young & McNaught, 2014: 478). This phase could be protracted for up to two years post injury, after which the matured skin will only have 50% of the tensile strength of uninjured skin (Young & McNaught, 2014: 478).

2.4 Factors influencing wound healing

Various factors could influence wound healing from the initial haemostatic process through to the remodelling phase. These factors are divided into local and systemic factors: Local factors refer to factors within the wound and periphery that could influence healing, and systemic factors refer to factors within the patient that could influence healing (Martin, 2013: 37).

Table 2.2 is a summary of the factors that could influence wound healing and their effect on wound healing.

Table 2.2 Factors in wound healing and their effect (adapted from Martin, 2013: 37)

Factors	Effect on wound healing
Local	
Inadequate wound perfusion	Increased risk of infection
Presence of non-viable or devitalized tissue	Increased risk of infection
Wound infection	Delayed wound healing / wound degradation
Excess proteases	Wound degradation
Systemic	
Immune deficiency or suppression	Inhibition of cellular proliferation
Adverse effects of treatment	Treatments such as radiation, chemotherapy, steroid therapy or anti-inflammatory drugs could be a co-factor in healing impairment
Systemic condition, e.g., diabetes	Hyper-glycaemia increases the risk of infection, wound ischaemia
Advanced age	Impaired immune response
Obesity	Increased risk of infection, wound dehiscence, pressure ulceration
Malnutrition	Protein loss, increased risk of skin breakdown

Factors	Effect on wound healing
Cigarette smoking	Vasoconstriction and hypoxia contribute to delayed wound healing and increased risk of complications

Perfusion of the wound tissues is vital for healing, because a reduction in oxygen levels is associated with reduced fibroblast proliferation, as well as impaired collagen production and poor healing (Stotts, Wipke-Tevis & Hopf, 2012:7583; Martin, 2013: 37). Although initial hypoxia is required to stimulate angiogenesis and re-epithelization, chronic hypoxia in the wound bed could result in the presence of devitalized tissues, which creates an ideal medium for bacterial growth and increases the risk of infection (Martin, 2013: 38; Young & McNaught, 2014: 376). With insufficient oxygenation, leukocyte activity is decreased, which further increases the risk of infection (Stotts, Wipke-Tevis & Hopf, 2012: 7583). Anaemia could be a contributing factor to delayed healing, but only in severe cases when haematocrit levels are below 18% (Stotts, Wipke-Tevis & Hopf, 2012: 7583).

Devitalized or non-viable tissue and bacteria release endotoxins that increase pro-inflammatory cytokines and matrix metalloproteases (MMPs), resulting in a prolonged inflammatory phase and delayed healing (Martin, 2013: 38). Furthermore, the presence of bacteria or devitalized tissue degrades growth factors and inhibits the proliferation of cells (Martin, 2013: 40). In the presence of infection or increased bioburden, bacteria compete with the fibroblasts for oxygen and nutrients and wound healing is thus delayed (Bryant and Nix, 2016: 76). Infection impedes wound healing due to the equilibrium in the wound being disturbed and the high levels of bacteria causing tissue destruction (Marston, Tang, Kirsner & Ennis, 2016: 138). Infection is discussed at length under point 2.7.3. Both a high level of micro-organisms and the presence of excess proteases such as polymorphonucleocytes (PMLs) and MMPs could augment a prolonged inflammatory phase due to the destructive nature of these enzymes and organisms (Percival, Finnegan, Donelli, Vuotto, Rimmer & Lipsky, 2014: 293). This will cause delayed healing.

Immunosuppression leads to an increased risk of infection due to the body's inability to respond to infection (Bryant and Nix, 2016: 76). Delayed healing is associated with immune-compromised patients, as they do not respond to injury as expected and inflammation is reduced (Martin, 2013: 54).

The iatrogenic effects of radiation, chemotherapy, steroids and anti-inflammatory drugs could also delay healing (Stotts, Wipke-Tevis & Hopf, 2012: 7751). Radiation leads to skin hypoxia due to the disruption of cell mitosis and obliteration of arteries, while chemotherapy interrupts the cell cycle and damages DNA (Stotts, Wipke-Tevis & Hopf, 2012: 7767). Steroids suppress the inflammatory response and all phases of healing, and so do non-steroid anti-inflammatory drugs (Stotts, Wipke-Tevis & Hopf, 2012: 7767).

Chronic diseases such as diabetes are associated with prolonged inflammation. This might be ascribed to impaired leukocyte migration or leucocyte dysfunction which causes ineffective control of the bacterial load and, in turn, an increased risk of infection (Stotts, Wipke-Tevis & Hopf, 2012: 7733; Bryant & Nix, 2016: 68). The formation of a mature extra-cellular matrix depends on collagen production and granulation tissue formation, and diabetes is indeed associated with delayed deposition of both granulation tissue and collagen, causing reduced tensile strength and epithelial migration, especially in the presence of hyper-glycaemia (Bryant & Nix, 2016: 70).

Age-related skin changes result in an overall decline in the function of the skin. This is caused by a decrease in epidermal regeneration, tensile strength, vascular response and the reproduction of the Stratum Corneum, all of which render the skin weaker and more prone to injury (Hess, 2013, p. 278). Other changes include the shrinking of the Langerhans cells and melanocytes which not only makes the skin more sensitive to sunlight damage, but also reduces the skin's ability to fight infection (Hess, 2013, p. 278). A reduction in the production of sebum and sweat results in dryness and the diminishing of subcutaneous tissue, which leads to a reduction in natural insulation (Hess, 2013, p. 290). Co-morbidities associated with advanced age also contribute to slower healing and a higher risk of wound complications (Young & McNaught, 2014: 478).

Obesity is linked to a higher incidence of infection due to the fact that adipose tissue is poorly vascularized (Bryant and Nix, 2016: 76). Obesity is also linked to malnutrition; thus, obese patients could be deficient of essential nutrients (Lewis, Bucher, McLean, Harding, Kwong & Robberst, 2017: 58897). Obese patients also suffer from increased pelvic congestion, with a concomitant reduction of blood flow which, in turn, causes the pooling of blood and oedema (Muldoon, 2013: 6189; Pannier & Rabe, 2015: 97).

Malnutrition, which results in inadequate levels of protein, reduces wound tensile strength and resistance to infection (Stotts, Wipke-Tevis & Hopf, 2012: 7618; Martin, 2013: 37). This, in turn, prolongs the inflammatory phase, reducing angiogenesis, fibroblast function, as well as collagen depositions (Young & McNaught, 2014: 479). Malnutrition, furthermore, increases susceptibility to pressure injuries and the risk of infection (Young & McNaught, 2014: 379). Both macro- and micro-nutrient deficiencies could affect wound healing negatively. Vitamin C levels affect collagen formation, vitamin B is involved in protein synthesis, granulation tissue formation and epithelization, while vitamin A is important in angiogenesis, chemotaxis and macrophage mobility (Stotts, Wipke-Tevis & Hopf, 2012: 7634; Martin, 2013: 37).

The effects of smoking are well documented, especially the triad of nicotine, carbon monoxide and hydrogen cyanide, whose interaction has toxic effects (Stotts, Wipke-Tevis & Hopf, 2012: 7634; Marston *et al.*, 2016: 139). Nicotine causes vasoconstriction and increased platelet aggregation. Carbon monoxide displaces oxygen from haemoglobin, thereby reducing the ability of haemoglobin to carry oxygen. Enzyme inhibition caused by hydrogen cyanide also reduces the cellular transport of oxygen (Stotts *et al*., 2007:216). Ultimately, the triad contributes to an increase in wound hypoxia. Decreased perfusion is associated with impaired healing rates and an increased risk of infection (Stotts *et al*., 2007:216).

2.5 Pathophysiology of venous lower leg ulcers

Ulceration is, ultimately, a clinical sign of underlying pathophysiological processes (Eberhardt & Raffetto, 2014: 334). The basic aetiology of venous lower leg ulcers is venous hypertension (Kirsner & Vivas, 2015: 380). The pathophysiological process of ulceration starts with chronic venous insufficiency caused by valvular incompetence, impaired venous return and consequential venous stasis (Vasudevan, 2014: 366).

Venous hypertension develops due to the incompetent valves, causing retrograde blood flow, pooling of the blood with increased pressure and dilation of the vessel walls, with subsequent ulceration (Eberhardt & Raffetto, 2014: 335). Chronic venous disease results in a “persistent elevated ambulatory venous pressure” (Ligi *et al.*, 2016: 1964; Raffetto, 2017: 4248). This venous hypertension leads to venous stasis with endothelial cell activation. Transcellular gaps form between the endothelial cells and, in turn, cause extravasation or erythrocytes and leucocytes (Ligi *et al.*, 2016: 1964).

Chronic venous insufficiency manifests as venous hypertension and execution deviations in either the deep or superficial venous systems or both. This leads to oedema, skin changes such as hemosiderin staining, purpura, eczema, lipodermatosclerosis and, ultimately, ulceration (Pannier & Rabe, 2015: 56; Carmel & Bryant, 2016: 190). Sibbald *et al*. (2007: 433) list ankle flare, lipodermatosclerosis, varicose veins, atrophy blanche, oedema and eczema as “differentiating features” in venous lower leg ulcers.

Venous hypertension, rather than venous stasis, seems to be the cause of ulceration, as well as the reason why these wounds do not want to heal (Sieggreen & Kline, 2012: 363). In the venous system the flow is intermittent and the veins are collapsible, which complicate the dynamics seeing that the flow also depends on gravity, hydrostatic pressure and extrinsic muscles (Sieggreen & Kline, 2012: 363; Blebea, 2017: 3425). Venous ulceration is often triggered by either asymptomatic or symptomatic thrombi, as they cause scarring and could lead to valvular incompetence (Sieggreen & Kline, 2012: 363). From a haemodynamic perspective, an obstruction in the superficial system might not be a major consideration, since the main venous outflow occurs through the deep veins (Eberhardt & Raffetto, 2014: 336; Blebea, 2017: 3271). In contrast, valvular incompetence and reflux in the superficial system are associated with both a clinical sequelae and hemodynamic effects (Blebea, 2017: 52). Weakness in the vein wall that causes venous dilation and valve ring enlargement is the primary aetiology of superficial valvular reflux (Blebea, 2017: 52; Eberhardt & Raffetto, 2014: 336). The abnormal elastic properties found in varicose veins support the theory that valvular incompetence is secondary to a vein wall defect (Blebea, 2017: 52).

Deep veins play a large role in the hemodynamics of the lower leg. Deep vein thrombosis is associated with a higher mortality risk than, for instance, a superficial thrombotic event, caused by pulmonary embolism and a more significant

hemodynamic impact due to obstruction (Blebea, 2017: 54; Carmel & Bryant, 2016: 192). An acute thrombosis in either the femoral or iliac veins can limit outflow to such an extent that arterial flow is diminished with ischaemia and possible loss of limb (Blebea, 2017: 54; Carmel & Bryant, 2016: 192). The hemodynamic changes and venous outflow are determined by the extent of the obstruction, as well as the formation of collateral pathways (Blebea, 2017: 56; Gordon *et al*., 2015: 56). Thrombi, whether occlusive or non-occlusive, could have significant hemodynamic effects and affect valve function, thus producing reflux and post-thrombotic damage which, together, is the most important cause of chronic venous insufficiency (Blebea, 2017: 56; Carmel & Bryant, 2016: 191).

2.5.1 Calf muscle pump

The functioning of the peripheral venous system depends on the potency of the one-way bicuspid valves within the vessels, as well as the calf muscle pump (Eberhardt & Raffetto, 2014: 335). The function of the valves, in conjunction with the muscle pump, is to return blood against gravity back to the heart (Eberhardt & Raffetto, 2014: 334). Contraction of the calf muscle forces blood out of the venous plexus to ascend up the deep venous system, and relaxation of the calf muscle allows blood to refill the deep venous system (Eberhardt & Raffetto, 2014: 335). Hippocrates noted already about 2 500 years ago that “it was better not to stand in the case of an ulcer on the leg”; however, the mechanism underlying the formation of a venous leg ulcer remains elusive (Raffetto, 2017: 4206).

The calf muscle plays a pivotal role in the compression of the deep veins and aiding venous return (Blebea, 2017: 57; Sieggreen & Kline, 2012: 363). Resting venous pressure in the leg is measured at about 100 mmHg, which then reduces to about 30 mmHg with calf muscle contractions (Blebea, 2017: 57; Carmel & Bryant, 2016: 192; Eberhardt & Raffetto, 2014: 336). Pressure around the ankle area is measured at about 90 mmHg in a standing position, but ambulatory pressure reduces to about 10-30 mmHg in the foot (Blebea, 2017: 57). Even with valvular incompetence in the deep system, the calf muscle can compensate to a certain extent but, with obstruction, coupled with fibrotic disease of the lumen and perforator incompetence, the calf muscle becomes ineffective (Blebea, 2017: 57).

With obstruction, severe valvular insufficiency and insufficient outflow in the deep system result in persistent ambulatory venous hypertension (Keijsers *et al.*, 2016: 2846). Obstruction can be caused by previous DVT, pregnancy, obesity, previous trauma or surgery to the leg, as well as tumours or congenital defects within the venous system (Patel, 2016: online).This ambulatory venous hypertension increases capillary hydrostatic pressure which, in turn, causes the exudation of high protein content with interstitial fluid and associated skin changes of chronic venous insufficiency (Blebea, 2017: 58; Keijsers *et al.*, 2016: 2846).

Exudation of the fluid into the interstitial space results in oedema (Sieggreen & Kline, 2012: 364). Red blood cells leak out into the tissue and, when they break, deposit haemoglobin into the tissues. This leads to hemosiderin staining or the brownish hue that discolours the leg in a "sock distribution" (Sieggreen & Kline, 2012:364). The accumulation of fluid and high protein content in the skin cause the skin to lose its normal texture and become sclerotic, shiny and tight in appearance (Sieggreen & Kline, 2012: 364). Thickened skin, hemosiderin staining, dermatitis, atrophie blanche and ulceration are all trophic changes linked with chronic venous insufficiency (Lohr & Bush, 2013: 39S). Ambulation could also aid in controlling the oedema by improving the function of the calf muscle pump (Gordon, Widener & Heffline, 2015: 55).

The pathophysiology of skin abnormalities is a complex process involving venous hypertension, injury to the glycocalyx glycosaminoglycan coating of the endothelial cells, and inflammatory cell activation and infiltration (Ligi *et al.*, 2016: 1963; Raffetto, 2017: 4193). Changes in the microcirculation, coupled with altered cellular function due to matrix metalloproteinase activation and overexpression of cytokines, result in tissue destruction and delayed wound healing. These changes are all subject to genetics and environmental influences (Raffetto, 2017: 4193).

Raffetto (2017: 4696) notes that the inflammatory cascade is initiated by leucocyte activity and that the dysfunctional leucocytes, senescent fibroblasts and macrophages play a key role in ulcer formation. Venous ulcer wound fluid also has an inhibitory effect on cytokines and the activation of matrix metalloproteinases, resulting in tissue destruction and a chronic inflammatory state (Raffetto, 2013: 62; 2017: 4525).

2.5.2 Theories regarding venous ulcer formation

Three theories have emerged regarding the pathophysiology of venous leg ulcer formation, the first of which is the fibrin cuff theory. According to Sieggreen and Kline (2015: 12107), sustained venous hypertension causes distention of the capillary bed, which leads to plasma leaking into the tissue and fibrin precipitation in the peripapillary space forming the fibrin cuff. The fibrin cuff impairs oxygen, as well as nutrient and growth factor transport (Sieggreen & Kline, 2015: 12107). Liu, Margolis & Isseroff (2011: 818) describe the cuff theory also based on the premise that increased fibrin deposits cause elevated venous pressure and increased vascular permeability which, in turn, result in enlarged endothelial pores with a subsequent increase in fibrinogen deposits. The dermal interstitium also contains collagen fibres that are in disarray, and the cuff mainly consists of extra-cellular matrix protein and collagen fibres (Abdel-Naby *et al*., 2017: 66). The fibrin cuff surrounding the capillaries was initially thought to reduce oxygen permeability, leading to tissue hypoxia and possible wounding (Vasudevan, 2014: 366). Recent evidence, however, suggests that the cuff could be the body's attempt to maintain vascular architecture and that it is the trapped cells and molecules in the dermis that cause fibrosis and inflammation (Abdel-Naby *et al*., 2017: 65).The second theory, the inflammatory trap theory or white cell trapping theory, claims that inflammatory cells such as leucocytes, which are trapped in the capillaries, release proteolytic enzymes and reactive oxygen metabolites with subsequent endothelial damage. Injured capillaries become more permeable and thus accentuate fibrin deposits, whereas occlusion by leukocytes contributes to tissue hypoxia and reperfusion damage (Vasudevan, 2014: 366).

A third theory refers to the entrapment of growth factors. Growth factors are important mediators in wound healing; thus, "trapping" them could result in delayed wound healing (Raffetto, 2017: 4178). These theories, although just theories, seem to be steering current research towards leukocyte function, the effects of growth factors and cytokines, as well as the role of peri-capillary changes in ulcer formation in the presence of chronic venous insufficiency (Raffetto, 2017: 4226).

2.6 Assessment of venous lower leg ulcers

Assessment of venous lower leg ulcers entails various aspects that include subjective data, objective data collection, classification, differential diagnoses, working or final diagnosis and, finally, developing a patient-oriented care plan. Re-assessment is essential to establish whether outcomes of the care plan are being reached (Benbow, 2016: 41). Figure 2.2 is a schematic representation of the assessment process.

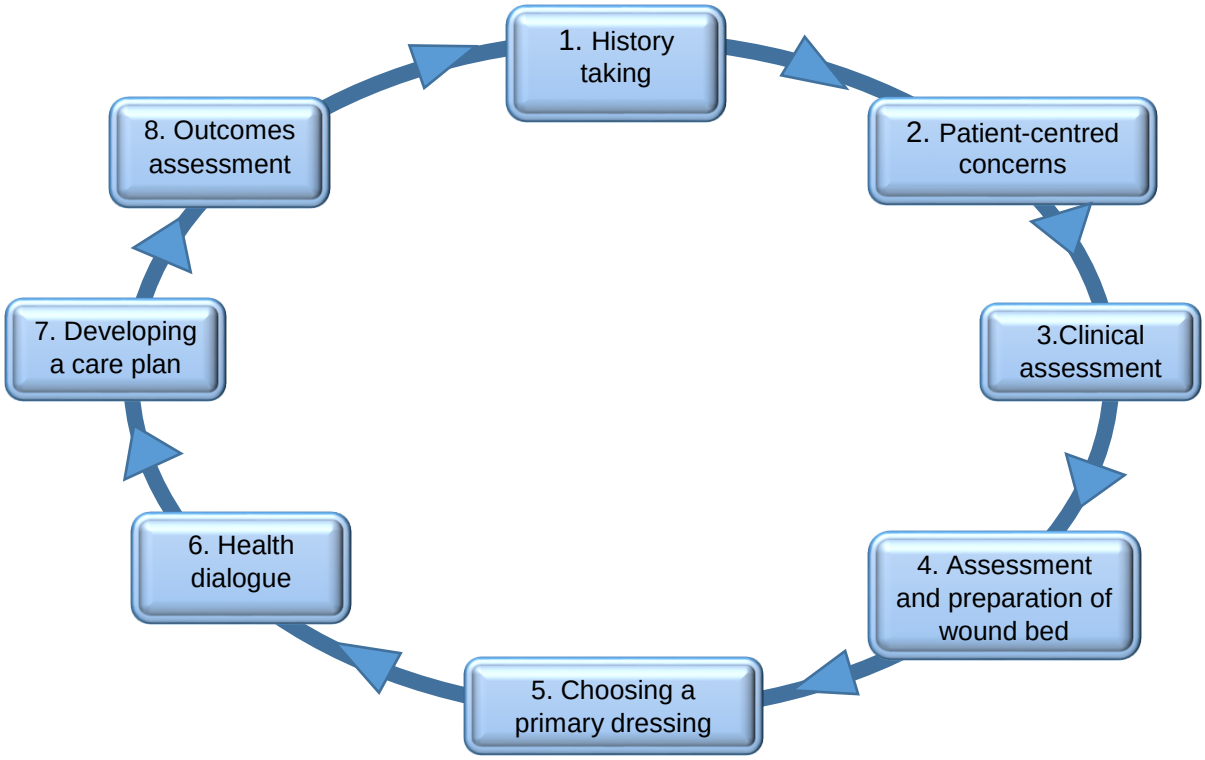


Figure 2.2 Schematic representation of the assessment process

Professional practice dictates that health professionals perform a holistic assessment of a patient. Such assessment should consider patient preference, as well as acceptance of and concordance with the treatment plan (Benbow, 2016: 40). Information collected by means of thorough history taking and wound assessment enables the care provider to develop a care plan that will meet the treatment goal. The purpose of follow-up assessments is to monitor outcomes and evaluate treatment effectiveness (Van Rijswijk & Eisenberg, 2012: 113). Both Cornforth (2013: S28) and Benbow (2016: 41) concur by stating that a comprehensive assessment, which is holistic and incorporates social, psychological and lifestyle assessments, as well as environmental aspects and psychosocial support, is key to accurate diagnosis and monitoring the effect of the intervention. Assessment tools assist clinicians in performing a holistic assessment and include all the aspects of assessment: from obtaining data on demographics and risk factors, to other factors that might impede wound healing. WHASA developed such an assessment tool in 2007 and published it in 2008 (Naudé, 2008: 16).

The information obtained from the holistic assessment should be interpreted by the health care professional to determine the diagnostic indicators towards ulcer aetiology as well as realistic expectations regarding the healing trajectory (Benbow, 2011: 11; Franks & Barker, 2016: S28). Sibbald *et al.* (2011: 416) state that one should "treat the patient and not the hole in the patient". Assessment is not only about the wound, but also about the patient's inherent ability to heal (Hamm, 2015: 1567). Based on the information gathered, appropriate treatment decisions can be made, progress monitored and complications avoided (Benbow, 2016: 41). The best quality wound management would be ineffective if risk factors and co-morbidities are not identified during the assessment and taken into consideration when developing the care plan (Benbow, 2016: 41; Stotts *et al*., 2012: 7542). The effectiveness of a specific intervention cannot be determined when there is no baseline data to compare it with; thus, assessment and re-assessment are the only way to determine whether the wound is progressing towards the desired outcome (Benbow, 2011: 12; Cornforth, 2013: S29; Van Rijswijk & Eisenberg, 2012: 113).

2.6.1 History taking

A holistic assessment is done in order to identify potential barriers to healing, prioritize treatment objectives, and consider treatment options, all while considering evidence-based efficacy and cost-effectiveness (Benbow, 2016: 42; Flanagan, 2013: 54). Demographic data are important to identify the patient, with age being vital, as many studies indeed indicate that advanced age reduces the skin's ability to repair and regenerate due to a reduction in collagen formation (Benbow, 2011: 7; Hellström *et al*., 2016: 2). Advanced age is a risk factor for the development of venous lower leg ulcers (Parker *et al*., 2015: 69). A comprehensive assessment includes a full history of the patient and the problem, a physical examination and diagnostic and laboratory tests (Mulder, Small, Botma, Zaidy & Mackenzie, 2002: 284). History should also include a family history of venous disease, factors that could contribute to valvular disfunction, calf muscle pump dysfunction and barriers to healing (Johnson, Yates & Burgess, 2016: 1781). Conditions that might compromise valvular function include obesity, multiple pregnancies, previous DVT or phlebitis, thrombophilia and inflammatory auto-immune diseases such as systemic lupus erythematosus (SLE) (Johnson, Yates and Burgess, 2016, p. 1783). Conditions that result in calf muscle dysfunction include advanced age, altered gait, sedentary lifestyle, reduced mobility and paralysis (Johnson, Yates & Burgess, 2016: 1783).

Table 2.3 sets out the aspects of history taking regarding the presentation of the problem, i.e., the ulceration, as well as the rationale thereof.

Table 2.3 Assessment of the presentation of the ulceration (adapted from Johnson *et al.*, 2016: 1783; Mulder *et al*., 2002: 284)

Presentation of the ulceration	
Assessment	Rationale
Cause of the injury?	Venous ulcer formation is associated with previous trauma and a history of DVT or fractures.
Triggers for ulceration?	Preceding events such as cellulitis, contact dermatitis, rapid onset oedema, burns, pruritis or insect bites.

Presentation of the ulceration	
Assessment	Rationale
Activities of daily living: How are they influenced?	Information about how the patient functions daily, mobilization, work, social behaviour and patient's self-concept.
Is this a recurrent ulcer?	Recurrence could indicate an unaddressed underlying cause.
Age of the wound: How long has the patient had the ulcer?	Chronicity increases risk of infection and stalled healing could be due to concomitant disease.
Pain: What action alleviates the pain or worsens the pain?	Pain could be subjective, but pain is often worsened with prolonged dependency and relieved with leg elevation in ulcers of venous origin. In contrast, with ischaemic ulcers, pain is reduced when feet are lowered. Pain might limit mobilization.
Associated symptoms: Oedema, skin discolouration, eczema, hair loss	Presence of oedema, leg discolouration and eczema are characteristics of an ulcer of venous origin, as well as feelings of heaviness and aching. Hair loss and pale limbs are characteristics of arterial insufficiency.
Previous treatment, current treatment and their efficacy	Previous and current treatment of the wound, including dressing history and efficacy of the treatment, should be collected, as this would influence future dressing choices, together with information about underlying causes that have not been addressed (Mulder *et al.*, 2002: 285; Hess, 2013: 824).
Progress towards healing	Progress towards healing is an indication of the effectiveness of treatment and when considering a healing trajectory, healing will not be possible by week 12 when the wound size has not reduced by 30% by week 4 (Sibbald, *et al.*, 2011: 418).

Previous hospitalization, chronic illnesses and trauma serves as a review of the patient's medical and surgical history (Hess, 2013, p. 823). Any previous venous or arterial surgery could indicate underlying pathology (Mulder *et al.*, 2002: 285). Sclerotherapy involves the use of hypertonic sodium chloride solutions or polidocanol foam to obliterate telangiectasias, varicose veins and venous segments with reflux (Eberhardt & Raffetto, 2014: 342). This treatment can be provided not only as a primary treatment in chronic venous insufficiency, but also in conjunction with surgery. A history of sclerotherapy could indicate underlying pathology (Mulder *et al.*, 2002: 285). Raffetto (2017: 4324) does, however, point out that the recurrence rate for varicose veins is measured at about 11% up to two years post sclerotherapy. Obtaining this information during history taking could aid in assessing the severity and history of chronic venous insufficiency.

Pain assessment also forms part of history taking. The Wong-Baker Faces Pain Rating Scale, originally developed by Dr Dona Wong and Connie Baker to assist children in communicating their pain, is now a universally accepted tool (Oliveira *et al.*, 2014: 122). Wound-associated pain has several documented detrimental effects on wound healing, for example, reduced tissue oxygenation levels due to stress-induced cytokine and neuroendocrine activity, with subsequent vasoconstriction, as well as overproduction of cortisol (Woo, Krasner & Sibbald, 2012: 86). Obtaining a thorough pain history that includes aggravating or alleviating factors is vital for pain management and a care plan that can improve quality of life (Woo, Krasner & Sibbald, 2012: 86).

Impediments to healing should be identified during history taking. They include underlying diseases such as diabetes, cardio-vascular disease such as hypertension and peripheral vascular disease, respiratory disease, rheumatoid arthritis, anaemia or other blood disorders, immune disorders, renal failure and obesity (Hess, 2013: 823; Johnson *et al.*, 2016: 1783; Mulder *et al*., 2002: 285). Any allergies should be excluded, as they could affect treatment choices (Hess, 2013: 824). During history taking, information about previous diagnostic tests could aid in making the correct diagnosis, which can prevent such tests from being conducted again and, thus, reduce cost (Mulder *et al.*, 2002: 285). Other factors to be considered include tobacco use, mobility, nutritional status, and stress (Benbow, 2016: 41). Smoking has a known detrimental effect on wound healing, as it contributes to vasoconstriction, arteriosclerosis and reduced oxygen supply.

Furthermore, there is a reduction in collagen formation in patients who smoke (Young & McNaught, 2014: 478). Lifestyle habits that contribute to a sedentary lifestyle and result in immobility, malnutrition and destructive habits, such as smoking, excessive alcohol consumption and inactivity, could exacerbate underlying pathology and contribute to chronic non-healing wounds (Marston *et al.*, 2016: 139).

Medication that might affect wound healing negatively include glucocorticoid steroids, non-steroidal anti-inflammatory drugs and chemotherapeutic drugs. The effects of the medication on wound healing are listed in Table 2.4. Because these medications have a negative effect on wound healing, they need to be identified and indicated as barriers to healing and considered as such within the care plan (Benbow, 2016: 42).

Table 2.4 Effects of drugs on wound healing (adapted from Guo & Dipietro, 2010: 224).

Type of drug	Effect on wound healing
Glucocorticoid steroids	Reduce cellular response Reduce fibroblast proliferation Impede granulation Impede wound contraction Increase risk for wound infection
Non-steroidal anti-inflammatory drugs	Inhibit proliferation Reduce tensile strength Delay epithelization
Chemotherapeutic drugs	Decrease fibroplasia Decrease neovascularization Inhibit cell migration

History taking also needs to include an overview of specific physical systems and information about the general condition of the patient, because any pathology in certain systems could either contribute to delayed wound healing or exacerbate underlying pathology (Hamm, 2015: 1553). Certain symptoms might also indicate an underlying disease. Table 2.5 gives a list of system-specific symptoms that need to be assessed.

Table 2.5 General overview of systems during assessment (adapted from Hamm, 2015: 1553; Mulder *et al*., 2002: 285)

Assessment	Rationale
General health: Weakness, malaise, fatigue, fever, rigors, recurrent infections, recent weight gain or loss	Could be indicative of an underlying infection or underlying chronic disease such as diabetes or renal problems.
Cardiopulmonary • Chest pain • Intermittent claudication • Shortness of breath • Lower extremity oedema	Shortness of breath or lower extremity oedema could indicate congestive heart failure or chest pain, or intermittent claudication could indicate arterial insufficiency.
Haemopoietic system	Anaemia contributes to ulcer formation as a result of reduced oxygen supply to the tissue.
Musculoskeletal • Pain • Cramps • Weakness • Mobility	Venous stasis results in oedema, pain, eczema and pruritis. Patients also often complain of “heaviness”, especially after standing or sitting for long periods. Inactivity reduces calf muscle pump function and venous return. Abnormal gait due to pain also results in muscle atrophy and exacerbation of symptoms.
Endocrine • Polyuria • Polydipsia	Symptoms suggest possible underlying diabetes mellitus with accompanying complications, i.e., increased risk of infection, peripheral arterial disease, neuropathy and delayed wound healing.
Integumentary	Hair loss, skin changes or discolouration such as pale skin could indicate peripheral arterial disease, vasoconstriction or anaemia. Cyanosis could indicate cardiac problems, and pruritis could indicate an allergic reaction or venous stasis eczema.

Finally, information about the psychosocial well-being of patients' needs to be obtained to assess psychological status. It is critical to assess patients' support structures at home, type of occupation and the effect it has on the patient, financial limitations, educational level and their perceptions about their disease (Mulder *et al.*, 2002: 287). Cultural and religious assessment is also important in order to avoid violation of patients' cultural and religious beliefs or practices (Saylor, 2017: 4564). This aspect could be addressed when assessing patient-centred concerns.

The chronicity of venous lower leg ulcers affects the quality of life of patients and their families or significant others, because these ulcers lead to impaired mobility in patients, restricted activities of daily living due to leakage, pain and odour, as well as extreme costs, both direct (dressings, bandaging, nursing services) and indirect (loss of income, travel expenses, loss of self-worth) (Regmi & Regmi, 2012: 62).

2.6.2 Patient-centred concerns

"Patient-centred care" is defined as "an approach to the planning, delivery and evaluation of healthcare that is grounded in mutually beneficial partnerships among patients, families and healthcare practitioners" and is linked to quality of care (Ayello, Courchene & Sibbald, 2012: 65). Patient-centred care places the patient in the centre and decisions are made that involve patient/person preference and concordance (Ayello, Courchene & Sibbald, 2012: 67). Patient-centred concerns, according to Sibbald's wound bed preparation paradigm, include activities of daily living, psychological well-being, access to care, and financial limitations (Sibbald *et al.*, 2011: 77).

Venous lower leg ulcers have, due to their chronicity and associated symptoms, a negative and debilitating impact on the quality of life of the person suffering from it (Woo, Van Den Kerkhof and Jimenez, 2015, p. 312). "Quality of life" is defined as individuals' subjective perception of their well-being (Woo, Van Den Kerkhof and Jimenez, 2015, p. 396). According to Szewczyk, Moscicka *et al.* (2015: 468), the level of quality of life is measured on three spheres: physical, psychological and emotional. Similarly, Vishwanath (2014: 397) proposes three factors that play a role in determining quality of life, namely physical functioning, psychosocial functioning and treatment aspects. For purposes of the study, the discussion below will address the physical, psychological, psychosocial, and financial impact of venous ulcers.

The physical sphere, as referred to by Szewczyk *et al.* (2015: 468), includes symptoms such as pain, exudate and odour, all of which can reduce physical activity. Vishwanath (2014: 398) concurs by listing the physical factors, namely exudate and odour, leakage, pruritus, infection; effects on sleep, mobility and activities of daily living; and the most significant factor, pain. Morton, Bolton, Corbett, Girolami and Philips (2013: 553) associate a reduction in quality of life with pain, leakage of exudate and associated odour, altered body image, reduced mobility, and discomfort due to bulky bandages. Gordon *et al.* (2015: 56) reiterates that pain, possibly caused by inflammation associated with skin changes and ulceration, is common and debilitating, whereas discomfort could be ascribed to the "feeling of heaviness".

Psychological factors associated with venous leg ulcers could lead to a reduction in physical activity which, in turn, has its own consequences and risk of co-morbidities such as obesity, anxiety and depression, and social isolation, all with a negative impact on quality of life (Kelechi, Johnson & Yates, 2015: 36). The presence of the ulcer is associated with changes in the patient's outward appearance and self-perception and, therefore, can affect quality of life negatively (Szewczyk *et al.*, 2015: 465). The psychological sphere also comprises the negative impact of ulcers on a patient's social functioning, specifically in areas such as professional activity, intimacy and social life (Szewczyk *et al.*, 2015: 468). Szewczyk *et al.* (2015: 468) also observed that having a lower leg ulcer affects relationships with both newly met individuals and family and friends. The third sphere Szewczyk *et al*. (2015: 469) refers to, namely the emotional sphere, pertains to emotional expression and perception as reflected in emotional limitations and disability. Patients with leg ulcers experience depression 54% of the time together with a significant amount of irritability and anxiety (Szewczyk *et al.*, 2015: 469).

Psychosocial factors are indicated as social isolation, depression, feelings of regret and loss, helplessness and powerlessness (Vishwanath, 2014: 397). The chronicity of the wound and its symptoms contributes to the psychosocial and treatment aspects (Vishwanath, 2014: 398). Treatment parameters should be identified to include the effectiveness of the treatment, especially with regard to progress towards healing, the duration of the treatment, and the cost-effectiveness of the treatment (Vishwanath, 2014: 398).

Studies conducted by Moffatt, Vowden et al. (2008: 4) on the quality of life of patients living with leg ulcers prove that these ulcers do not only contribute to a poor quality of life for the patients, but also place a significant socio-economic burden on both patients and the community they live in. Woo (2013: 538) emphasizes that chronic wounds create a substantial burden on both the health care system and the patient. According to Szewczyk *et al*. (2015: 468), inappropriate therapy places a significant burden on the patient, because it could result in prolonged and expensive treatments and contribute to a loss of income. Patients who present with these ulcers seem to have significantly low levels of functional capacity, which translates into a lower quality of life (Szewczyk *et al.*, 2015: 468).

Vishwanath (2014: 399) refers to the "Cardiff Wound Impact Schedule" which discriminates changes by age, size and duration of the venous leg ulcer. Vishwanath (2014: 399) concludes that, although newer treatment modalities keep emerging, pain and poor quality of life still contribute to a significant morbidity. Therefore, the assessment of quality of life could assist in planning strategies and improving not only patients' quality of life, but also the quality of care they receive.

Morton *et al.* (2013: 554) point out that the implementation of a well-established guideline could improve effectiveness of treatment and quality of care. Considering the impact of chronic lower leg ulcers on patients, whether social, economic or psychological, the challenge remains to deliver a standardized, evidence-based service and, thus, ensure high quality care (Franks *et al.*, 2016: 7). Szewczyk *et al*. (2015: 469) contend that "patients with skin lesions require comprehensive care to cover all aspects of impaired functioning within the physical, psychosocial and emotional spheres".

2.6.3 Clinical assessment

In clinical assessment, objective data are gathered by doing a physical examination and evaluating the body and its functions. This is done by inspection or observation, palpation, percussion and auscultation. Inspection or observation and palpation are used in assessing the patient with a wound (Lewis *et al.*, 2017: 4049).

A leg inspection forms a vital part of the assessment. The aim is to exclude arterial involvement and examine the level and characteristics of, for example, the oedema, skin presentation and visibility of varicose veins (Lewis *et al.*, 2017: 4049). It is important to assess both legs (Franks & Barker, 2016: S28; Lewis *et al.*, 2017: 4940). Assessment of the skin should also be included, because treating the surrounding skin in chronic venous insufficiency or ulceration is imperative (Gordon, Widener and Heffline, 2015: 57). Patients who present with venous eczema and dry flaky skin could scratch the surrounding skin and contribute to further injury (Gordon, Widener and Heffline, 2015: 57).

Vital signs are measurements of the body's most basic functions, and routine tests such as blood pressure, pulse and blood glucose levels will aid in making a diagnosis (Flanagan, 2013: 59). Moreover, baseline data regarding blood pressure, pulse and blood glucose levels could aid in identifying co-morbidities such as hypertension and diabetes. Both hypertension and diabetes could contribute to reduced blood flow and oxygenation and are detrimental to healing (Brinkley, 2017: online; Stotts *et al*., 2012: 7651). Height and weight measurement is used to determine body mass index (calculated from height and weight [kg/m^2]) (Lewis *et al.*, 2017: 4940). Palpation yields information regarding foot pulses (normal and present), tenderness or pain, oedema, moisture, texture and lipodermatosclerosis (Lewis *et al.*, 2017: 4940).

2.6.4 Classification of venous disease

The underlying pathophysiological processes of chronic venous insufficiency manifest as oedema and varicose veins initially, and as ulceration ultimately. This disease progression was classified in 1994 by the American Venous Forum which developed the CEAP classification of chronic venous disease and the clinical manifestations thereof (Kistner & Eklöf, 2017: 2657). The CEAP classification is a descriptive system, based on the "Clinical", "Etiological", "Anatomic" and "Pathophysiological" entities of chronic venous disease (Kistner & Eklöf, 2017: 2659; Sieggreen & Kline, 2015: 363). Table 2.6 is an outline of the CEAP classification.

Table 2.6 The CEAP classification for chronic venous disease as revised in 2004 (Kistner & Eklöf, 2017: 2659)

Clinical classification class	**Description**
C0	No signs of clinical disease
C1	Telangiectasia or reticular veins
C2	Varicose veins
C3	Oedema
C4a	Skin changes: Pigmentation and/or eczema
C4b	Lipodermatosclerosis and/or atrophie blanche
C5	Healed ulcer
C6	Active ulcer
S	Symptoms including ache, pain, tightness, skin irritation, heaviness and muscle cramps
A	Asymptomatic
Aetiological classification	
Congenital (Ec)	
Primary (Ep)	With undetermined cause
Secondary (Es)	With known cause
Anatomical distribution classification	
Superficial veins (As)	Segment 1-4 include superficial veins, telangiectasia or reticular veins and the greater saphenous vein (1), above the knee (2), below the knee (3), lesser saphenous (4)
Deep veins (A^D)	Segment 5-14 include the deep veins, inferior vena cava and iliac veins, as well as femoral and popliteal veins, crural and muscular veins
Perforating (A_P)	Thigh and calf perforators
Pathological classification	
Reflux (P^R)	Blood pooling due to incompetent valves or vein distention
Obstruction (P^O)	Outflow obstruction
Reflux and obstruction (P^{RO})	Combination of P^R and P^O

The American Venous Forum, the International Union of Phlebology and the European Venous Forum reached consensus in 2007 regarding terminology used in the CEAP classification (Kistner & Eklof, 2017: 2694). The clinical classification indicates progressive severity and is divided into seven classes from C0, indicating no disease, to C6, indicating an active ulcer. C4 has two subdivisions, a and b. Terminology used in this part of the classification includes telangiectasia, reticular veins, pigmentation, lipodermatosclerosis and atrophie blanche, which are defined in Table 2.7.

Table 2.7 Terminology in clinical classification of chronic venous disease (adapted from Kistner & Eklöf, 2017: 2820)

Terminology	Description
Atrophie blanche	Localized, whitish atrophic skin areas surrounded by dilated capillaries and hyperpigmentation. This indicates severe chronic venous disease.
Eczema	Erythematous dermatitis that can progress to blistering, weeping or scaling eruption of the skin.
Lipodermatosclerosis	Trophic skin changes associated with chronic inflammation within the skin, resulting in induration, pigmentation and oedema.
Oedema	Movement and accumulation of fluid from the capillaries to the interstitium due to hydrostatic pressure or gravitational pressure.
Pigmentation	Leakage of red blood cells into the tissues causes them to break and deposit hemosiderin into the tissues. This results in a brownish discolouration, or hemosiderin staining.
Reticular veins	Subdermal veins that are bluish and dilated, between 1 mm and 3 mm in diameter.
Telangiectasia	Also referred to as spider veins, hyphen webs or thread veins, that presents as a convergence of dilated intradermal venules of less than 1 mm in diameter.
Varicose veins	Subcutaneous veins that are dilated and measures more than 3 mm in diameter in a vertical position.

As a supplement to the CEAP classification, the American Venous Forum developed the Venous Severity Score (VSS) in 2000. The VSS is a three-part scoring tool that consists of the VCSS (Venous Clinical Severity Score), the VSDS (Venous Segmental Disease Score) and the VDS (Venous Disability score). The VCSS, based on the clinical elements of the CEAP, was revised in 2010 and consists of six descriptors, namely pain, varicose veins, venous oedema, skin pigmentation, inflammation, and induration (Sieggreen & Kline, 2012: 367). The rating or severity is scored from 0-3, with 0 being absent and 3 being severe. The two tools are meant to be used in conjunction, as they complement each other and is a method of communicating information about disease severity and progression (Sieggreen & Kline, 2012: 367).

The diagnosis of chronic venous insufficiency is based on clinical characteristics observed in the skin as a direct result of chronic venous hypertension with consequent oedema, visible capillaries around the ankle (corona phlebectatica), hyperpigmentation because of hemosiderin deposits, atrophie blanche, induration (lipodermatosclerosis) and stasis eczema (Ligi *et al.*, 2016: 1965; Raffetto, 2017: . 4293). Sibbald, Williamson, Contreras-Ruiz & Burrows *et al.* (2007: 432) differentiate between acute and chronic lipodermatosclerosis. Acute lipodermatosclerosis presents with a diffuse purplish-red discolouration of the leg accompanied by tenderness, while chronic lipodermatosclerosis presents with sclerotic brown pigmentation and chronic pain.

The aetiological classification is divided into three classes: congenital, primary and secondary disease. “Congenital” refers to recognized problems present at birth, “primary” disease is caused by reflux typified by varicose veins, and “secondary” disease refer to acquired deformities with elements of obstruction and/or reflux as in post-thrombotic disease (Carmel & Bryant, 2016: 11510; Kistner & Eklöf, 2017: 2726).

The anatomical classification is divided into three categories: superficial, deep and perforator vein association. These categories are supported by 18 segments naming the veins. The final section is the pathophysiological classification which indicates pathology with regard to either reflux or obstruction, or both (Kistner & Eklöf, 2017: 2741).

“Reflux” is defined as a “retrograde venous flow in any segment” irrespective of duration and could be caused by idiopathic valve dysfunction (primary), thrombosis, trauma or mechanical injury which is referred to as secondary reflux or congenital reflux in the absence of or due to abnormal development of valves (Kistner & Eklöf, 2017: 2864; Vasudevan, 2014: 366). “Obstruction” is a narrowing or occlusion of a vein and could be a partial or total blockage (Kistner & Eklöf, 2017: 2864).

2.6.5 Differential diagnosis

Table 2.8 provides a comparison of the characteristics of lower leg ulcers of venous origin caused by venous insufficiency and arterial ulcers caused by arterial disease. The ulcers that have a combination of both pathophysiological causes are called “mixed ulcers”.

Table 2.8 Comparison of characteristics of lower leg ulcers (adapted from Franks et al., 2016: 24)

	Venous	Mixed	Arterial
History			
Patient history	History of DVT or varicose veins. Incompetent calf muscle pump. Obesity causing obstruction.	Diabetic, inflammatory conditions associated with immune-suppression. Vasculitis.	Limb pain at night, pain improvement when limb hangs. Smoking and diabetes can play a role. Intermittent claudication or critical limb ischaemia.
Pain	Relieved when leg is elevated.	Subjective (according to patient’s pain threshold)	Greater at night or with elevation. Intermittent claudication.

	Venous	Mixed	Arterial
Inspection			
Site/Area	Ankle area close to malleolus or anterior tibial area. Pigmentation, eczema, induration, varicose veins, scars of previous ulceration. Hair might still be present on the lower legs and toes.	Various sites that might include gaiter area.	Tips of toes, between toes, lateral aspect of foot and lateral malleolus, as well as dorsum of the foot. Skin is dry glossy, thin, pale, mottled, and cold. Dependent rubor, pallor on elevation. Hair loss.
Depth	Superficial	Mixed features	Deep
Wound bed	Sloughy (yellow) or red (granulating) large surface area, often circumferential.	Mixed features	Pale inclined to scab formation or necrosis. Manipulation causes no or little bleeding. Usually small but can be large when neglected.
Wound edge	Diffuse or irregular edges.	Diffuse or irregular edges.	Clearly demarcated.
Oedema	Generalized to the whole lower leg	Generalized to lower leg	Localized to the wound area, but often no oedema.
Palpation			
Skin	Atrophie blanche. Warm.	Same clinical features as venous ulcers and could also present with clinical features of arterial impairment	Poor skin perfusion, (Capillary refill delayed)

Pulse	Present/normal	Present – might be abnormal.	Weak or absent.
	Venous	**Mixed**	**Arterial**
Auscultation			
ABPI	≥0,8	0,6-0,8	≤0,6
Treatment options			
Treatment options	Moist wound healing per tissue type and wound healing phase. Compression therapy.	Moist wound healing per tissue type and wound healing phase. Modified compression.	Moist wound healing per tissue type and wound healing phase. Referral to vascular surgeon.

Leg ulceration is a symptom of an underlying disease and is diagnosed based on clinical characteristics such as location, oedema, visible dilated capillaries around the ankle (corona phlebectatica) and telangiectasias, trophic skin changes such as hyperpigmentation caused by hemosiderin deposits, atrophie blanche, induration of the skin and underlying tissue (lipodermatosclerosis), and stasis eczema (Franks *et al.*, 2016: S25). These clinical features aid in making a differential diagnosis and excluding arterial involvement (Franks *et al.*, 2016: S26). The final confirmation of the diagnosis, however, depends on the value of the ABPI as outlined in Table 2.9.

2.6.6 Diagnostic tests

Clinical examination and an ankle brachial pressure index (ABPI) measurement, are in most cases sufficient to make a diagnosis regarding the severity of the vascular disease and to determine whether any further examinations are needed (Franks *et al.*, 2016: S29). Table 2.9 provides a list of possible vascular investigations with their purposes (Franks *et al.*, 2016: S26). In an outpatient setting, however, the handheld Doppler is usually the only equipment available (Harding *et al.*, 2015: 8).

Table 2.9 Vascular investigations and their purposes (Franks *et al.*, 2016: S26)

Investigation	Purpose
Ankle brachial pulse index (ABPI)	Provides estimate of central systolic blood pressure and presence and severity of arterial disease. In patients with incompressible arteries due to calcification (e.g., patients with diabetes or renal disease), a toe brachial pressure index (TBPI) could be more reliable. An ABPI of between 0,6 and 0,8 suggests arterial disease and requires investigation by a specialist, as well as modified compression.
Transcutaneous oximetry ($TcPO_2$)	Determines arterial aetiology and identifies ulcers that have the potential for delayed healing. The equipment is very costly and not readily available in outpatient clinics (Harding *et al.*, 2015).
Skin perfusion pressure	Determines the extent of venous disease and potential for delayed ulcer healing by analysing blood flow with a laser Doppler sensor. Aids in diagnosis of limb ischaemia to exclude peripheral arterial disease and aid in diagnosis of venous ulceration.
Pulse oximetry	A secondary diagnostic tool that measures the level of oxygenation of the blood and assesses arterial disease.
Blood pressure measured in both arms	Indicates a range of cardiovascular diseases.

The tests described in Table 2.9 are used to differentiate between venous disease and arterial disease. Furthermore, they are used to support the physical examination by identifying underlying co-morbidities such as pulmonary disease and cardiovascular diseases, as these are all indicated as being barriers to healing (Parker *et al.*, 2015: 44). A vascular assessment that includes an ABPI should be performed to identify the aetiology of the ulcer and exclude arterial involvement, as insufficient arterial blood supply will require a different type of management with possible revascularization before application of compression or any other surgical wound repair (Franks *et al.*, 2016: S28). A hand-held Doppler test is a baseline test applied to exclude peripheral arterial disease and support the differential diagnosis of venous stasis ulcers (Ghauri & Nyamekye, 2010: 43; Rabe & Pannier, 2017: 58).

According to Marston et al. (2016: 222), an ABPI of >0,8 mmHg is acceptable for the application of full compression (30-40mmHg). Table 2.10 indicates the ABPI value in relation to peripheral arterial disease (PAD) severity.

Table 2.10 ABPI and disease severity (Harding, 2015: 8)

ABPI value	Disease severity
>1.3mmHg	Arterial calcification may cause incompressible arteries (lead pipe syndrome)
1.0-1.3	Probably no PAD*
0.8-0.9	No significant or mild peripheral occlusion disease
0.6-0.7	Moderate PAD
<0.6	Severe PAD

*peripheral arterial disease

Weir, Smart, Van Marle, Marshall, Fourie, Berzen, Bruwer, Ramdeen, Pearce and Reynolds (2015:7) state that arterial blood supply is directly proportional to the healing potential of the wound. In addition, the WHASA consensus document recommends that ABPI be used to measure adequate blood supply, especially in non-diabetic patients. Transcutaneous oximetry ($TcPO_2$) could also aid in the assessment of healing potential with regard to arterial supply (Weir *et al.*, 2015: 6), but the equipment is costly and not necessarily accessible to all practitioners. Training in the use of the transcutaneous oximeter is essential.

Skin perfusion pressure quantitatively analyses blood flow by means of a laser Doppler to aid in the diagnosis of critical limb ischaemia or to exclude PAD (Pitts, 2014: 213). Excluding PAD is vital to determine appropriate treatment. Normal skin perfusion pressure ranges from 50-100 mmHg, while a measurement of 30-50 mmHg indicates marginal ischaemia with a limited healing potential, and a reading below 30 mmHg indicates critical limb ischaemia (Pitts, 2014: 214). The equipment is costly and needs extensive training.

Pulse oximetry measures the level of available oxygen in the blood and could aid in respiratory assessment and identifying underlying co-morbidities such as chronic obstructive pulmonary disease or even anaemia (Mondor, 2017: 31408). Pulse oximetry equipment is expensive and might not be available in an outpatient setting.

Blood pressure measurement, when taken in both arms, could be helpful in comparing values and indicating cardiac function (Lewis *et al.*, 2017: 5199).
A sphygmomanometer and a stethoscope are relatively inexpensive and should be available in an outpatient setting, as they are needed to collect baseline data (Lewis *et al.*, 2017: 12791).

2.7 Wound bed preparation

2.7.1 Identifying underlying causes and cofactors

Identifying the cause of a lower leg ulcer is pivotal to ensure effective management and to prevent complications (Regmi & Regmi, 2012: 58). Sibbald *et al*. (2011: 20) describe the wound bed preparation paradigm as a holistic approach to wound diagnosis. This approach involves treatment of the cause, identification and addressing of patient-centred concerns, classification of wounds as healable, non-healable or maintenance, all before addressing local wound care issues, i.e., debridement, infection, moisture balance and epidermal advancement.

Identifying and treating the cause of the wound are vital. The clinician needs to determine whether blood supply is adequate to support healing and identify co-factors or co-morbidities that could impede healing (Weir *et al.*, 2015: 14). This is specifically important in the case of lower leg ulceration since arterial involvement needs to be excluded. To develop an individualized care plan, patient-centred concerns need to be identified and addressed as mentioned previously. Only then can local wound care issues be addressed.

2.7.2 Determining healability

Determining healability, as described by Sibbald *et al.* (2011: 417), consists of classifying the wound as healable, non-healable or maintenance. A “healable” wound is a wound that, when the underlying cause is treated, has the potential to heal. Clinical criteria for healing include palpable pedal pulses, an ABPI of more than 0,5, $TcPO_2$ of more than 30 mmHg, or toe pressure of more than 55 mmHg (Baranoski, Ayello & Langemo., 2012: 105; Krasner *et a*l., 2007: 429; Sibbald *et al*., 2013: S12). Thus, to determine healability, the clinician needs to ascertain whether the cause is treatable, whether blood supply is adequate and whether there are any co-factors that might impede healing (Baranoski *et al*., 2015: 3694; Sibbald, Ayello *et al.*, 2015: 467).

A healable wound would have adequate blood supply and healing potential if the underlying cause were addressed (Sibbald, Ayello *et al*., 2015: 467).

Wounds that are unable to heal due to an untreatable cause or co-factors that cannot be addressed are referred to as “non-healable” wounds. In contrast, maintenance wounds develop due to the patient’s refusing certain therapies, possible financial constraints or the facility not rendering optimal treatment due to insufficient treatment modalities or lack of training, which could prevent the patient from receiving the correct treatment (Sibbald *et al*., 2011: 417; Sibbald, Ayello *et al*., 2015: 467).

2.7.3 Assessing and preparing the wound bed

Wound bed preparation is a concept formulated in 2000 by Falanga to aid clinicians in assessing the wound bed and identifying the clinical action required. The TIME principles describe the wound bed according to tissue viability, presence of infection and inflammation, moisture and edge. This guideline, developed by a group of experts in 2003 already (Leaper, Schultz *et al*., 2012: 2) and sited by Flanagan (2013: 56) was designed to “aid the clinician in making a systematic interpretation of the observable characteristics of a wound and decide on the most appropriate treatment” (Moffatt, Flanagan *et al*., 2004:58). Sibbald *et al.* (2011: 419) conceptualized the wound bed preparation paradigm to include treating the cause and addressing patient centred concerns before assessing the wound bed. Both the TIME guideline and the wound bed preparation paradigm were developed to aid clinical decision making and be a “practical bedside enabler” (Flanagan, 2013: 3104; Sibbald *et al.*, 2011: 417). The TIME enabler focuses more on the wound bed assessment and clinical action required, whereas the wound bed preparation paradigm guides holistic, evidence-based care by incorporating the diagnosis of the underlying cause and patient preference (Sibbald *et al*., 2011: 415).

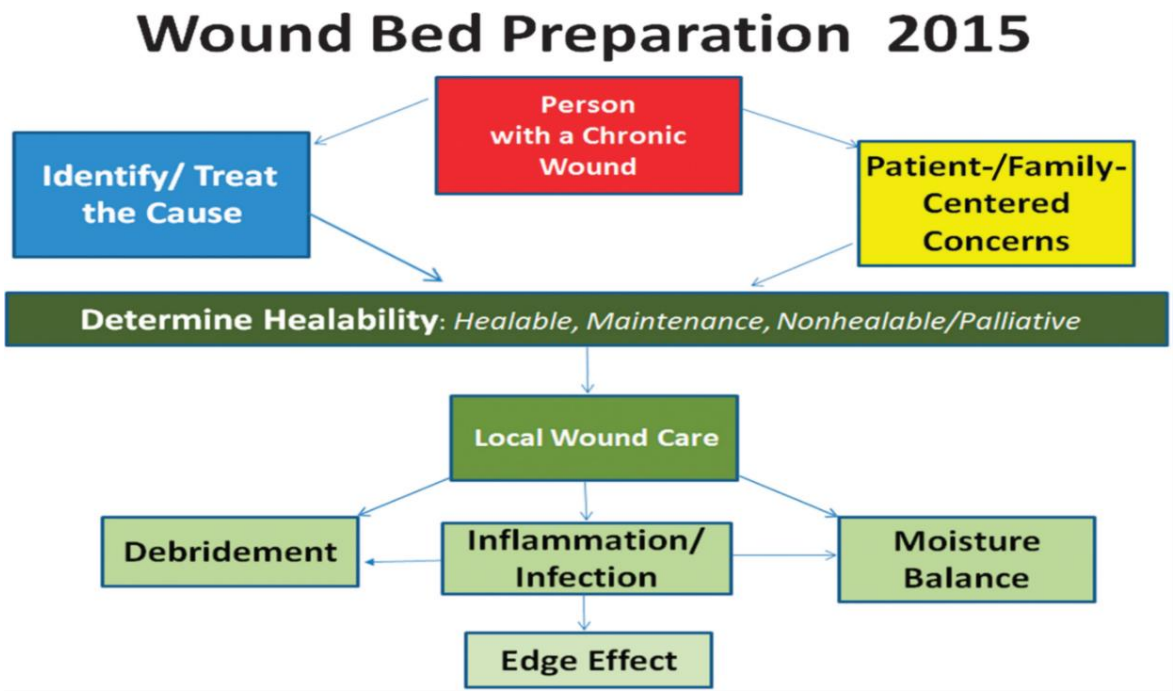


Figure 2.3 Wound bed preparation (as adopted from Sibbald *et al*., 2011: 419)

Sibbald *et al*. (2011: 415) updated the initial wound bed preparation enabler in 2011, linking the enabler to BPGs and evidence-based practice. The wound bed preparation paradigm allows a holistic approach towards wound management by stressing the importance of accurately identifying and treating the cause of the wound, addressing patient-centred concerns, and determining healability to aid treatment choices (Sibbald *et al*., 2011: 416).

Wound bed assessment should include data regarding the location of the wound, wound size and category or classification, as well as wound measurements (Baranoski, Ayello & Langemo, 2012: 106; Van Rijswijk & Eisenberg, 2012: 3885). Furthermore, wound bed assessment should provide a description of the extent of tissue damage (Van Rijswijk & Eisenberg, 2012: 3791). Wound bed assessment aids in determining the "goal of care", as continuous clinical assessment assists in determining whether the wound is progressing towards the goal of care or outcome (Van Rijswijk & Eisenberg, 2012: 3828).

“Location of the wound” refers to the anatomical location of the wound and should be described using the correct anatomical terms (Baranoski, Ayello and Langemo, 2012: 101). Venous lower leg ulcers are usually located over the gaiter area, which refers to the area just above the medial malleolus (Sieggreen & Kline, 2016: 363). In classifying the wound as acute or chronic, it is important to note the age of the wound. Not only does a period of more than six weeks indicate a chronic wound, but also healing progression. Chronicity is determined by progression towards healing or not, and not necessarily by the time frame (Sibbald *et al.*, 2011: 415; Baranoski, Ayello & Langemo, 2015: 3849). Baranoski *et al*. (2015: 3849) include aetiology, as well as the size, shape and category of the wound, as part of wound assessment. Assessment of the wound should further include an indication of any sinus tracts, tunnelling and undermining. Sinus tracts, tunnelling and undermining are measured in centimetres and described by means of the “hands of the clock”, i.e., 12 o’clock position of the wound (Sibbald *et al.*, 2011: 416).

Wound bed assessment provides objective data about the wound which can be used to not only influence treatment choices, but also alert the clinician with regard to changes in the healing progress or deterioration (Baranoski, Ayello and Langemo, 2012: 101). Clinical studies have shown that a reduction in ulcer area of approximately 20-40% after two to four weeks of treatment is a predictor of healing (Van Rijswijk & Eisenberg, 2012: 4043).

Wound size is determined by wound measurement and provides information about progress towards healing and the clinical effectiveness of the treatment method (Baranoski, Ayello and Langemo, 2015: 3883). Consistency in measurement contributes to reliability and needs to be part of the facility’s protocols (Baranoski, Ayello & Langemo, 2015: 3883). Methods to measure wound size could be two- or three-dimensional, i.e., length, width and depth, and include linear methods or digital photography. In order to ensure consistency and reliability, measurement should be taken at the “greatest head-to-toe length and greatest side-to-side width perpendicular to each other” (Wood & Nelson, 2013: 77; Baranoski, Ayello & Langemo, 2015: 3883). With regard to assessing wound depth, Van Rijswijk and Eisenberg (2012: 3995) suggest finding “markers for wound depth”, for instance, the presence of epithelial tissue that could indicate a superficial wound, or exposed underlying structures, in which case the wound can be classified as deep or full-thickness. A sterile swab could

aid in measuring depth by inserting it at a 90° angle and measuring depth with a gloved forefinger at skin level.

The swab is then placed next to a calibrated measuring guide (Van Rijswijk & Eisenberg, 2012: 3995; Baranoski, Ayello & Langemo, 2015: 110). Undermining or tunnelling could also be assessed in this manner (Van Rijswijk & Eisenberg, 2012: 3996). Table 2.11 gives a description and comparison of current measurement methods, their application, and their advantages and disadvantages.

Table 2.11 Wound measuring methods and their advantages and disadvantages (adapted from Van Rijswijk & Eisenberg, 2012: 3887)

Method	Description	Advantages	Disadvantages
Tape measure or ruler	Length (longest area of tissue breakdown) and width (longest measurement perpendicular to the length) are measured using a disposable measuring guide/ ruler calibrated in centimetres. Record length, width and depth, as well as patient position.	Easy, fast and inexpensive. Good inter- and intra-rater reliability. Clinically reliable record of progress.	Might be difficult to determine wound edges. Length and width do not provide actual wound size due to irregular shape. The bigger the wound, the less reliable this method becomes. Might not be suitable for research purposes.
Tracing (Transparencies)	Disposable double layer acetate sheet, measuring guide or plastic bag is held over the wound while tracing edges with fine-tip permanent marker. Add location	Easy, fast. Expense determined by material used. Excellent inter- and intra-rater reliability.	Might be difficult to see wound margins. If transparency does not contain grid, measuring could be difficult. Manual counting of squares on grid could cause over- or

Method	Description	Advantages	Disadvantages
	markers (head, toes, etc.), date and patient number. Contaminated side is discarded, and sheet attached to patient chart. Records patient position.		undercalculation of actual area.
Digital photography	Should include sample measure. Digital camera no smaller than 1,5 megapixels is recommended. Angle, distance and lighting should be considered: **Angle**: Parallel with wound base. **Distance**: Focal length distance from the lens, i.e., the focal point to achieve the sharpest quality image. **Lighting**: Natural light, but always a flash to ensure optimal lighting. Use the “macro” setting. **Background**: Green or light green.	Provides visual record. Aids in clinical decision making. Could assist with wound bed assessment. Could be used for telemedicine.	Equipment could be expensive. Training is needed. Incorrect lighting or angle could obscure image. Risk of inconsistency if not done by the same person.

The process of digital wound photography for assessment requires that the camera be parallel to the wound bed, about 30 cm from the wound bed, and that the image indicate date and time. Incorporating the photograph into assessment documentation is necessary for record-keeping purposes. Wound measurement is essential to assess progress towards healing and effectiveness of the treatment. In the digital age, data capturing by means of digital photography or specialized computer software has proven to reduce inconsistency and improved accuracy (Van Rijswijk & Eisenberg, 2012: 4056; Seat & Seat, 2017: E73).

Obtaining informed consent from the patient is a legal requirement (Geyer, 2005: 5). The Health Professions Council of South Africa (HPCSA, 2008: online) provides guidelines for informed consent. They refer to South African law which stipulates that proper informed consent involves the following:

- Patients must have knowledge of the nature or extent of the harm or risk;
- Patients must appreciate and understand the nature of the harm or risk;
- Patients must consent to the possible harm or assume the risk; and
- The consent must be comprehensive, i.e., extend to the entire transaction, inclusive of its consequences.

The same applies to collecting data on the patient's wound using a digital camera. The health care worker is not only responsible for obtaining informed consent to capture the data, but also to safely store and distribute the data. Data should be password protected and the patient needs to be informed about the intent of sharing the data with other health care professionals, i.e., team members or the funder (Geyer, 2005: 17).

2.7.3.1 TIME

The TIME guideline was initially developed by a panel of wound care experts in 2002 as a practical guide to aid the management of chronic wounds healing by secondary intention (Leaper, Schultz *et al*., 2012: 1). "TIME" is an acronym of the four components comprising the guideline, namely tissue management, infection and inflammation control, moisture balance, and epithelial (edge) advancement (Flanagan, 2013: 57). Each of these components will be discussed below.

Tissue Management

The “T” represents the viability of the tissue, specifically whether the tissue on the wound bed is viable, which refers to the presence of devitalized tissue, i.e., slough or necrosis. Because devitalized tissue is a medium for bacterial growth, the presence of necrotic or devitalized tissue disrupts the normal process of healing and increases the risk of infection (Martin, 2013: 31). Reducing this bacterial burden by debriding the devitalized tissue not only reduces the risk of infection, but also aids healing, because the clinical outcome of debriding is expected to be a viable wound bed (Flanagan, 2013: 3016). Treatment decisions are further assisted by indication of the tissue type, i.e., necrotic tissue (black), sloughy tissue (soft yellow), granulation (healthy red or friable) or epithelization (pink), and the percentage thereof (Baranoski *et al*., 2012: 106; Dowsett, Drouard & Harding., 2015: 2; Sibbald, Ayello *et al*., 2015: 467; Van Rijswijk & Eisenberg, 2012: 3887).

In the case of non-healable wounds, conservative methods that do not include sharp debridement are suggested, while healable wounds that have sufficient arterial supply could be debrided using sharp, surgical, autolytic, mechanical, enzymatic or biological debridement (Sibbald, Goodmam and Reneeka, 2013: S12). Table 2.12 gives a list of debridement methods with their advantages and disadvantages.

Table 2.12 Debridement methods (adapted from Leaper, Schultz *et al*., 2012: 4; Widener, 2015: 139)

Debridement method	Advantages	Disadvantages
Surgical debridement	Rapid results	Costly Requires hospitalization
Sharp debridement	Cheap Fairly quick results	Could cause pain Potential bleeding Can only be done by a skilled professional Might need follow-up procedures
Autolytic debridement	Pain free	Takes longer than surgical or sharp debridement

Debridement method	Advantages	Disadvantages
		Could produce wound malodour
Mechanical debridement: Wet-to-dry dressings Hydrotherapy Wound irrigation	Relatively inexpensive	Could cause pain and trauma to the wound bed Non-selective (could harm healthy tissue) Could cause bleeding Hydrotherapy could cause maceration and has a high risk of infection
Enzymatic debridement	Selective (Enzyme only results in breakdown of necrotic tissue)	Requires daily application according to product information
Biological debridement	Selective (Enzyme secreted only breaks down necrotic tissue)	Patient and wound specific

Both sharp and surgical debridement involve the use of scissors, forceps, surgical blades or hydro-surgery devices (Versajet™) to remove devitalized tissue from the wound bed (Ayello *et al*., 2016: 5692; Sibbald *et al*., 2013: S12). Surgical debridement requires hospitalization, because the procedure needs to be performed in theatre by a surgeon. Although this might be a fast and effective way of debridement, it is costly, and the patient's general condition might not allow for general anaesthetics. On the other hand, sharp debridement is less expensive, but the clinician needs to be skilled and have knowledge about the anatomy of underlying structures. Furthermore, sharp debridement could cause bleeding, but adequate and continuous debridement have been associated with improved healing times (Ayello *et al.*, 2016: 5700).

Occlusive dressings are used to achieve autolytic debridement and use the body's endogenous enzymes to debride necrotic tissue (Flanagan, 2013: 3023). The moist environment enables the macrophages and proteolytic enzymes to break down and separate devitalized tissue from the wound bed (Flanagan, 2013: 3032; Ayello *et al.*, 2016: 5723). This method takes longer, but is especially suitable for patients who are not eligible for invasive procedures (Flanagan, 2013: 3032).

Mechanical debridement methods are non-selective and could cause trauma, pain and bleeding (Sibbald, Goodmam and Reneeka, 2013; Ayello *et al.*, 2016: 5646). These methods include "wet-to-dry" dressings, hydrotherapy and pulsed lavage (Ayello *et al.*, 2016: 5678). Wet-to-dry dressings involve the application of moist saline gauze to the wound bed, allowing it to dry and then removing it again to facilitate the removal of devitalized tissue (Ayello *et al.*, 2016: 5663). This method is not recommended, especially not for large wounds, and should be limited or excluded in general. Both hydrotherapy and pulsed lavage have a high risk of infection and could require administration of pain medication before treatment (Ayello *et al.*, 2016: 5692).

Enzymatic debridement involves the use of topical enzymes to aid debridement of necrotic tissue. It is safe, effective and easy to apply (Ayello et al., 2016: 5763; Leaper, Schultz *et al*., 2012: 4). Enzymatic debridement is selective, as the collagenase only breaks down collagen bonds of the devitalized tissue. However, it is advisable to cut a "crosshatch" or grid into the eschar to improve efficacy (Ayello *et al.*, 2016: 5770). Ayello *et al*. (2016: 5790) point out that other agents such as silver or zinc oxide could interfere with enzymatic action and should not be used in conjunction with an enzymatic debrider.

Biological debridement is achieved by applying medicinal *Lucilia sericata* larvae of the green bottle fly. The larvae secrete a proteolytic enzyme that destroys necrotic tissue and digests bacteria, thus aiding in the debridement and reduction of the bioload. But there seems to be a fair amount of contradiction regarding the use of larvae. Patient preference could be a deciding factor in the choice of this application as it might not be acceptable to the patient and it could be painful (Flanagan, 2013: 3039; Ayello *et al.*, 2016: 5790).

The choice of debridement method depends on the healability of the wound, the size, depth and location of the wound, financial constraints and risks involved, skill and training of the practitioner, and the type of care facility in which it will be performed (Ayello *et al.*, 2016: 5920). Although debridement is probably the most important part of wound bed preparation, there are limited data identifying the most effective debridement method for optimal healing (Tang, Marston & Kirsner, 2012: 626).

Infection and Inflammation

The second component of the TIME guideline is infection and inflammation. The normal inflammatory response following wounding with the classic signs of inflammation, i.e., erythema, oedema, pain and loss of function, was discussed under 2.3. Inflammation forms part of normal wound healing, but infection is not only associated with delayed wound healing but also an increase in morbidity (Flanagan, 2013: 3725). In both the TIME guideline and the wound bed preparation paradigm, identifying and treating infection form part of local wound care (Flanagan, 2013: 3749; Sibbald, Goodmam and Reneeka, 2013: S14). Wounds International and the World Union of Wound Healing Societies have published criteria for identifying wound infection, distinguishing between superficial and deep infection in both acute and chronic wounds (Flanagan, 2013: 3749).

“Infection” is defined as the presence or invasion of a wound by proliferating microbes or micro-organisms in sufficient numbers or virulence to evoke a local or systemic host response (International Wound Infection Institute IWII) (Swanson, Angel, Sussman & Cooper, 2016: 3). Wound infection is also described as being a continuum.

The presence of bacteria alone does not lead to adverse effects in the wound, but rather the relationship between the virulence of the microbes and the ability of the host to respond (Swanson *et al.*, 2016: 4). Swanson *et al*., (2016: 5) divides the infection continuum into five phases which describe the gradual increase in the amount and virulence of the microbes, namely contamination, colonization, local infection, spreading infection and systemic infection. Flanagan (2013: 3825) refers to “critical colonization” which precedes infection and is associated with delayed healing or a static wound. The IWII, however, notes that the term “critical colonization” has been described as ambiguous.

Owing to the “covert” characteristics of the signs of infection in “critically colonized” wounds, a more specific description was needed, hence the terms “local infection” and “spreading infection”(Tickle, 2013: S18; Swanson *et al.*, 2016: 5). Table 2.13 outlines the signs and symptoms of infection along the continuum of infection or otherwise indicated as the levels of bioburden.

Table 2.13 The infection continuum (adapted from Leaper, Assadian *et al*., 2015: 351; Tickle, 2013: S17).

Term	Definition
Contamination	Presence of bacteria without multiplication by either exogenous or endogenous organism (Flanagan, 2013: 3725; Tickle, 2013: S18). No apparent host response noted (Tickle, 2013: S18). No signs and symptoms.
Colonization	Presence of bacteria with multiplication, but still no host response or clinical signs and symptoms (Tickle, 2013: S17).
Critical colonization/ local infection or superficial infection	Multiplication of bacteria that results in delayed healing. Immune system can no longer control the microbes (Landis, Ryan, Woo & Sibbald, 2007: 303; Tickle, 2013: S17). Subtle or covert signs include: • Presence of debris of the wound bed • Delayed or compromised healing • Increased exudate • Malodour • Increase/changes in pain levels • Localized oedema • Friable red granulation tissue
Spreading infection or deep infection	Bacteria or microbes are multiplying at a rate that exerts a host response with associated clinical signs and symptoms of infection, i.e., erythema, oedema, heat and pain. Additional signs and symptoms may include: • Extended erythema • General lethargy • Inflammation and swelling of lymph glands • Wound breakdown or satellite lesions

	• Malodour • Visible bone • Increased size of the wound • Increase in peri-wound temperature • Increase in exudate levels

Critical colonization/local infection or superficial infection is characterized by increased exudate, malodour, increased pain levels and localized oedema. For this reason, it is important to monitor the amount of exudate. Exudate varies from none to “heavily exuding” and according to specific characteristics, namely serous, sanguineous or purulent (Sibbald *et al.*, 2011, p. 416). The amount and type of exudate give an indication of the status of the wound and guide clinical decision making regarding dressing choices (Van Rijswijk & Eisenberg, 2012: 4151).

Odour is usually associated with infection, although all wounds have an odour. Important, though, is the fact that wounds should be cleansed before assessing odour (Van Rijswijk & Eisenberg, 2012: 4168). Different types of tissue on the wound bed will affect the odour and, although odour is subjective, it is vital to note any change, as it could suggest a change in the wound status (Van Rijswijk & Eisenberg, 2012: 4189).

Landis *et al.* (2007: 303) distinguishes between superficial and deep infection by using the mnemonics NERDS and STONEES. **NERDS** indicates **N**on-healing, **E**xudate increase, **R**ed friable granulation, **D**ebris on the wound surface, and **S**mell, more specifically malodour (Landis *et al.*, 2007: 303; Sibbald, Woo *et al.*, 2007: 32; Sibbald *et al*., 2011: 417). According to Landis *et al.* (2007: 303), these signs and symptoms point to superficial infection. The International Wound Infection Instutite’s (IWII) consensus documents concur, but add hyper-granulation, increase in pain or new pain, and epithelial bridging and pocketing in granulation tissue to the list of signs and symptoms of local infection (Swanson *et al.*, 2016: 5).

Landis *et al.* (2007: 303) and Sibbald *et al*. (2011: 415) use the mnemonic **STONEES** to identify deep infection as a **S**ize increase, **T**emperature increase in the surrounding skin, exposed bone (**O**s) or probing to bone, **N**ew breakdown or satellite areas of breakdown, and the three **E's** (erythema, exudate and oedema), together with **S**mell (malodour). These signs and symptoms indicate deep infection. Again, the IWII (2016: 7) add symptoms such as lymphangitis, crepitus, malaise or lethargy, as well as loss of appetite and swelling of lymph glands (Stotts, 2016: 269). Sibbald, Woo & Ayello (2008: 31) argues that the severity of the infection is related directly to the virulence of the organism and the immune response of the host, or host resistance. Similarly, Percival *et al.* (2014: 293) states that the virulence of the bacteria and the type of interaction with the host determine the risk of infection.

Infection is detrimental to healing, as some bacteria or microbes can impair neutrophil function and prolong the inflammatory phase of wound healing (Stotts, 2016: 268). Organisms compete for oxygen and nutrients and produce endotoxins and exotoxins (Stotts, 2016: 268). These toxins interfere with cellular activities and alter cellular functions, with subsequent increased pro-inflammatory cytokines matrix metalloproteinases (MMPs) and neutrophils that continue to degrade the wound matrix and delay the healing process (Stotts, 2016: 268). Because of the covert characteristics of infection in chronic wounds, it is difficult to diagnose infection because the presence of biofilms complicates the matter (Leaper *et al*., 2015: 351). Biofilms form as a result of organisms aggregating and embedding themselves in a polysaccharide protein and lipid matrix, already containing multiple organisms, all of which can now communicate and alter genotypes and phenotypes (Leaper *et al*., 2015: 351; Stotts, 2016: 268). Leaper *et al.* (2015: 351) explain that biofilms contribute to excessive inflammation, resulting in delayed healing that requires persistent debridement and topical antiseptic application.

Changes in the surface body temperature are significant for identifying signs of infection, and infrared thermometry has been shown to help detect peri-wound deep and surrounding infection (Mufti, Coutts & Sibbald, 2015: 12; Sibbald, Armstrong *et al.*, 2015: 38). Infrared thermometry can detect subtle temperature changes that might not be detectable with palpation and aid in quantitative data collection and identification of infection (Mufti *et al*., 2015: 12).

Ineffective treatment or neglect of infection could be life-threatening (Leaper et al., 2015: 351). Effective management of the bioburden depends on optimizing the host response, as well as reducing the bacterial load and managing accompanying symptoms such as pain (Flanagan, 2013: 3989). Optimizing the host response includes managing co-morbidities and reducing factors that increase the risk of infection. To achieve this, the patient's general health needs to be improved by means of optimal nutrition and hydration (Flanagan, 2013: 3996; Swanson *et al.*, 2016: 13). Reducing the bioload or bacterial burden requires prevention of contamination, continuous debridement and management of excessive exudate (Flanagan, 2013: 3999). This needs to be supported by antimicrobial treatment for superficial infections or antibiotic treatment, which should be reserved for deep or spreading infection (Flanagan, 2013: 3999; Leaper *et al.*, 2015: 352).

The inverse relationship between a slow healing wound, which is more susceptible to infection, and infection which contributes to impaired healing, requires the effective management of infection, since the reduction of the bioburden is vital to accomplish healing (Stotts, Wipke-Tevis & Hopf, 2012,7664).

Cleansing of the wound is critical to help reduce the bioload, as debris is removed and infection reduced (Davis, Harding, Gil, Parajon, Valdes, Solis & Higa., 2017: 1; Queirós, Santos, Apostolo, Cardoso & Cunha, 2016: 133). Wound irrigation at between 8 and 15 pounds per square inch (psi) (or 413-775 mmHg) with a non-toxic solution effectively removes surface contaminants, debris and microbes, thereby improving the wound environment (Shetty, Paul, Barret, Sreekar & Dawre, 2012: 590; Tariq, Cullen *et al.*, 2016: 3). Jet-ox® is a wound cleansing system that uses compressed air/oxygen and cleansing fluid to deliver a psi of between 4 and 9. Cleansing requires the use of cleansing agents which are bactericidal, but with low toxicity, no adverse effect on cellular activities, and the ability to promote wound healing (Sibbald, Goodmam and Reneeka, 2013: S15; Widener, 2015: 61; Tariq *et al.*, 2016: 1). Irrigation seems to be the preferred method of cleansing and saline or water the preferred cleansing solutions, seeing that excessive cleansing and antiseptic solutions could be detrimental to healing (Queirós *et al*., 2016: 134).

Antiseptics are used widely as part of infection control (Percival *et al.*, 2014: 294), Tariq *et al.* (2016: 2) point out that saline and water have no antimicrobial properties and, although not harmful to wounds, might not be able to remove inflammatory cytokines and microbes present in chronic wounds. Table 2.14 gives a list of antiseptic solutions and their effects.

Table 2.14 Antiseptic solutions and their effects (adapted from Sibbald *et al.*, 2013: S17)

Antiseptic solution	Effect
Acetic acid (0,5-1%)	Lowers pH Effective against *Pseudomonas* Could cause burning
Chlorhexidine 2% (biguanide cationic detergent)	Broad-spectrum Low toxicity Antimicrobial properties depend on concentration Retains activity in presence of blood, wound fluid and burned tissue
Povidone iodine 10% aqueous solution	Broad-spectrum Antimicrobial activity decreased in presence of pus or purulent exudate
Hydrogen peroxide	Fizz Cytotoxic in high concentrations
Sodium hypochlorite	Toxicity depends on concentration Possibility of penetrating biofilm
Polyhexamethylene biguanide	Surfactant antimicrobial that disrupts biofilm attachments Toxicity is low to none Reduced possibility of resistance

Antiseptic solutions such as hydrogen peroxide, povidone iodine and sodium hypochlorite have shown to impair wound healing, reduce wound strength and increase infection, and their use does not seem to be evidence based (Queirós *et al.*, 2016: 134). Antimicrobial solutions should be evaluated for their ability to effectively reduce the bioload at a concentration that is non-toxic (Tariq *et al.*, 2016: 2). Moreover, cleansing solutions such as povidone Iodine or peroxide are cytotoxic (Tariq *et al.*, 2016: 3).

New cleansing solutions developed recently contain Polyhexamethylene biguanide and betaine and have been found to be effective in reducing bioload, improving wound conditions for optimal healing and managing odour without being cytotoxic (Queirós *et al*., 2016: 135). Wound cleansing forms part of wound bed preparation and removes loose material and reduces the bioload.
Therefore, the choice of irrigation solution should be based on the wound requirement as determined by a thorough holistic assessment (Tariq *et al*., 2016: 3; Woo *et al*., 2012: 538).

Superficial infection or an increased bacterial burden is treated by using topical antimicrobials, whereas deep infection requires systemic antibiotics (Sibbald, Goodmam and Reneeka, 2013: S17). However, Schultz and Bjarnsholt *et al*. (2017: 752) recommend the use of topical antimicrobials, as listed in Table 2.16, in stalled wounds. Antimicrobials to consider include silver, iodine in a cardexomer carbohydrate or poly-ethylene glycol slow-release formulation, Polyhexamethylene biguanide, hydrophobic dressings (Cutimed Sorbact™), and honey, although honey seems to be indicated more as a debriding agent. Medical grade honey (specifically Manuka honey) is used as an antimicrobial in superficial infections, because the mode of action involves a hygroscopic effect and increases acidity and the presence of a natural hydrogen peroxide (Ismail, Alshehabat, Hananeh, Daradka, Ali & El-Najjar, 2015,: 79). The use of any antimicrobial should be reviewed regularly, i.e., every one to two weeks (Tickle, 2013: S20).

Laboratory tests and cultures could aid in diagnosing and managing infection (Stotts, 2016: 270). Wound cultures are used mainly to identify the specific anaerobic or aerobic organism and its susceptibility to antibiotics. However, it is generally accepted that culture results underrepresent the number and type of organism (Leaper, Ayello *et al*., 2012: 12; 2015; Stotts, 2016: 271). A wound culture should be taken from viable tissue after cleansing with saline or a non-antiseptic solution to remove topical bacteria and prevent a false positive result. This can be done by biopsy, fine needle aspiration or a wound swab (Schultz *et al.*, 2017: 746).

Although they are deemed the “gold standard” in wound culture, wound biopsies are rarely performed routinely due to cost, access to services and patient discomfort related to the invasiveness of the procedure. Furthermore, biopsies require a skilled health care professional and access to a laboratory (Swanson *et al*., 2016: 12). Other disadvantages include the risk of wound contamination and of bleeding in the case of patients using anti-coagulants (Swanson *et al.*, 2016: 12; Stotts, 2016: 270). Schultz *et al.* (2017: 748) conclude that biopsies are more reliable than swabs in identifying the presence of biofilms in chronic non-healing wounds, but in the absence of diagnostic testing, clinical assessment could be used to confirm the presence of biofilms.

Needle aspiration involves aspirating fluid from the wound bed with a needle. This procedure also requires skill and training, and the needle could damage the wound. The third and most common technique is obtaining a wound swab. Two methods are used, namely the Z technique and the Levine technique. The Z technique is performed by moving the swab in a Z pattern over the wound bed, whereas the Levine technique requires the clinician to apply pressure to the wound bed to generate some fluid from the deeper wound bed. The Levine technique has proven to have a higher sensitivity and specificity than the Z technique (Leaper, Assadian *et al*., 2015: 355).

Inflammatory markers as indicated by raised erythrocyte sedimentation rate and c-reactive protein levels could be helpful in diagnosing infection. However, cultures should be taken only when there are clinical signs of infection or the wound is not progressing towards healing, and should not be done routinely (Swanson *et al*., 2016: 11; Leaper, Assadian *et al.*, 2015:355; Stotts, 2016: 269; Tickle, 2013: S38).

The most common bacteria to invade chronic wounds are *Staphylococcus aureus, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli* and *Corynebacterium* spp. (Bessa, Fazii, Di Giuloi & Cellini., 2015: 49). Up to 27% of chronic wound infections is polymicrobial, in other words, more than one species are present (Bessa *et al.*, 2015: 50). Once a clinical diagnosis has been made of deep tissue infection and susceptibility has been determined, a culture is utilized to aid in decision making regarding systemic antibiotic use. Broad-spectrum anaerobic antibiotics are recommended for empirical use, but should be de-escalated once microscopy, culture and susceptibility have been completed (Weir *et al.*, 2015: 14).

Although microbes are present in all wounds, not all wounds become chronic or infected (Tariq *et al.*, 2016: 1). The microbes either present as planktonic phenotypes, i.e., free-floating single cells, or biofilm phenotypes which form a fixed polymicrobial community that adheres to the wound bed and is protected from the host's immune system by a self-secreted matrix. Also, their reduced metabolism makes them less susceptible to the effects of antimicrobials (Leaper, Ayello *et al*., 2012: 1; Tariq *et al.*, 2016: 3).

Clinical indicators for the presence of a bacterial biofilm include recalcitrance to treatment with antibiotics or antiseptics, treatment failure regardless of appropriate antibiotic or antiseptic delayed healing, and cycles of recurrent episodes of infection or exacerbation thereof (Schultz *et al.*, 2017: 749).

Moisture

In the TIME guideline the "M" refers to moisture and the management thereof (Flanagan, 2013: 3104). Wound fluid forms part of the inflammatory phase of wound healing because of vasodilation. The wound fluid is not only the transport medium that facilitates cell movement of white blood cells, cytokines and growth factors, but also the supplier of nutrients to these cells, and an aid in creating a moist wound environment (Flanagan, 2013: 3104; Jones & Harding, 2007: 202; Tickle, 2015: S38). Chronic wounds are associated with high volumes of exudate, dressing strikethrough and leakage, as well as peri-wound excoriation and maceration, with accompanying interruption of the healing process (Flanagan, 2013: 3104; Tickle, 2015: S38). Clear differences have been noted between acute and chronic wound fluid, of which elevated levels of MMPs are the most significant because of their detrimental effect in the later stages of wound healing, although important in all phases (Jones & Harding, 2007: 202). When assessing exudate, it is imperative to consider colour, viscosity, odour and strikethrough to help make the most suitable dressing selection and thus prevent skin maceration, pain and malodour (Tickle, 2015: S38).

Moisture balance at the wound interface is achieved by using interactive dressing or therapies and should be individualized according to the level of moisture and the ability of the products available (Sibbald, Ayello, Elloit *et al*., 2015: 470). The dressing absorbency should match the exudate level of the wound (Broussard and Powers, 2013: 451). Chronic wound fluid is associated with delayed healing, and copious amounts of exudate result in strikethrough, odour, peri-skin maceration, contact

dermatitis and infection (Flanagan, 2013: 3105). Dressings need to prevent desiccation and maceration by balancing the moisture level (Flanagan, 2013: 3119).

Types of dressing to manage exudate include calcium alginates, polyurethane foam dressings and Hydro fibre dressings (Sibbald, Ayello, Elliot *et al*., 2015: 472). These dressings are all designed to absorb and retain fluid and promote moist wound healing, but evidence suggests that better healing rates are achieved with foam dressings (Sibbald, Ayello, Elliot *et al*., 2015: 472). Dressings utilized for moisture management are discussed in Table 2.16.

Epidermal Advancement

The "E" in the TIME guideline refers to epidermal advancement. This is the ultimate outcome to be achieved through wound bed preparation, and is one of the most significant signs of healing (Pudner, 2015: 32). For epidermal advancement to occur, the epidermal edge should slope into the wound bed (Pudner, 2015: 32). Woo *et al.* (2007:100) refer to the "edge effect", namely when cliff-like edges of the epidermal margin fail to result in epidermal migration. The normal process of epithelization occurs towards the end of the proliferative phase of wound healing and requires a healthy, well-vascularized and granulated wound bed for the epithelial cells to migrate from the edge of the wound (Young & McNaught, 2014: 477; Pudner, 2015: 33). Epithelial-mesenchymal transition (EMT) allows epithelial cells to gain motility and migrate across the wound bed (Young & McNaught, 2014: 478). A balance in the moisture levels in the wound is essential for optimal epithelization (Pudner, 2015: 34; Sibbald, Ayello, Elliot *et al.*, 2015: 475). Factors that might impede epithelization are listed and described in Table 2.15.

Table 2.15 Factors that might impede epithelization (adapted from Pudner, 2015: 34)

Factor	Description
Hypoxia	Lack of oxygen
Devitalized tissue	Necrotic tissue on the wound bed will prevent epithelization.
Imbalance in moisture levels	Overhydration results in maceration, and desiccation results in tissue death.

Factor	Description
Abnormal wound edges: • Rolled • Fibrotic • Hyperkeratotic • Undermined	Rolled edges could indicate dehydration of the wound bed or over granulation due to too much moisture or even malignancy. Fibrotic or keratotic edges are formed due to repetitive trauma. Undermined edges could prevent epithelial advancement.
Chemical imbalance	An imbalance in protease levels results in stalled healing or cell senescence. An imbalance in the pH level of the wound could also delay healing.
Senescent cells	Cells that have become inactive

Hypoxia (a lack of oxygen) could result in devitalized tissue and delay wound healing and epidermal migration (Pudner, 2015: 33). The presence of necrotic or devitalized tissue increases the risk for infection, keeps the wound in an inflammatory phase, and prevents healing (Flanagan, 2013: 3119; Young & McNaught, 2014: 478). An imbalance in the moisture levels could result in overhydration or maceration when the wound is too wet, and dry or desiccated tissue will also impede epithelization (Martin, 2013: 35).

If the wound edges do not slope into the wound bed and become rolled, fibrotic or is undermined, the epithelial edge cannot advance (Pudner, 2015: 34). Rolled edges could occur due to a lack of moisture in the wound bed or even malignancy (Pudner, 2015: 34). Malignancies should be ruled out with a biopsy. Once the cells on the edges become inactive, they are referred to as “senescent cells” or “dysfunctional cells”. These cell will not divide mitotically and will not migrate over the wound bed (Pudner, 2015: 35). Elevated levels of MMPs result in a chemical imbalance and cause the wound to stall in a “destructive mode. MMPs break down the extra-cellular matrix, and prevent epithelial migration (Young & McNaught, 2014: 478).

The treatment of surrounding skin mainly aims at preventing skin trauma, treating varicose eczema, and reducing oedema. Skin care comprises of cleansing using gentle irrigation to dislodge debris but not harm healthy tissue. It is recommended that an emollient be applied to moisturize the skin (Sibbald, Alvari *et al.*, 2012: 207; Sieggreen & Kline, 2015: 12274). The treatment of the peri-wound area is a critical part of wound care, because the peri-wound is exposed to topical applications, cleansers, dressings, bandages and ointments, as well as wound exudate (Sibbald, Alvari *et al.*, 2012: 208).

Wound exudate contains enzymes that could break down the surrounding skin (Sibbald, Alvari *et al.*, 2012: 208). Continuous contact with exudate can cause maceration or overhydration of the peri-wound area; thus, protection against the destructive nature of the wound exudate is vital to prevent the wound diameter from increasing and to reduce the risk of infection. Emollients such as glycerine, urea and propylene glycol are humectants that help the epidermis retain moisture (Sibbald, Alvari *et al.*, 2012: 207). Emollients could aid in the repair of the skin's natural barrier, help protect against irritation and infection, and reduce redness, swelling and pruritus (Sibbald, Alvari *et al*., 2012: 207). Liquid paraffin and white soft paraffin are combined in a 50:50 ratio and used as an emollient. Barriers used as protection of the peri-wound area include petrolatum or zinc oxide. Petrolatum tends to cause folliculitis and could prevent the secondary dressing to adhere, while zinc oxide could make visualization of the surrounding skin difficult, and might interact with silver dressings (Sibbald, Alvari *et al*., 2012: 209).

2.7.4 Choosing a primary dressing

When choosing a dressing to apply to the wound, the following should be considered: characteristics of the wound, patient needs, availability and cost, as well as ease of application (Kelechi, Johnson & Yates, 2015: 40). Allergens should also be considered (Kelechi, Johnson & Yates, 2015: 40). Broussard and Powers (2013: 450) state that an "understanding of wound dressing properties" should guide dressing selection, as it needs to match wound characteristics. Table 2.16 outlines the classification of dressings and their indications.

Table 2.16 Classification of dressings and their indications (adapted from Sibbald, Ayello, Elliot *et al*., 2015: 417)

Dressing classification	Characteristics	Indications
Alginate	Highly absorbent Converts to viscous hydrophilic gel when wet Requires secondary dressing	Moisture control Partial- to full-thickness wounds Moderate to heavy exudate
Hydro fibre	Highly absorbent ribbons of sodium carboxymethyl-cellulose	Deep, highly exuding wounds
Foam	Hydrophilic open-cell polyurethane	Moisture control Partial- to full-thickness wounds Moderate to heavy exudate
Superabsorber	Contains polymers Locks away the exudate Requires secondary dressing	Highly exuding wounds
Hydrocolloids	Made of gelatine, pectin or carboxymethyl cellulose Occlusive Absorbs light exudate, forms gelatinous contact with wound base	Superficial Dry/low exuding wound Aids autolytic debridement
Hydrogel	Water-base with polymers Donates moisture Requires secondary dressing	Wounds that are dry or have minimal exudate Rehydrates wound base Can cause maceration of peri-wound skin
Antimicrobial dressings	Silver Iodine Polyhexamethylene biguanide	Indicated for superficially infected wounds, as well as in conjunction with systemic antibiotics for deep infection

Dressing classification	Characteristics	Indications
Hydrophobic dressings	Fatty acid-coated dressings that repel water but bind with bacteria to reduce bioload	Superficial infected wounds or wounds with increased bioburden
Honey	Some antibacterial activity Evidence for use inconclusive	Autolytic debridement Might have anti-inflammatory properties
Gauze	Dry, woven or non-woven Made of cotton, polyester or rayon	Absorbs but does not wick away moisture
Impregnated gauze/tulle	Gauze impregnated with petroleum jelly to reduce adherence	Superficial wounds
Protease modulators	Derived from bovine, porcine or avian sources Could enhance collagen deposits Chemoattractant to granulocytes and fibroblast Requires secondary dressing	For slow healing or stalled wounds Only use when wound bed is repaired and bioload reduced
Basic non-adherent dressings	Open-weave cloths soaked in paraffin, petrolatum emulsion or silicone gel Designed to reduce adherence and allow exudate to pass through to secondary dressing	Superficial wounds Patients with fragile skin Reduce risk of damage due to dressing removal

Although consensus has been reached regarding the use of dressings that maintain a moist-healing environment, data are limited regarding which is superior (Tang *et al.,* 2012: 627). Managing moisture balance seems to be key to healing progression, since exposure to wound fluid has been associated with delayed healing (Sibbald, Ayello, Elliot *et al.*, 2015: 470; Tang *et al.*, 2012: 627).

The use of absorbent dressings such as hydro fibre and alginates assists in managing moisture, especially in highly exuding wounds. Because it turns into a gel, hydro fibre has the added benefit of aiding autolytic debridement (Kelechi *et al.*, 2015: 42; Sibbald, Ayello, Elliot *et al.*, 2015: 470).

Foams, usually made from polyurethane, are designed to not only wick exudate away from the wound bed, but also donate some moisture to achieve a "fluid equilibrium" (Sibbald, Ayello, Elliot *et al*., 2015: 470). The disadvantage of the fluid exchange could be peri-skin maceration or excoriation which would require the use of a barrier (Cook, 2011: 38; Sibbald, Ayello, Elliot *et al.*, 2015: 470). It is not advisable to use an adhesive dressing under compression or on fragile skin due to the risk of skin damage on removal (Tang, Marston & Kirsner, 2012: 626).

Superabsorbers have the same polymer-like structure found in diapers and feminine hygiene products and are indicated for use in highly exuding wounds (Sibbald, Ayello Elliot *et al*., 2015: 473). These polymers have a "liquid lock" system that could aid in preventing peri-wound maceration; unfortunately, superabsorbers also expand as they absorb the moisture (Cook, 2011: 38; Sibbald, Ayello, Elliot *et al.*, 2015: 473). This expansion results in a 2,5% sub-bandage pressure increase when used under a four-layer compression system, which alters the sub-bandage pressure profile (Cook, 2011: 40).

Hydrocolloid dressing usually contains a gel-forming agent such as carboxymethyl cellulose and is classified as an occlusive dressing that could aid autolytic debridement (Niezgoda, Baranoski, Ayello, MacIntosh, Montoya & Scarborough, 2016: 6358; Sibbald, Ayello, Elliot *et al*., 2015: 473). Although they could help reduce wound pain, hydrocolloids are not recommended for highly exuding wounds due to risk of maceration (Niezgoda *et al.*, 2016: 6358). Venous lower leg ulcers characteristically have high exudate levels and hydrocolloid dressing is thus contra-indicated.

Hydrogels contain mostly water and aid in moist wound healing and autolytic debridement. However, adding moisture to an already highly exuding wound, as in the case of venous lower leg ulcers, could contribute to peri-wound maceration (Niezgoda *et al.*, 2016: 6358; Sibbald, Ayello, Elliot *et al.*, 2015: 470).

Topical antimicrobials are designed to provide broad-spectrum coverage against bacteria and are indicated for use in superficial and deep infections in wounds (Sibbald *et al*., 2013: S12; Sibbald, Woo & Ayello, 2007: 32). Antimicrobials include dressings that contain silver, iodine and Polyhexamethylene biguanide (PHMB) (Niezgoda *et al.*, 2016: 6358). Kelechi *et al*. (2015: 40) state that there is limited evidence to support the use of honey to treat infection. Both silver and iodine are seen as broad-spectrum antimicrobials and indicated for use in the treatment of superficially infected wounds (Adis Medical Writers, 2014: 217; Broussard & Powers, 2013: 455). Wounds International supports "antimicrobial stewardship" to reduce the overuse of antimicrobials and antibiotics and prevent resistance (Leaper, Ayello *et al*., 2012: 10; 2015: 173). Without clinical or laboratory evidence of infection, empirical antibiotic use is not promoted (Kelechi, Johnson & Yates, 2015: 42).

Hydrophobic dressings provide a mechanism for bacterial binding through hydrophobic interaction. The bacteria bind to the dressing surface and are rendered inactive, thus reducing the bioburden without the risk of resistance (Green, 2012: 17). The benefit of hydrophobic dressings is that there is no endotoxin release from broken bacterial cells; therefore, inflammation can be reduced (Anon, 2016: 18).

Gauze made of woven cotton is inexpensive when compared with other more advanced dressings, but cost per unit can be misleading. Gauze does not create the moisture-retentive environment needed for optimal healing; thus, the frequency of dressing changes required makes gauze an expensive option (Niezgoda *et al.*, 2016: 6291; Adis Medical Writers, 2014: 216). Gauze can adhere to the wound and cause damage to the newly formed granulation tissue (Adis Medical Writers, 2014: 216). In addition, gauze is not an effective barrier against microbes, which increases the risk of infection (Niezgoda *et al.*, 2016: 6307).

Impregnated gauze or tulle gras comprises a gauze cloth impregnated with paraffin for non-traumatic removal. But Green (2012: 17) points out that these dressings could adhere to the wound bed and cause damage on removal, in addition to having very limited absorbency and requiring secondary dressings and frequent dressing changes.

Proteases are enzymes that break down proteins. In wound healing MMPs are the main proteinases, and excessive proteases result in the degradation of the extra-cellular matrix and prolonged wound healing (Harding, Armstong and Barrett, 2011: 2). Protease modulating dressings bind to excess proteases in the wound to enable an increase in the availability of growth factors (Harding, Armstong and Barrett, 2011: 2).

Basic non-adherent dressings are open-weave cloths soaked in paraffin, petrolatum emulsion or silicone gel. They are designed to reduce adherence to the wound bed, to reduce tissue trauma, and to allow exudate to pass through to secondary dressing. These dressing are recommended for use in the treatment of venous lower leg ulcers (Kelechi, Johnson & Yates, 2015: 40; Franks *et al.*, 2016: S37).

A basic non-adherent dressing is recommended by most guidelines for treating venous lower leg ulcers (Rai, 2014: 408; Franks *et al.*, 2016: S13). Hussain (2015: 2) points out that dressings for use on venous ulcers are often chosen for their antibacterial properties, as well as their ability to manage exudate and odour. This is supported by the Wound International consensus document stating that the dressing of choice should be a simple, non-adherent dressing that could manage exudate and possibly treat infection (Harding *et al.*, 2015: 11). Franks *et al*. (2016: S37) conclude that, in making the appropriate dressing choice, the practitioner needs to consider:

- Ulcer size and location;
- Wound tissue characteristics and phase of wound healing;
- Wear time of the dressing;
- Amount and type of exudate;
- Presence of infection;
- Pain levels;
- Peri-wound and surrounding skin;
- Patient tolerance and preference;
- Ease of application and removal; and
- Cost-effectiveness of the application and availability.

2.7.5 Topical negative-pressure wound therapy

Topical negative-pressure wound therapy (NPWT) is the application of sub-atmospheric pressure to the wound bed, resulting in micro- and macro-deformation (Gestring, 2017: online). The mechanism of action causes wound contraction, a reduction in oedema, a reduction in bioload, and a reduction in pro-inflammatory cytokines, and it promotes angiogenesis (Gestring, 2017: online; Niezgoda *et al*., 2016: 6696). Dumvill, Land, Evans and Peinemann (2015: 11) conclude that, although there is clinical evidence of the effectiveness of negative pressure, there is no evidence on its use as a primary treatment. It is imperative that the underlying cause, namely venous hypertension, be addressed (Franks *et al.*, 2016: S24; Ghauri & Nyamekye, 2010: 43).

2.7.6 Treatment options

2.7.6.1 Compression therapy

The data collected during history taking and physical examination are amalgamated and used to identify the problem and develop a care plan for the patient (Lewis *et al.*, 2017: 2702). The care plan needs to be patient centred and consider underlying causes and identified co-factors (Ayello, Courchene & Sibbald, 2012: 396). Once an assessment is completed and a differential diagnosis made, treatment options need to be considered. Several studies have concluded that compression therapy is the “gold standard” of treatment of lower leg ulcers of venous origin (Australian Wound Management Association, 2011: 136; Harding, 2015: 13; Partsch & Mortimer, 2015: 359; Sibbald, Ayello, Elliot *et al*., 2015: 466). Table 2.17 outlines factors that might affect the choice of compression therapy systems (Harding, 2015:12).

Table 2.17 Factors that might affect the choice of compression therapy systems (adapted from Harding, 2015: 12)

Factors	Possible reason
Training	Competency and experience of the health care practitioner applying compression: in health care systems where there is a high turnover of staff it may be preferable to mainly use a compression therapy system that is relatively straightforward in application, e.g., two-component compression bandaging.
Wound status	Size of the ulcer and exudate levels
Patient mobility	Patient dexterity and ability to self-apply compression therapy
Previous experiences of the patient and likely concordance with treatment	Unpleasant previous experience might influence compliance with treatment.
Pain levels	Increased pain levels might influence concordance.
Access to care	The possible frequency of clinic or home care visits could affect choice.
Level of compression required	When adjustment is likely to be required to enhance tolerance
Availability of compression therapy systems	Where restrictions occur, the minimum provision should be multicomponent compression bandaging and compression hosiery.

According to Harding *et al*. (2015:14), the health care worker's level of training will affect not only the choice of bandage, but also the application method. Proper application techniques are not achieved by reading textbooks, but by hands-on training (Partsch, 2017: 8). Several variables within the clinical setting affect the amount of sub-bandage pressure required (Harding, 2015:13):

- **Bandage properties**: The high stiffness of inelastic components produces greater pressure fluctuations during walking and low resting pressure (Partsch, 2017: 7).
- **Number of components applied**: The stiffness increases with the number of components applied. Multilayer bandages contain elastic components, but still measure an increased stiffness index.
- **The technique and skill of the operator**: Applying the bandage with increased stretch produces higher pressures. To achieve a target pressure of 50-60mmHg inelastic bandages should be applied at full strength or 100% stretch (Partsch, 2017: 8).
- **Size and shape of leg**: Very thin legs, due to calf muscle wasting or bottle-shaped legs, could make it difficult to generate therapeutic levels of pressure. For this reason, shaping the leg with absorbent material and applying the bandages with evenly distributed pressure are vital for bandage effectiveness (Harding *et al.*, 2015: 19; Partsch, 2017: 8).

Patient mobility affects the choice of compression, as inelastic bandages have been shown to achieve much higher pressures in an upright position (60-90 mmHg) and resting pressures of less than 20 mmHg (Partsch, 2017: 8). In supine position intravenous pressure reduces to below 20 mmHg, and in a standing position intravenous pressure ranges between 80 and 100 mmHg, depending on the patient's height and weight (Partsch, 2017: 7; Partsch & Mortimer, 2015: 173). Inelastic bandages could still be effective in reducing oedema in patients who are immobile and have oedema due to immobility while avoiding damage to the skin cause by the sustained pressure from elastic bandages (Partsch & Mortimer, 2015: 173).

The level of compression should correlate with the required treatment, to reduce oedema and improve hemodynamics (Partsch, 2017: 8). High pressure is needed for patients with lymphoedema or severe venous disease, whereas patients with concomitant arterial occlusive disease require modified compression with sustained pressure not exceeding the arterial perfusion pressure (Partsch, 2017: 8; Partsch & Mortimer, 2015: 363). Some compression is better than none, but the treatment decision depends on the individual needs of the patient, resource availability and the practitioner's competence (Carvalho & Olivera, 2015: 629). In addition, access to care and financial limitations seem to be a universal problem (Sibbald *et al*., 2011: 419). These patient-centred concerns need to be addressed, because patients must be involved in all decisions regarding their care and well informed on the financial impact thereof. Other concerns are patients' ability to adhere to the suggested treatment plan and their access to resources to visit the facility.

Patient perception and previous experience could affect how treatment is perceived, as well as adherence to the treatment (Harding *et al.,* 2015: 2). A lack of understanding of the purpose and the need for compression, or previous experience with a clinician who lacked skill, could result in non-adherence (Harding, 2015: 2). Negative experiences such as pain, uncomfortable bandaging, bandage slippage or strikethrough of exudate could also contribute to how the patient perceives the treatment. Financial constraints, for example, affordability of the treatment or the inability to attend appointments due to a lack of transport or work commitments, could affect patients' adherence to the treatment plan (Harding *et al*., 2015: 3; Muldoon, 2013: 6513).

Compression not only reduces the distention of superficial veins, but also prevents retrograde blood flow by supporting the calf muscle pump and reducing oedema (Kelechi et al., 2015: 37). Several studies have shown the effectiveness of compression bandaging in the treatment of venous leg ulcers (Fletcher, Moffat, Partsch, Vowen & Vowden., 2013: 3; Partsch & Mortimer, 2015: 64). In general, high compression seems to be more effective than low compression bandaging (Partsch & Mortimer, 2015: 63). Table 2.18 outlines different types of compression, their performance characteristics and pressure applied.

Table 2.18 Types of compression and associated performance characteristics (adapted from Kelechi et al., 2015: 37)

Type of compression	Example	Performance characteristics
Inelastic	Zinc paste (Ulce3™, Coflex UBZ™)	High working pressure, high stiffness index
Short stretch (single component)	Rosidal™ Comprilan™	High working pressure, high stiffness index Tolerated during rest
Short stretch (two component)	Actico™ Coban™	High working pressure, high stiffness index Tolerated during rest Washable and re-usable
Short stretch + long stretch (multi-component)	Profore™ Comprifore™	High working pressure, high stiffness index Well tolerated during rest
Long stretch	Surepress™	Low stiffness index Needs to be removed at night
Elastic compression: Stockings, hosiery, leggings	Jobst™ (BSN-Jobst USA), Sigvaris™ (Sigvaris USA)	Delivers 20-30 mmHg, 30-40 mmHg, 40-50 mmHg, >50 mmHg pressure
Dynamic compression: Intermittent compression pumps	Lympha Press™ (Lympha Press USA), Flexitouch™ (Tactile Systems Technologies), Mobility™ (DermaScience)	Air pump connected to sleeves/gloves/boots to apply pressure from the toes upward Delivers 30-60 mmHg pressure
Velcro wraps	Air-filled compression therapy device of flexible material and loop straps Aero-wrap™	Graduated pressure that delivers 50 mmHg at the ankle graduating up to 38,5 mmHg just below the tibial crest Working pressure

Type of compression	Example	Performance characteristics
		Easy self-application
African Bandage System	Bandaging system developed for low socio-economic sector Consists of two rolls of 150 mm retention knitted bandage and one role orthopaedic wool	Pressure varies between 28 and 32 mmHg

To reap the benefits of the different types of compression, it is important to apply the right type considering the treatment objectives, duration of the treatment, as well as patient tolerability (Harding *et al.*, 2015: 12). For compression to be effective, the abnormal hemodynamics and ambulatory venous hypertension caused by chronic venous insufficiency must be overcome (Corle, Partsch & Moneta, 2017: 16268).

Inelastic bandages could either be “no-stretch” or “short-stretch” bandages, depending on their extensibility (Fletcher *et al.*, 2013: 13; Partsch, 2017: 6). Zinc paste bandages can be described as no-stretch, while short-stretch bandages with maximum extensibility can stretch 100% (Partsch, 2017: 6). Short-stretch bandages have a high stiffness index and produce the greatest variations in interface pressure during ambulation, thus, improving venous return (Fletcher *et al.*, 2013: 13; Partsch & Mortimer, 2015: 363).

The stiffness index is defined by the difference in sub-bandage pressure from a supine to a standing position (Partsch, 2017: 7). High stiffness systems seem more effective in improving venous flow and outcomes for the patient, whereas low stiffness systems have a higher resting pressure (Harding *et al.*, 2015: 13). Short-stretch bandages have a low resting pressure with improved tolerance during rest. These bandages are often re-usable, but the patient could experience pressure loss caused by a reduction in oedema and in the volume of the limb, which can result in reduced effectiveness of the bandage and discomfort (Fletcher *et al.*, 2013:13).

Long-stretch bandages can stretch to double their size, have a low stiffness index, and apply sustained pressure. Multicomponent compression bandage systems contain both short-stretch and long-stretch components (Harding *et al.*, 2015: 13). Multilayer bandages have the advantage of maintaining compression for a longer period of time and distributing pressure evenly (Corle, Partsch & Moneta, 2017: 16438). Velcro wraps are another treatment modality indicated for use when the patient has fragile skin, or as an alternative to bandaging (Todd, 2014: 467). Velcro wraps consist of inelastic yet flexible straps that overlap around the limb. They have the potential to promote self-care and reduce costs (Todd, 2014: 467).

The African Bandage System was developed for use in lower socio-economic areas where the greatest challenges are funding and access to care. The design of the bandage is based on the principle that “any pressure is better than none”. The bandage consists of two rolls of 150 mm retention knitted bandage and one roll of orthopaedic wool that is sandwiched between the two layers of knitted bandage (Smart, 2014: 14). The bandage system seems to deliver between 28 and 32 mmHg interface pressure with significant oedema reduction and wound healing rates noted (Smart, 2014: 15).

2.7.6.2 Mechanism of compression

The mechanism underlying compression therapy is based upon Pascal’s law, namely:

- Pressure applied to an enclosed system of an incompressible fluid is evenly distributed (Corle, Partsch & Moneta, 2017: 16281).
- The pressure gradient between the interstitial space and the intravascular space causes fluid to move into the venous and lymphatic systems, and the rigidity of the compression augment this (Corle, Partsch & Moneta, 2017: 16281).
- The sub-bandage pressure or interface pressure is determined by the number of layers of bandage applied, as well as the tension at which they are applied.
- With regard to the patient’s leg circumference, “the smaller the circumference, the higher the pressure”(Sibbald *et al*., 2007: 481).

When choosing an appropriate bandage according to the patient's individual needs, the practitioner needs to consider La Place's law, which states that an ankle circumference of less than 18 cm could achieve a sub-bandage or interface pressure of up to 45 mmHg (Sibbald *et al*., 2007: 483). When standing, the intravenous pressure in the lower leg is between 80 and 100 mmHg, but an external pressure, such as achieved with compression therapy of between 35 and 40 mmHg, could narrow the vein and support retrograde blood flow (Corle *et al*., 2017: 16293; Kelechi *et al*., 2015: 37).

The therapeutic effects of compression was collated by Carvallo and Olivera (2015: 629) in a literature review. These authors concluded that, although high compression seems to be better than low compression, some compression is better than none. They also found no significant differences in the effectiveness of the different bandages, but that all resulted in some form of oedema reduction, improved healing rates and, in general, improved quality of life.

Contra-indications for the use of compression bandaging include inadequate blood supply as determined by differential diagnosis and an ABPI measurement (Woo and Cowie, 2013: 67). The presence of pedal pulses is an unreliable indicator of arterial supply and an inadequate indication for the use of compression. If the ABPI is <0,5 or >1,3 the patient should be referred for further examination and no compression should be applied (Muldoon, 2013: 169). Elastic bandages are contra-indicated in patients with peripheral arterial insufficiency (Sigman, Ochoa & Rowe, 2015: 3468). Compression is also contra-indicated in undiagnosed DVT (Bryant & Nix, 2016: 201). Compression of oedematous limbs results in mobilization of interstitial fluid into the circulatory system, potentially increasing the preload volume which could precipitate pulmonary oedema (Carmel & Bryant, 2016: 201). Congestive cardiac failure is also a contra-indication, but compression could be used in conjunction with diuretics and very close monitoring of fluid balance and breathing (Carmel & Bryant, 2016: 202). Patient preference and possible claustrophobia could also be contra-indications.

Mixed ulcers have both a venous and arterial component and occur in about 15% of the population that presents with lower leg problems (Pannier & Rabe, 2013: 56). Mosti (2014: 13) further notes that 15-30% of venous ulcers might have a co-existing arterial component, and that compression may be applied. Pannier and Rabe (2013: 57) describe mixed ulcers as having the typical signs of venous disease, but with the presence of black necrosis on the wound bed. Compression needs to be applied with reduced pressure that will not permeate the arterial pressure (Pannier & Rabe, 2013: 57; Mosti, 2014: 13). Mosti (2014: 14) concludes that inelastic (short-stretch) bandaging improves venous hemodynamics without affecting arterial flow.

Intermittent pneumatic compression therapy is another treatment modality that could be considered for patients who are immobile, cannot tolerate bandages, or have an arterial component in their ulcer aetiology (Sieggreen & Kline, 2015: 12342). Intermittent pneumatic compression devices consist of plastic sleeves with air chambers that periodically inflate and deflate (Alguire, 2016: online). It is not a standalone treatment and should be used in conjunction with, for example, stockings, and for between one and four hours daily (Sieggreen & Kline, 2015: 12342).

Compression Stockings

The recurrence rate in venous lower leg ulcers is as high as 28% (Carmel & Bryant, 2016: 167). Compression stockings play an imperative role in the maintenance of venous lower leg ulcers and the prevention of recurrence (Tang, Marston & Kirsner, 2012: 630). Although it is associated with a reduced rate of recurrence, higher grade compression also plays a role in patient non-adherence to treatment (Tang, Marston & Kirsner, 2012: 630). Compression stockings are designed to apply graduated compression, with the highest amount of pressure around the ankle decreasing gradually up the leg (Alguire, 2016: online). Stockings can aid in the reduction of ambulatory venous pressure by improving the calf muscle ejection fraction, decreasing reflux and reducing residual volume fraction (Eberhardt & Raffetto, 2014: 340; Lim & Davies, 2014: E391; Sieggreen & Kline, 2015: 12334). Stockings need to be measured to fit, as the benefit is directly proportional to the fit (Sieggreen & Kline, 2015: 12334; Alguire, 2016: online). Long-term and continuous use should be encouraged (Sieggreen & Kline, 2015: 12350). Complications caused by compression stockings include ischaemia, blistering and contact dermatitis, which can be avoided if the patient is assessed, measured and fitted correctly (Lim & Davies, 2014: E392).

The multicomponent bandaging system are often perceived as “hot and uncomfortable” and although stockings are indicated for use in maintenance and prevention of recurrence, they could also be considered as treatment options. Some stocking variants could give a graduated pressure of 40 mmHg and even up to 50 mmHg around the ankle (Eberhardt & Raffetto, 2014: 340). Adherence to treatment seems to be better in this case, because the stockings are more comfortable than bandaging systems. Female patient tend to opt for this option because it enables them to were normal shoes and not oversized shoes required when in bandages (Lim & Davies, 2014: E391).

2.8 Health dialogue

Although dressing application and treatment with compression bandaging are seen as the “gold standard” in treating venous lower leg ulcers, the patient’s adherence, or rather concordance, to the treatment plan is key to the success and effectiveness of the prescribed treatment (Wade, 2017: 32). It is, therefore, essential that the health care provider engage in health dialogue with the patient and significant others to agree on the treatment plan (Ayello, Courchene & Sibbald, 2012: 70).

Educating the patient with regard to the mechanism of work of the compression system and the possible side-effects or complications, i.e., skin breaks, blisters or necrosis, could improve the patient’s understanding of the treatment (Lim & Davies, 2014: E392). The patient needs to understand that stockings aid in oedema reduction and control, and that a reduction in oedema, in turn, can assist in pain management and wound healing. Furthermore, it is imperative that the patient understand that only continuous use of the compression garment will aid in reducing the risk of recurrence (Manjunath Shenoy, 2014: 387).

Table 2.19 is an example of a health dialogue with a patient regarding the use, application and care of compression stockings (Lim & Davies, 2014: E392).

Table 2.19 Example of health dialogue regarding compression stockings

When to use the compression stockings:
○ Stockings should be applied before getting up in the morning.
○ Stockings should be worn daily but removed before sleeping.
How to apply and remove the stockings:
○ Remove all jewellery before application to prevent damaging the stocking.
○ Stockings are applied from the foot, then over the heel, gently working the stocking up the leg and smoothing out wrinkles.
○ Apply lotion to the legs but let it dry before putting on the stockings.
○ A little baby powder or corn-starch on the legs could help the stockings slide up.
○ Put on rubber dishwashing gloves to help adjust the stockings and smooth them out.
○ Use a gadget called a “stocking donner” to slide the stocking over your foot. A stocking donner can be obtained from a medical supply store or online.
○ To remove the stocking, gently roll it down the leg and remove over the heel and foot.
Care of the stocking:
○ Read the care instructions carefully and adhere to them.
○ Stockings should be hand-washed and dried flat.
○ Do not dry stockings in the sun
○ Do not use bleach or fabric softener.
○ Do not wring or dry in the tumble drier.
○ Stockings should be replaced every six months.

Possible complications of compression in general

Patients should be informed about complications and the signs thereof. They should contact their health care practitioner or remove the stocking or bandages immediately when they experience numbness or tingling, pain or an increase in pain, changes in the colour of the foot or toes, or if a new wound develops (Lim & Davies, 2014: E392; Harding *et al.*, 2015: 12).

Contra-indications for the use of compression hosiery are PAD, either suspected or confirmed, or a history of peripheral arterial bypass grafting. An ABPI of less than 0,5 is a contra-indication for the use of compression (Sibbald *et al.*, 2011: 421; Rai, 2014: 408; Harding *et al.*, 2015: 15). Peripheral neuropathy or any sensory impairment is also listed as contra-indications, as well as possible allergies to the stocking material. Skin conditions such as fragile skin or gangrene, oozing dermatitis and severe cellulitis, as well as a recent skin graft, are also contra-indicated. Finally, a massive leg oedema or pulmonary oedema caused by congestive cardiac failure, or any leg deformity that would influence the fitting of the stocking, is a contra-indication for the use of graduated compression hosiery (Lim & Davies, 2014: E395).

Exercise, weight management and smoking cessation form part of health dialogue. Despite the lack of direct evidence supporting the effectiveness of these measures, they are considered to be supportive and preventative in the management of venous ulcers because of the reduction in venous load associated with exercise and weight management (Manjunath Shenoy, 2014: 386). Elevating the legs above the level of the heart for at least 30 minutes three to four times a day helps to reduce oedema and improve blood flow (Alguire, 2016: online). Leg elevation could also reduce recurrence rate (Shenoy, 2014: 386). Exercise involving flexion and extension of the foot and rotation of the ankle could further aid in reducing symptoms (Alguire, 2016: online; Blebea, 2017: 58). An impaired calf muscle pump is a contributing factor in the majority of patients with venous ulcers. Thus, walking is good exercise for the calf muscle and reduces pressure within the calf which, in turn, reduces venous hypertension (Alguire, 2016: online; Blebea, 2017: 57; Manjunath Shenoy, 2014: 386). Deep breathing exercises promote venous return to the right atrium (Carmel & Bryant, 2016: 197).

2.9 Evidence-based care

Evidence-based practice is defined as a conscientious, explicit and judicious use of current best evidence in making decisions about client care and involves the combination of best research evidence with clinical expertise and patient needs (Grove & Burns, 2015: 591). Evidence-based care is based upon research from randomized control trials (RCTs), meta-analysis, analytic, non-experimental, historic and experimental studies, as well as expert opinion and consensus statements. Sackett *et al*. (2000) (in Orsted *et al*., 2007: 177) define “evidenced-based medicine” as “the integration of best research evidence with clinical expertise and patient values”.

According to Grove and Burns (2015: 600), clinical expertise or expert opinion depends on years of clinical experience, current knowledge of research and clinical literature, as well as educational preparation. In general, the treatment of lower leg wounds seems to have been based on anecdotal reports and retrospective data; lately, however, there appears to be a growing emphasis on the use of evidence-based practice to guide clinical decision making (Richmond, Maderal & Vivas, 2013: 187). The stronger the nurse's clinical expertise, the better the clinical judgment and application of evidence-based research (Grove & Burns, 2015: 600).

The Registered Nurses Association of Ontario (RNAO) Best Practice Guidelines was published in 2005, and guidelines from the Wound Healing Society in America were published in 2006 (Babul, Robson, Steed, Hopf, Whitney & Phillips., 2006: 646). According to Orsted, Keast & Campbell (2007: 177), evidence alone does not seem to be sufficient to ensure best practice. Evidence-based clinical guidelines tend to amalgamate external evidence and expert knowledge to aid decision making regarding specific clinical problems (Grove & Burns, 2015: 592). Clinical guidelines are imperative in promoting evidence-based practice, because promoting interventions with proven advantages could help improve outcomes, while simultaneously discouraging ineffective treatment (Kredo, Bernhardsson, Machingaidze, Young, Louw, Ochodo & Grimmer, 2016: 122). High quality, evidence-based clinical guidelines could bridge the gap between policy, best practice, local contexts and patient preference (Kredo *et al.*, 2016: 122). Clinical guidelines form an integral part of quality medical care (Kredo *et al.*, 2016: 123).

Orsted *et al*. (2007: 177) refer to BPGs as "systematically developed statements" to assist practitioners in making appropriate decisions regarding specific clinical circumstances in the health care system. These guidelines combine evidence, experience and opinion to help improve patient care and outcomes by decreasing inappropriate practice variations and promoting high quality, evidence-based health care (Orsted *et al*., 2007: 177). The IOM initially defined "clinical guidelines" as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances". This definition was updated in 2011 to the following:

“Clinical guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”.

Standards of care are rules or models of care established by professional organizations or regulatory bodies and tend to determine the minimum acceptable level of care. When compared with Standards of care, BPGs assist health care professionals in defining effective and appropriate practices based on current and scientific research (Orsted *et al*., 2007: 178). Karavan, Olerud, Bouldin, Taylor and Reiber (2015: 745) state that, although evidenced-based guidelines exist in both the specialty and general care settings, the delivery of evidence-based ulcer care is not uniform.

Inconsistencies in assessment and care highlight the need for a clinical guideline in management with more directives and standardization of care, as well as nurse education, to deliver high quality care (Furlong, 2015: S22). Variations in the implementation of guidelines or a lack of rigor in implementation could influence the quality and reliability of the care. Tariq *et al*. (2016: 5) list several barriers to the implementation of evidence-based practice, including a lack of training, shortage in resources, a lack of motivation, and resistance to change. Evidence-based practice promotes quality, safety and cost-effective outcomes (Grove & Burns, 2015: 582). Orsted *et al*. (2007: 179) point out that guidelines are to be used as recommendations, and not as rules, to not only aid the practitioner in providing the best possible care by adopting new information, but also to promote change in practice.

According to Orsted *et al*. (2007: 178), guidelines involve change, and the change should be based upon a need. This need, in turn, should be based on a needs assessment that identifies the gap in care. Various guidelines indicate the use of the Doppler measurement or ABPI as an absolute requirement to rule out arterial involvement (Franks *et al.*, 2016: S15). The guidelines stipulate that a holistic, comprehensive assessment must be performed to determine the aetiology and co-morbidities of the ulcer that could influence treatment choices (Harding *et al.*, 2015: 111). Sibbald *et al.* (2011: 415) notes that regular measurement of size, by measuring the length and width of the ulcer, is also indicated as a “reliable index of healing”.

Evidence-based practice has been associated with improved outcomes in ulcer care (Karavan *et al.*, 2015: 745). Richmond *et al*. (2013: 194) conclude that the development of standard care practices and subsequent treatment algorithms for hard-to-heal ulcers have resulted in improved outcomes for patients.

Table 2.20 provides a comparison of the guideline content of the Society of Vascular Surgery (SVS) (USA), Wound Healing Society (WHS) (UK), the Australian Wound Management Association (AWMA), the European Wound Management Association (EWMA), and WHASA. Di and Clark (2016: 745) compared several different guidelines and concluded that, although they seem evidence based and cite similar resources, there are still variables within the recommendations.

Table 2.20 Comparison of guidelines (adapted from Di & Clark, 2016: 745)

Guideline instruction	SVS (2014)	WHS (2015)	AUS (2011)	EWMA (2016)	WHASA (2015)
DIAGNOSIS					
Peripheral arterial disease must be ruled out	ABPI should be >0,9	ABPI should be >0,8	If ABPI <0,8, refer to specialist	ABPI <0,8 is suggestive of arterial disease and requires investigation	PAD should be excluded: ABPI <0,5
Infection	No routine swab should be taken	Only take swab if infection is suspected	Only take swab with signs of clinical infection	Only take swab with signs of clinical infection	Diagnosis of deep infection should be supported by a wound swab and laboratory investigation
Antibiotic use: Systemic	Recommended for ulcers with clinical evidence of infection	Use if cellulitis is present	Not for use in standard care, only with clinical signs of infection	Not for use in standard care, only with clinical signs of infection	Empirical use of broad-spectrum antibiotics should be de-escalated to more direct treatment according to MC&S result
Topical antimicrobials	Does not recommend use of topical antimicrobials	Recommended for use in control of bacterial levels	No benefit over standard care	Recommended for use in superficial infection	Should be used with caution, recommended for reduction in bioburden

Guideline instruction	SVS (2014)	WHS (2015)	AUS (2011)	EWMA (2016)	WHASA (2015)
TREATMENT					
Wound cleansing	Non-irritating, non-toxic solution	Non-irritating, non-toxic solution	Potable water	Non-irritating, non-toxic solution	Non-irritating, non-toxic solution
Debridement	Remove necrotic or devitalized tissue	Remove necrotic or devitalized tissue	Remove necrotic or devitalized tissue	Remove necrotic or devitalized tissue	Only debride if PAD is excluded
Compression	Multi-compression better	High strength compression better	Any compression is recommended	High compression better than low compression	Implement appropriate compression if ABPI >0,8
Dressings	Use dressing that will manage exudate and maintain moist wound healing	Use dressing that will maintain moist wound healing environment	Use moist wound healing principles, no specific dressing recommended	Simple non-adherent dressing	Non-adherent dressing
Surrounding skin	Should be treated/protected	Should be treated/protected	Should be treated/protected	Should be treated/protected	Treat and protect surrounding skin

Franks et al. (2016: S37) also compared several guidelines and found that all patients who present with a lower leg ulceration must be assessed holistically by trained clinicians. This assessment must entail a physical examination that includes an ABPI to rule out peripheral arterial disease before commencing compression therapy. The ABPI measurement should be repeated every 12 weeks (Franks *et al.*, 2016: S14). Compression in the form of bandaging, specifically inelastic compression bandages or short-stretch, is recommended for treating active ulcers, and compression hosiery for healed ulcers. Evidence-based clinical practice guidelines are designed to improve quality of care and reduce practice variations.

2.10 Quality of care

Structure, processes and outcomes can be seen as foundational components of quality management and measurement (Collins & Mannon, 2015: 49). Providing prompt, accurate care according to BPGs defines the quality of the care (Collins & Mannon, 2015: 48); however, limited data on quality of care is available in South Africa. Andrews and Langley (2015: 59) conducted a qualitative study regarding nurses' perceptions on current practices in South Africa and found a general lack of appropriate management of wounds as a direct result of a knowledge deficit regarding wound management (Andrews & Langley, 2015: 62). Similarly, Herberger, Heyer, Blome, Sandner, Altheide and Augustin (2013: 468) state that most patients with chronic wounds are not being treated in accordance with modern principles of wound management.

Donabedian (1966: 66) applied the structure-process-outcome model to assess quality of care. Campbell *et al*. (2000: 1612) and Cooperberg *et al*. (2009: 411) both referenced this model and, more recently, Burstin, Leatherman and Goldman (2016: 154) referred to this model as part of the evolution of health care quality measurement, stating that measurement is fundamental in the process of improving health care. Campbell *et al*. (2000: 1612) distinguishes two dimensions of care, namely access and effectiveness, which correlate to both structure and process and are assimilated into the assessment of quality. Campbell *et al.* (2000: 1612) further point out that the balance of these measures should ideally be dictated by the specific clinical question. Rockville (2012: online) emphasizes that the complexities of health care demands a balance between structure, process and outcome measures in quality monitoring.

Figure 2.4 is a schematic representation of the structure-process-outcome model based on the work of Avis Donabedian (1966: 166).

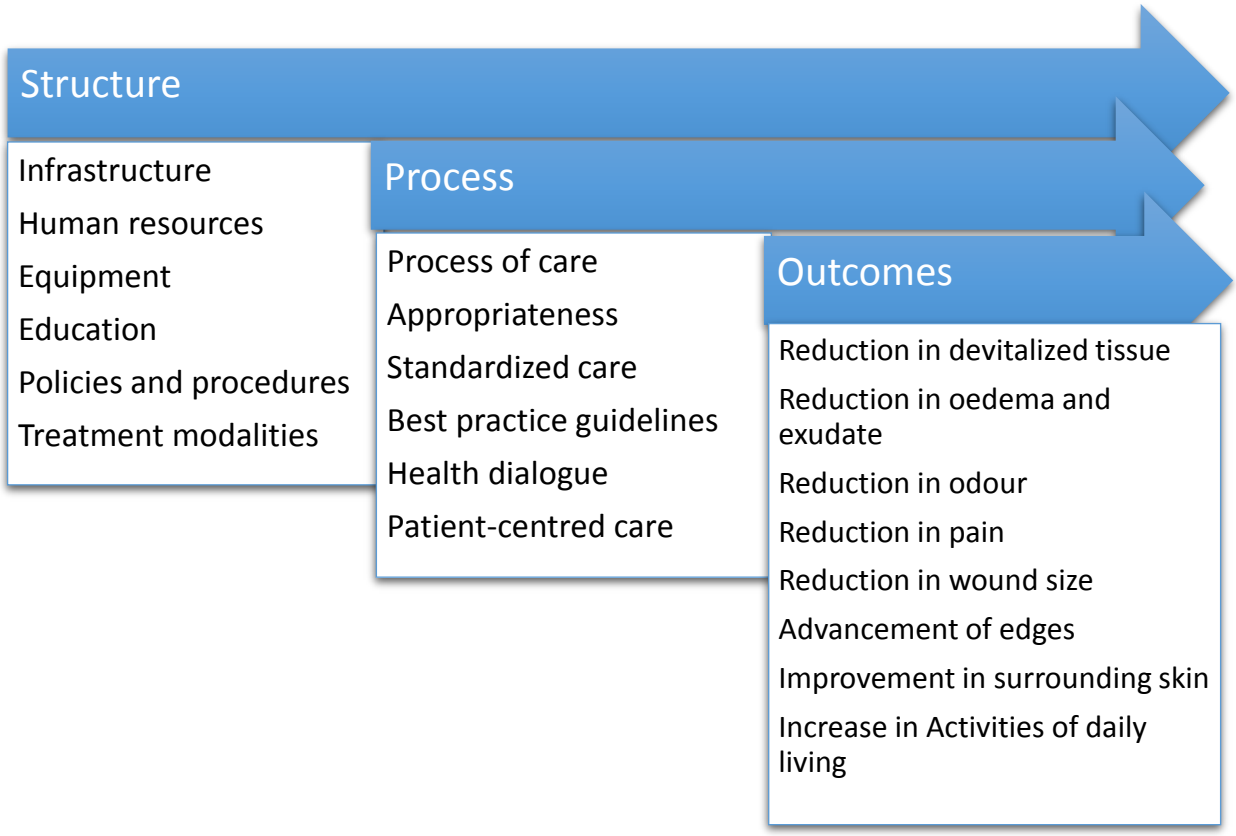


Figure 2.4 Schematic of the structure-process-outcome model with regard to lower leg care (adapted from Donabedian, 1966: 194)

Donabedian's construct is based on the relationship between structure, process and outcome by which an effective structure could support better processes and, in turn, result in better outcomes (Soter, Gomes-Olive, Kahn *et al.*, 2017: 5). Donabedian (1966: 194) used the process by which the care is delivered, as well as the structure in which the care is delivered and the outcome reached, as measures for the assessment of quality. There is a direct correlation between the quality of the facility, i.e., type of infrastructure and type of equipment available, and the quality of the care provided. When assessing the structure, specifically with regard to personnel education at the structure, it should be clear that the type of training and education of the practitioner or service provider directly affects the quality of the care provided. Although outcome is seen as the "ultimate validator" of quality of care, Donabedian contends that effectiveness of care validates the quality of the care.

Although there are known correlations between structure and process, these concepts are described by Donabedian as complex and having high levels of ambiguity due to the many variables involved.

The Donabedian assessment model includes the assessment of the physical setting in which the care takes place, as well as the equipment, administrative properties, i.e., policies and procedures, for the structure. The examination of the process of care assesses the appropriateness and effectiveness of the therapy applied. Finally, Donabedian uses outcomes as a measure of quality. Outcomes could be an indicator of quality, but the measured outcome needs to be relevant to the clinical problem. The outcomes measurement also involves the perception of the client with regard to the value of care, which equates to the quality of the care divided by the cost (Collins & Mannon, 2015: 49). Improved quality of care could be achieved only by measuring the quality (Burstin *et al*., 2016: 154).

According to Donabedian, measurement depends on the development of standards. Donabedian explained that standards are derived from two sources. The first source is empirical standards derived from actual practice where medical care in one setting is compared with care in another setting or statistical averages. The second source is normative standards derived from sources that legitimately set the standards of knowledge and practice. They represent “best medical care” which stems from a body of knowledge and values. Donabedian goes further to say that highly directive standards are associated with the preselection of specific dimension of care for evaluation. By measuring the structure, processes and outcomes, quality assurance systems can be put into place to measure standards of care (Rockville, 2012: online). Evidence-based improvement strategies are needed to help aid quality of care (Burstin *et al*., 2016: 159).

Morton *et al.* (2013: 553) mention the conditions required to support improvement in health care, namely (1) reliable assessments; (2) operationally described protocols; (3) empirically described results; and (4) feedback mechanisms that inform both the assessment and intervention processes. These conditions could be met by applying standardized assessment instruments and methodologies with high inter-rater reliability.

Unfortunately, variation in clinical care prevents the implementation of best practice (Tomson & Van der Veer, 2013: 20). Furthermore, Weller (2012: 333) argues that the reluctance from practitioners to refer patients to advanced facilities for specialized care contributes to patients' not receiving optimal care. The inadequate knowledge of nurses attending to patients could also be a contributing factor to the variations in practice (Tomson & Van der Veer, 2013: 21).

Reliable wound assessments guide decision-making. Through validated algorithms containing appropriate procedural and product choices, healing outcomes should improve, and with improved outcomes quality of care improves (Baranoski, Ayello and Langemo, 2015: 3683). Several studies indicate that guideline-based management of chronic wounds and treatment at specialized wound centres leads to faster healing, improved quality of life and lower costs (Herberger *et al.*, 2013: 227; Edwards, Finlayson, Gibb, Parker, Graves *et al.*, 2014: 226).

The first step in the evaluation and planning of the demand or need for care is to determine the actual quality of care of chronic wounds (Herberger *et al*., 2013:495). Herberger *et al*. (2013: 233) note that deficiencies and possibilities in the provision of appropriate care can be characterized and then used as an instrument to influence political discussions concerning health and the provision of health care. Disease-specific quality indicators are needed to assess quality of care and guideline-based treatment. Quality indicators are increasingly being valued for the assessment of care and for the measurement of changes in health care structures (Collins & Mannon, 2015: 49; Herberger *et al*., 2013: 496). Quality indicators could be defined as "measurable parameters which provide information about the quality of healthcare and which deliver hints for improvements", or as "a measurable element in the process or outcome of care whose value suggests one or more dimension of quality and is theoretically to change by the provider" (Collins & Mannon, 2015: 49). These definitions emphasize the possibility of improving health care through assessments using indicators which have already been demonstrated to positively affect the quality of health care (Herberger *et al.,* 2011: 228). The combination of evidence-based research being applied by expert nurse clinicians contributes to providing quality, safe and cost-effective care to patients and their families (Grove & Burns, 2015: 607).

Chapter 3: Research methodology

3.1 Introduction

This chapter focuses on the research design and tools used in the study. New measurement instruments were developed in this study to assess structure, process and outcome. These instruments, as well as logistics regarding sampling, were tested during the pilot study. In this chapter a detailed description is provided of the sampling grid that guided both the sampling of research sites and the number of files selected to be audited per site. Fieldworkers conducted structured interviews to gather data pertaining to structure and audited files to gather data pertaining to process and outcome. These data collection processes are detailed in the chapter. This chapter also describes the processes of data coding, capturing and analysis. The validity and reliability of the measuring instruments are discussed, together with methodological rigour. The chapter concludes by outlining the limitations of the study and challenges faced by the researcher, as well as ethical considerations.

The study aims to describe the current management of venous leg ulcers within wound care practices in Gauteng by applying the Donabedian quality improvement model.

3.2 Study design

A quantitative descriptive research design was selected, because the researcher formally, objectively and systematically collected data on an observable phenomenon, analysed the data statistically, and presented the results in numerical values (Grove, Gray & Burns, 2015: 1619; Polit & Beck, 2017: 379). Current practice regarding the treatment of lower leg venous ulcers was the observable phenomenon and was systematically observed according to structure, process and outcome as construed in the Donabedian model of quality care (Donabedian, 1988: 1746). Table 3.1 gives a summary of descriptive research and the application thereof in this study.

Table 3.1 Descriptive research and its application in the study (Rovai, Baker & Ponton, 2014: 33)

Concept	Definition	Application
Descriptive research	Explore and describe phenomena of which current knowledge is incomplete or lacking.	Little is known about the quality of lower leg ulcer care in wound care practices in Gauteng. The Donabedian structure-process-outcome model was applied to describe the extent to which the management of venous lower leg ulcers encompasses best available evidence.

This study is descriptive in nature, because it aimed to accurately portray the nature of venous lower leg ulcer care in Gauteng and the frequency with which certain practices occur by using statistics to describe and summarize the data collected (De Vos *et al.*, 2011: 156; Polit and Beck, 2012: 379). By conducting descriptive research, knowledge can be gained about venous lower leg ulcer care practices, because information regarding the quality of lower leg ulcer care is not forthcoming in South Africa (Grove, Gray & Burns, 2015: 1643; Gray, Grove & Sutherland, 2017: 2367).

Figure 3.1 is a schematic representation of the research process that was followed from problem identification through to interpretation and report writing.

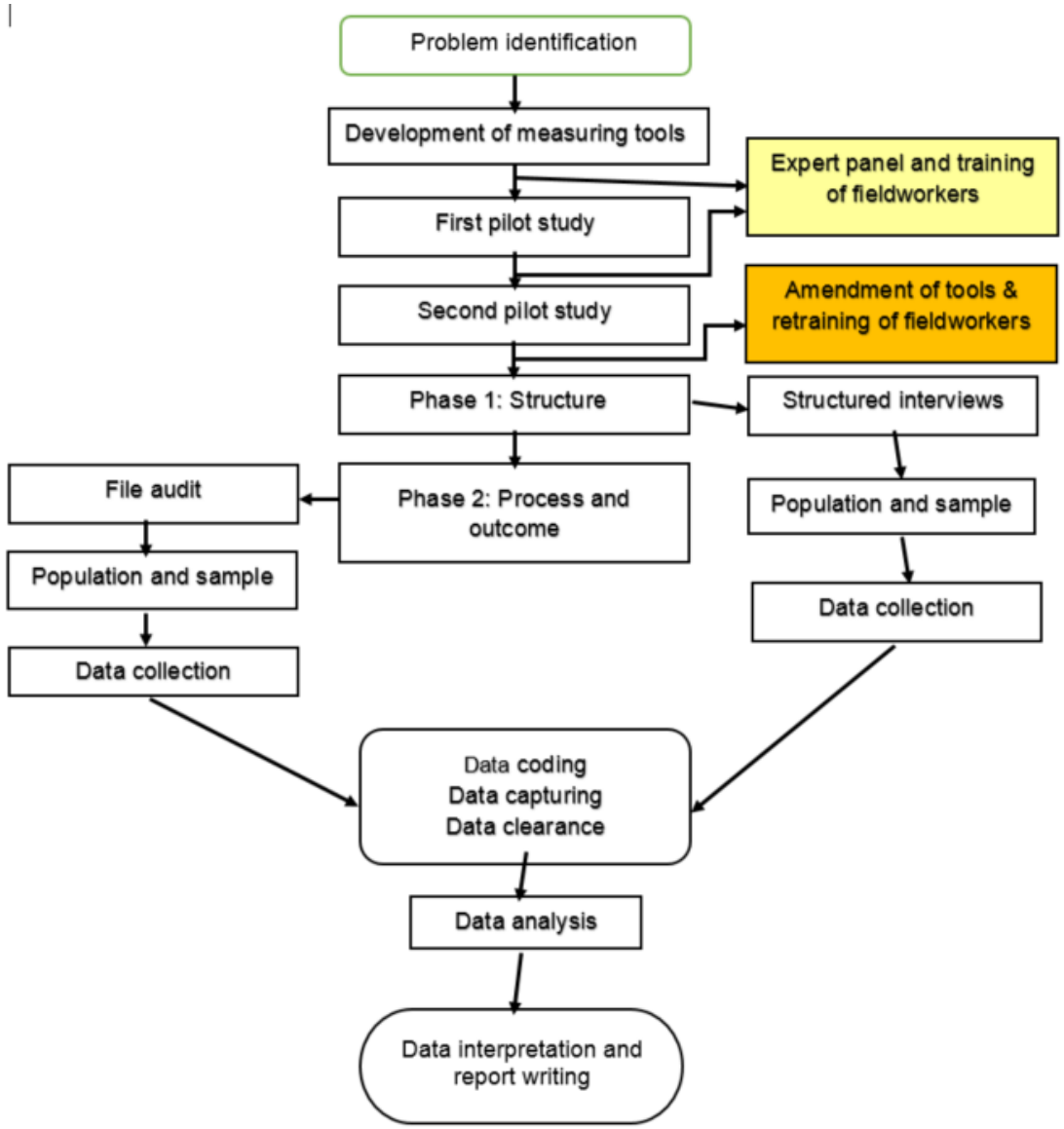


Figure 3.1 Outline of the research process

3.3 Development of measurement tools

Donabedian (1966: 166) proposed that the level of quality of care could be assessed by first investigating the structure of the setting in which care is being provided, secondly, measuring the process of care, and finally assessing the outcome of the care delivered. In this study, two tools were required for the different data collection techniques, namely structured interviews by means of a questionnaire and file auditing by means of a checklist.

The initial questionnaire and checklist were designed using available BPGs and consensus documents. Published BPGs were used to develop the draft measuring tools. Sources from the WHS (UK), SVS (USA), EWMA and WHASA were consulted, as well as Dutch Venous Ulcer Guidelines and Australian and New Zealand clinical practice guidelines. These guidelines, position documents and consensus documents were analysed for similarities regarding the diagnosis and treatment of venous lower leg ulcers. The draft questionnaire consisted of items extracted from the above-mentioned documents and which are aimed at measuring the minimum requirements for wound care practitioners to be able to provide care according to BPGs.

In both the questionnaire and the checklist (Appendices D and F respectively) the questions were designed to be clear, concise and direct to ensure the best possible response (De Vos *et al.*, 2011: 198). The interviews were structured according to the questionnaire, and the checklist was used to conduct the file audit. Table 3.2 provides an outline of the considerations in constructing a questionnaire followed in the study.

Table 3.2 Considerations in constructing a questionnaire (Botma *et al*., 2010: 135; Gray et al., 2017: 2919; Rovai *et al*., 2014: 764)

Do's	**Don'ts**
Use clear, concise language	Avoid "double-barrel" phrases in other words two questions in one i.e. "Was the infection treated and with what?"
Use short, "to the point" questions	Avoid lengthy questions
Use appropriate questions	Avoid negatively worded phrases
Give clear instructions on how to utilize the questionnaire (Appendix K a and Kb)	

3.3.1 Development of the questionnaire to measure structure

As mentioned previously, “structure” refers to the characteristics of the setting in which care is delivered. These include organizational characteristics, i.e., the physical setting (building or other form of structure, e.g., mobile clinic) or infrastructure; human resources, i.e., staff, educational level of personnel, equipment available; and policies and protocols related to care delivery (Donabedian, 1966: 166).

Training provided by the facility and supervision could also be seen as part of structure (Gebrekidan, Tesfaye, Hambisa & Deyessa, 2014: 2). The focus of the study was to determine whether the participating wound care practices have the minimum equipment required to render care according to BPGs. Minimum requirements for structure, as deduced from the guidelines, are:

(a) trained and skilled personnel;
(b) a handheld duplex Doppler to assess the ABPI;
(c) basic equipment to adhere to aseptic techniques when dressing wounds; and
(d) treatment modalities to aid the use of the TIME guideline when assessing and treating wounds.

Essential consumables would be remedies to:

(a) debride devitalized tissue;
(b) treat superficial infection;
(c) create or maintain moisture balance;
(d) promote epidermal advancement; and
(e) treat the underlying cause, i.e., venous hypertension (Marston, Tang, Kirsner & Ennis, 2016: 137; Sibbald *et al*., 2007: 429).

Table 3.3 provides an overview of the components of the questionnaire.

Table 3.3 Overview of the components of the questionnaire

Component	Question number
Biographical data	1
Access to site	2
Basic equipment	3
Staff	4-6
Policies and procedures	7-10 and 13
Debridement equipment	11.1.1 - 11.1.5, 11.7, 11.9
Moisture management	11.2-11.3, 11.5, 11.6, 11.8
Infection management	11.4
Compression therapy	12
Advanced modalities	14

The first draft of the questionnaire (Appendix C), related to the assessment of structure, was done on an MS Excel spreadsheet. The questionnaire was divided into the components as outlined in Table 3.3. Demographic data pertained to the type of facility, i.e., private wound clinic, pharmacy clinic, general practitioner practice, public health care clinic or home-based care, to stratify the facilities into the different strata. Most of the questions were dichotomous, with “yes” being a positive response and “no” negative.

The initial questionnaire drafts were subjected to several minor changes and re-assessment until the final draft was presented to a panel of wound care experts and a biostatistician. The panel suggested that some of the questions be expanded. The final version of the questionnaire (Appendix D) consisted of 14 questions. The components of the questionnaire remained the same, but the questions were refined and adapted to be more descriptive yet concise, as suggested by the panel. Also, most questions remained dichotomous.

3.3.2 Development of the checklist to measure process and outcome

“Process” assesses whether the patient did, in fact, receive “good quality care”, with reference to BPGs and evidence-based care. In other words, it answers the question whether and how BPGs are being implemented in the facility (Polit and Beck, 2012, p. 260). “Process” also evaluates the interpersonal process such as providing

information, emotional support, and involving the patients in decisions regarding their care; thus, it assesses whether patient-centred concerns are being addressed (Grove *et al*., 2015: 1643; Polit & Beck, 2012: 261). According to the Donabedian model, assessment of the process measures the appropriateness and effectiveness of the therapy applied or care delivered (Donabedian, 1966: 166). Therefore, in this study, the focus of the instrument was to assess whether best practice principles were being implemented and applied during patient care and what the outcomes were. Processes were measured by describing how assessment was performed, what information was collected, what clinical data were collected and whether this was guideline based, what treatment modalities were implemented, and whether patient-centred concerns were addressed.

“Outcomes” refers to a change in health status due to the care the client received and outcome could provide a measure of the effectiveness of the wound care intervention (Hanefeld, Powell-Jackson & Balabanova, 2017: 368). According to the Donabedian model, both the relevance and measurability of the outcome should be determined. An increase in access to high quality care reduces the detrimental effects of inadequate care (Gebrekidan *et al.*, 2014: 2). Patient-relevant outcome measures are designed to assess clinical practice with special attention to patient-centred data (Polit & Beck, 2012: 261). In this study, the outcome measures were any changes in health status according to the following criteria:

- Reduction in devitalized tissue;
- Reduction in oedema;
- Reduction in pain;
- Reduction in wound size;
- Advancement of wound edges;
- Reduction in malodour;
- Reduction in exudate level;
- Increase in daily activities; and
- Improvement in the surrounding skin condition.

The first draft (Appendix E) of the checklist was drawn up in MS Word, comprised of 35 questions, mostly dichotomous. Table 3.4 provides an outline of the components of the checklist used in the file audit.

Table 3.4 Components of the checklist used in the file audit

Component	Question number
Type of assessment tools used, and consent signed	1, 2
Referral structures	3
Patient assessment	4, 5, 6
Wound history	5.8-5.8.6
Diagnostic tests done	5.9-5.11
Wound bed assessment	5.12, 10, 11
Patient-centred concerns addressed	6
The use of CEAP classification	7, 8
Assessment of oedema	9
Assessment of infection	12-14
Treatment of infection if present at assessment	15-16
Infection assessed and treated at the three-week interval	29, 30-36
Wound cleansing	17
Compression therapy	18-19
Health dialogue	20-21
Adjunctive therapy	22
Pain management strategies	23
Primary dressings	24-25
Treatment of surrounding skin	26
Frequency of re-assessments	37
Outcome measures and follow-up care	27, 28, 38, 39, 40, 41

The questions related to the initial assessment of the patient, clinical examinations performed on the patient, treatment of the infection, treatment modalities used, and outcomes reached regarding healing trajectory, management of symptoms, health dialogue, and follow-up care. The initial draft (Appendix C) was re-assessed and some of the questions expanded to be more descriptive. After scrutiny by the researcher's supervisors, it was decided to change the format of the checklist.

The checklist was divided into sections relating to the different intervals of measurement to assist in identifying correlations between the processes followed and outcomes reached. These sections were: initial assessment, three-week follow-up and completion of treatment. Processes implemented, and outcomes reached were evaluated. Based on a recommendation by the panel of wound care experts, a period of three weeks was selected because it is the period when infections occur most frequently. Appendix F shows the format change from portrait to landscape with subsections covering the processes and outcomes. The latest version of the checklist was used to retrain the fieldworkers in face-to-face and one-on-one sessions.

The fieldworkers received written instructions (Appendix Ka and Kb) from the researcher on how to use the questionnaire and checklist.

3.3.3 Validity of the measuring tools

A panel consisting of wound care experts and a biostatistician evaluated the questionnaire and file audit checklist for content and face validity. Experts determined whether the measurement tools represent the concept(s) being measured and whether the tool appears to measure the concept (Botma *et al.*, 2010: 174; De Vos *et al.*, 2011: 173). The validity of a measuring instrument correlates with its empirical measurability and how well it can reflect the real meaning of the concept being measured (De Vos *et al.*, 2011: 172). The input of the expert panel in this study contributed to a well-developed measuring tool which, in turn, contributed to the rigour of the study (Grove, Gray & Burns, 2015: 1734). The pilot study also enhanced the rigour of the study.

Validity, as indicated by Polit and Beck (2012:336), refers to the degree to which an instrument measures what it is supposed to measure, whereas reliability refers to the consistency with which an instrument measures the target attribute (Polit & Beck, 2012: 331). The use of the newly developed, guideline-based, quality indicator index measurement tools (Appendices D and F) is supported by evidence from studies conducted by Herberger *et al*. (2013: 495) on the quality of care for leg ulcers.

3.3.4 Reliability of the measuring tool

"Reliability" refers to the consistency of the measuring tool, in other words, whether the tool will deliver the same results when applied to different groups under comparable circumstances (Botma *et al.*, 2010: 177; De Vos *et al.*, 2011: 178). Reliable measuring tools have an acceptable margin of error. In this study, only two well-trained fieldworkers were used to limit intra-observer variation. Furthermore, the data collection process was supervised by the researcher, who also performed periodic checks. Missing data due to incomplete files or incorrect recording of data may have a negative effect on the reliability of the measurement tools (De Vos *et al.*, 2011: 178)

The following procedures enhanced the reliability of the measuring tool:

- The measuring tools were designed to measure adherence to lower leg ulcer treatment protocols and the outcome thereof. Internal consistency involves that each part of the test measures the correct construct. The measuring tools were designed to measure structure, processes implemented, and outcomes reached on different intervals, i.e. assessment, three-week follow-up, and completion.
- Instructions for use were standardized (Appendix K).
- Dichotomous questions reduced the degree of difficulty.
- The effects of external events were reduced as far as possible by conducting interviews and file audits in a separate room from where patients are attended to.
- The pilot study tested inter alia the ease with which the tools can be completed, understanding of each item in the tools, and consistency in recording the results.
- The researcher incorporated the results from the training sessions and pilot study into the measurement tools.

3.4 Pilot study

A pilot study, which is a small-scale version of the original study, was undertaken to test the methods of the study and the newly developed instruments (Polit and Beck, 2017: 195). The pilot study also aided in determining the feasibility of the study, which contributed to refining the budget and preventing financial loss (Botma *et al.*, 2010: 137; De Vos *et al.*, 2011: 195).

Two unemployed nurses, who were willing to assist and had some wound care knowledge and experience, were recruited by the researcher. Using fieldworkers can reduce the time spent on data collection, as interviews tend to be very time consuming (De Vos *et al.*, 2011: 243). In this study, the fieldworkers signed non-disclosure agreements, after which the researcher discussed and explained the protocol. Training of the fieldworkers comprised basic principles of wound care and lower leg ulcer aetiology, diagnosis and assessment (De Vos *et al.*, 2011: 244), as well as the basic principles of GCP, namely obtaining voluntary and uncoerced informed consent from participants. Instructions were given to the fieldworkers on how to complete the questionnaire and checklist, on the confidentiality of the information, and the importance of accuracy, while comprehensiveness of data was emphasized (Grove, Gray & Burns, 2015: 1819). The fieldworkers practised under supervision of the researcher on files from the researcher's own wound care clinic.

Convenient sampling was used to obtain participants for the pilot study (Botma *et al.*, 2010: 125). From the original list of facilities, five were selected conveniently, in other words, they were easily accessible and willing to participate (Botma *et al.*, 2010: 125). Initial contact was made telephonically to confirm details and explain the study in broad terms. A follow-up e-mail was sent that contained an introductory letter, the protocol summary and informed consent form (De Vos *et al.*, 2011: 189). Appointments were set up with those clinics that showed a positive response during the phone conversation or via e-mail. The fieldworkers scheduled appointments at the convenience of the participants.

The results of the pilot study indicated that the measuring tool, specifically the checklist for the file audit, was not comprehensive enough to determine correlations between process and outcome. Thus, the checklist was scrutinized and redesigned. The initial portrait layout was modified to reflect assessments at different intervals, i.e., initial assessment, three weeks into the treatment, and on completion, to aid in the assessment of both the process implemented and the outcomes reached. Retraining of the fieldworkers focused on errors made during the first pilot study and the use of the new checklist (De Vos *et al.*, 2011: 195).

The biostatistician suggested a second pilot to evaluate the revised checklist. Again, the researcher randomly selected five files from a site and the fieldworkers collected the data by using the revised checklist. The researcher assessed the quality of the data collected, and the biostatistician approved the quality of the data, as well as the coding and capturing thereof.

The second pilot study revealed that the fieldworkers needed continuous debriefing to limit misunderstandings about clinical practice protocols and optimize data collection. Data collected during both pilot studies were not included in the main study.

3.5 Data collection

Although the data collection occurred concurrently, the process will be described as two separate phases for clarity purposes. Phase 1 comprised structured interviews according to a questionnaire to collect data on the structure of the facility delivering the care. Phase 2 entailed collecting data on the processes applied and outcomes reached by means of a checklist. Each phase will be discussed according to the data collection method used i.e. structured interview and file audit, population and sampling method, and data collection process. Data analysis will be discussed under one heading.

3.5.1 Phase 1: Structure

In this phase the emphasis was on the care providers, their qualifications, tools and resources, as well as the physical and organizational setting of the facility (Donabedian, 1966: 166).

3.5.1.1 Structured interviews

The fieldworkers used the formal written questionnaire as a set of questions (Appendix D) to collect quantifiable data regarding structure (De Vos *et al.*, 2011: 186; Polit & Beck, 2012: 297; 2017: 10044). Although De Vos *et al.* (2011: 186) point out that interviews are time consuming, the questionnaire was short, with mostly dichotomous questions that required only a yes or no answer. According to Polit and Beck (2012: 265), interviews are often more costly than questionnaires that are sent via post or e-mail and require intensive preparation and training. However, they are still regarded as the best way to collect data, as refusal rates are low and the quality of the information gathered is high (De Vos *et al.*, 2011: 195).

3.5.1.2 Population and sampling for structured interviews

"Population" generally refers to a collection of individuals, items or units that are the subject of investigation (Fowler, Jarvis and Chevannes, 2009: 440). In this instance, the population consisted of practices with a wound care service, i.e., either private wound clinics, public-sector hospitals with an outpatient wound clinic, general practitioners with a wound care service at the practice, pharmacies that deliver a wound care service, or home-based care practitioners who visit patients at their homes.

The researcher compiled a list of all the known private clinics, home-based care practices, general practitioner practices, pharmacies with clinics, and public-sector clinics in the Gauteng area. These facilities comprised five strata. Contact details were sourced from Google and associations such as WHASA and SPNP. The initial population consisted of 20 private wound clinics, seven public-sector clinics, 30 pharmacies, 18 general practitioner practices and 30 home-based care nurses.

The population consisted of heterogeneous groups; therefore, stratified random sampling ensured proportional representation of each group in the sample (Gray, Grove & Sutherland, 2017: 10138). Because they were selected randomly, all the facilities in the study population had an equal chance of being selected (Gray, Grove & Sutherland, 2017: 10122). The researcher listed facilities alphabetically per stratum and numbered them. Every third number on the list was selected and a new list generated. The facilities were contacted first through an introductory telephone call to confirm their contact details and their willingness to participate. An e-mail containing

an introductory letter, protocol summary and informed consent form was then sent to those facilities who responded positively (De Vos *et al.*, 2011: 193). Incorrect e-mail addresses were telephonically verified and resent. A list was compiled of the facilities that responded favourably after initial contact. Clinics or practitioners who indicated that they were not interested in taking part and wished to be withdrawn from the study were replaced randomly using the same technique as described previously (Gray, Grove & Sutherland, 2017: 10138). The list was updated to 82 possible sites, of which a 50% sample of 41 facilities was identified, with representatives from each stratum.

Randomization was selected to give the whole population an equal chance to participate and to minimize bias, since the researcher works within the wound care community, and many of the private practices are known to her (Polit and Beck, 2017, p. 6408). “Bias” is described as “any influence that produces a distortion or misinterpretation of the outcome of the study” (Botma *et al.*, 2010: 85).

Sampling in the public-sector stratum required that a specific process be followed. The Department of Health was contacted via the website, and the contact person responded by providing the details of the relevant research coordinator. The research coordinator was contacted via e-mail and indicated that the following documentation was required:

1. A letter requesting permission to conduct research at a public facility (Gauteng Provincial Department of Health);
2. The full study protocol;
3. The questionnaire and file audit checklist;
4. Ethical approval from the relevant university; and
5. A list of facilities where the research was to be conducted.

All the above-mentioned documents were e-mailed to the research coordinator at the Department of Health. A few days later, the researcher followed up the e-mail telephonically. The research coordinator instructed that registration on the National Health Research Department (NHRD) website is required, which the researcher subsequently did (GP2017RP16560) (see Appendix I).

The department heads of the participating Department of Health (DoH) clinics had to complete the annexure received from the DoH (Appendix I). The researcher contacted the relevant person at the facilities weekly to follow up on progress. Documents requested by the Chief Executive Officers (CEOs) of two of the facilities were hand-delivered to the personal assistant of the CEO for his approval and signature. Another two facilities required that three bounded hardcopies of all the documentation be delivered to the office of the CEO. The request to participate in the research was then tabled at the monthly management meeting of the facility, after which the CEO granted permission.

Figure 3.2 is a schematic representation of the sampling of facilities.

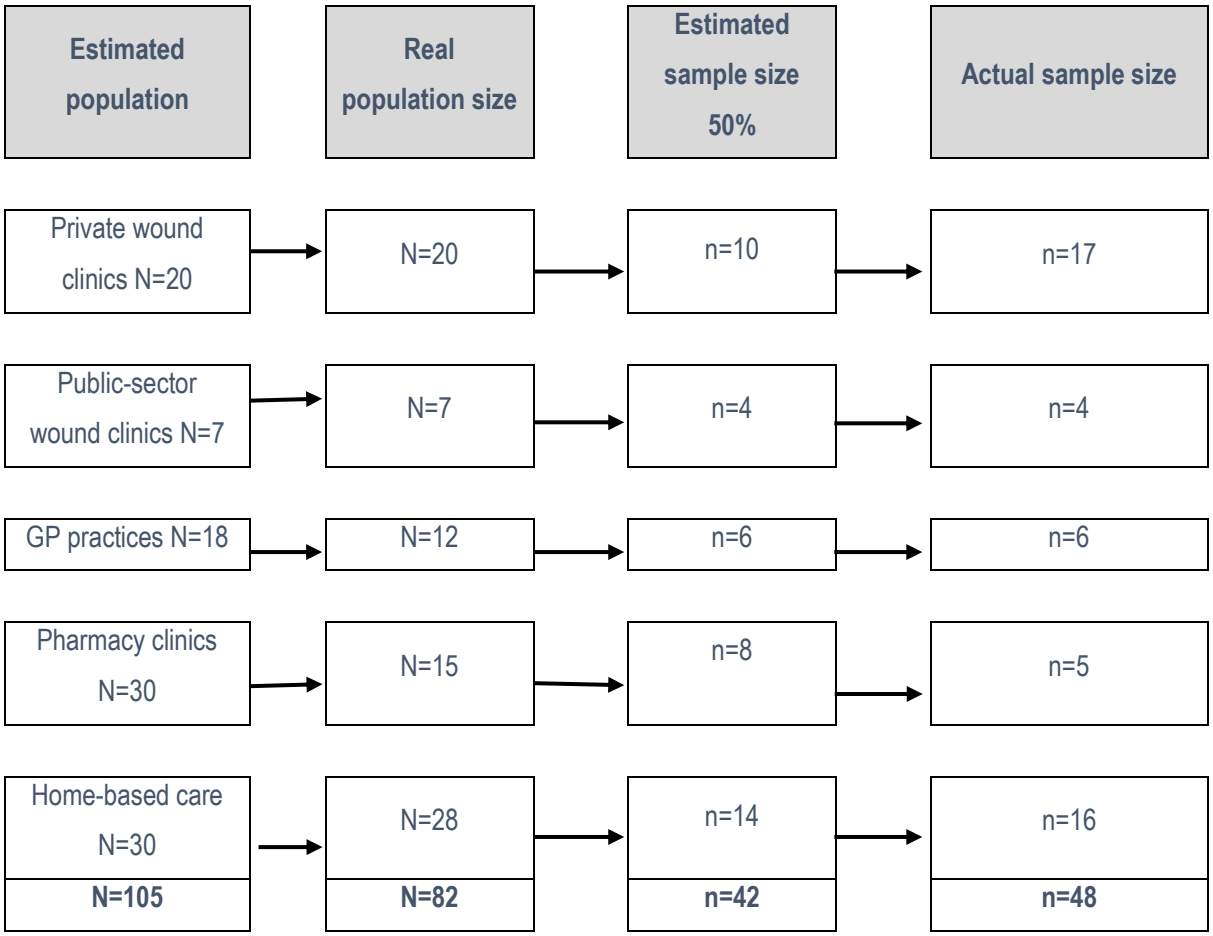


Figure 3.2 Schematic representation of facility sampling

The initial sample size from the list of possible participants was calculated at 50% to be representative of the population. The calculation was made on the initial estimate of possible participants based on information obtained from various associations and internet sources such as LinkedIn. Figure 3.2 shows that the population, in fact, slightly differed from the estimation. For a survey, Rovai *et al*. (2014: 23) suggest a minimum sample size of 50% to be representative of the population. Only once the file audit had started did it become clear that the number of files collected was not sufficient to constitute a representative sample. After consultation with the biostatistician it was decided to increase other strata, if possible, to ensure a representative sample of the larger population and aid in obtaining a representative sample of the files that needed to be audited. Of the proposed population of 18 general practitioner sites listed, the final population comprised only six participants, as one practice had closed, and several others on the initial list had declined participation.

The researcher attempted to replace the participants, but unfortunately could not locate other general practitioner practices willing to participate which, in turn, affected the population size, as well as the sample size. Of all the pharmacy groups initially included in the population, only one participated, as well as a few small independent pharmacies, which changed the profile of the population significantly by reducing the sample size. The inclusion criteria were that the facilities had to:

- Treat lower leg ulcers of venous origin;
- Fall in any one of the mentioned strata;
- Be located within a radius of maximum 75 km from the researcher's base in Gauteng (Germiston) (Google Maps was used to determine distances to the various facilities); and
- Be willing to participate in the study.

3.5.1.3 Data collection regarding structure

The fieldworkers made appointments telephonically with the contact persons at the different facilities. Scheduling appointments with the government clinics proved to be more complex, and the fieldworkers had to overcome several barriers. The government clinics could not be contacted telephonically for an appointment, the fieldworker had to go to the clinic with the signed access to facility form as well as the signed annexure (Appendix I) received from the CEO. The fieldworker then had to locate the manager of the clinic.

The manager was then consulted regarding a suitable time for the interview. A few times the fieldworker had to return on a later date suitable to the unit manager to conduct the interview.

The researcher provided each fieldworker with a cell phone with access to Google Maps to find the facilities with ease. The researcher also gave them copies of the informed consent form, Access to Facility form and the measuring tools, i.e., the questionnaire and checklist, as well as a travel log to calculate distance travelled and large envelopes in which the documents were to be placed and sealed once completed.

For the private wound clinics, the practice managers had to read and sign the Access to Facility form, after which the fieldworkers could conduct the interview with the clinicians at a location of their convenience. Interviews with home-based care nurses were conducted at a location of their convenience, e.g., where they performed their administrative duties or at their private residences. The owners of the private wound clinics and home-based care practices signed the Access to Facility (Appendix L) form and interviews were conducted in an agreed upon location, mostly after hours as not to disrupt the practitioner's routines. At general practitioner practices either the practice manager or the general practitioner themselves signed the Access to Facility form. Interviews were then conducted with the doctors themselves or the registered nurses attending to patients in the practice. At the pharmacy clinics, the pharmacists or pharmacy managers signed the Access to Facility form and interviews were conducted in an allocated room on the pharmacy premises with either the pharmacist or the nurse attending to patients.

First contact with government-based clinics was made via e-mail, specifically with the research liaison who submitted the research proposal to the District Research Committee for approval. Thereafter, the Chief Director gave permission in writing. After notification of the approval, the researcher uploaded the research title, aim and objectives onto the NHRD website. Tshwane Health Department responded via e-mail requesting that the hospital management complete a form for the researcher/fieldworkers to gain access to hospital premises and files.

In public hospitals, the first contact was with the CEO's personal assistant who set up an appointment with the CEO or the clinical manager; thus, the fieldworker had to return on the appointment date. Once the CEO granted access to the facility, the fieldworkers had to make an appointment with the unit manager to arrange for an interview and retrieval of the files.

Upon arrival on the scheduled date and time, the fieldworkers completed their travel logs, indicating time arrived, facility number and kilometres travelled, and then entered the facility. This was done to confirm that the site was located within the 75 km radius as stipulated in the inclusion criteria, as well as to aid the researcher in renumeration of the fieldworkers, as they were refunded for travel expenses.

Once inside the facility, the fieldworkers introduced themselves and confirmed the appointment and reason for the visit. The receptionists then called the relevant facility manager and the fieldworkers again introduced themselves and confirmed the appointment. The fieldworkers then briefly explained what the file audit and data collection entailed and confirmed the estimated duration of the interview. The participants had to read and sign the Access to Facility and informed consent forms, which were then placed in an Access to Facility/Informed Consent (ATF/ICF) file pouch and later filed at the researcher's facility. Once these formalities had been completed, the fieldworkers conducted the interviews in a designated consulting room or private area.

3.5.2 Phase 2: Process and outcome

Clinical effectiveness focuses on the process of care or how the care was administered, while an outcome-based measure of quality focuses on outcomes reached and the patient's response to the care delivered (Hanefeld, Powell-Jackson & Balabanova, 2017: 368). Care processes require an evidence base to act as a benchmark against which interventions could be measured (Hanefeld, Powell-Jackson & Balabanova, 2017: 369). Donabedian's model utilizes both process and outcome to measure quality of care. Process is aimed at the implementation of BPGs and evidence-based care and whether the patient was centre to the decision-making process during the implementation of the guidelines (Donabedian, 1966: 166).

Process is measured by evaluating actual care given, whereas outcome is measured by outcomes reached. In this study, process and outcome were measured by auditing the files of patients with venous lower leg ulcers according to a checklist (Appendix F).

3.5.2.1 Auditing of files

The fieldworkers perused the files of patients with venous lower leg ulcers and used a checklist to record information regarding adherence to known and accepted guidelines (De Vos *et al.*, 2011: 220). Processes were measured by the extent to which guidelines were followed at assessment, process was followed with a specific incident, i.e., when infection developed within the first three weeks of assessment and finally what outcomes were reached at completion of treatment.

3.5.2.2 Sampling of files

During initial contact with facility managers, the fieldworkers requested to pre-select files of patients who presented with lower leg ulcers that meet the following inclusion criteria:

- The ulcer must be confirmed as venous of origin; and
- The last treatment must have been within the last six months, but only files of patients who were not currently receiving treatment were included. If the patient was still being treated, this would require informed consent from the patient, which could complicate data collection, prolong the estimated time spent on data collection and give an obscured assessment of outcomes.

The fieldworkers randomly selected the first file from the pile supplied by the facility manager, and then every second file until an estimated 20% sample was collected (De Vos *et al*., 2011: 230). According to Botma *et al.* (2012: 130), a 10% sample is sufficient for controlling sampling errors; thus, a 20% sample can aid the researcher in drawing conclusions and making predictions. Unfortunately, the different sites that were visited did not have incidence and prevalence data of the venous lower leg ulcers they treated. Thus, files were requested that fit the criteria, and a random selection was done of these files. The biostatistician suggested that a minimum of 160 audited files would be representative of the population.

Figure 3.3 is a schematic representation of the sampling of files.

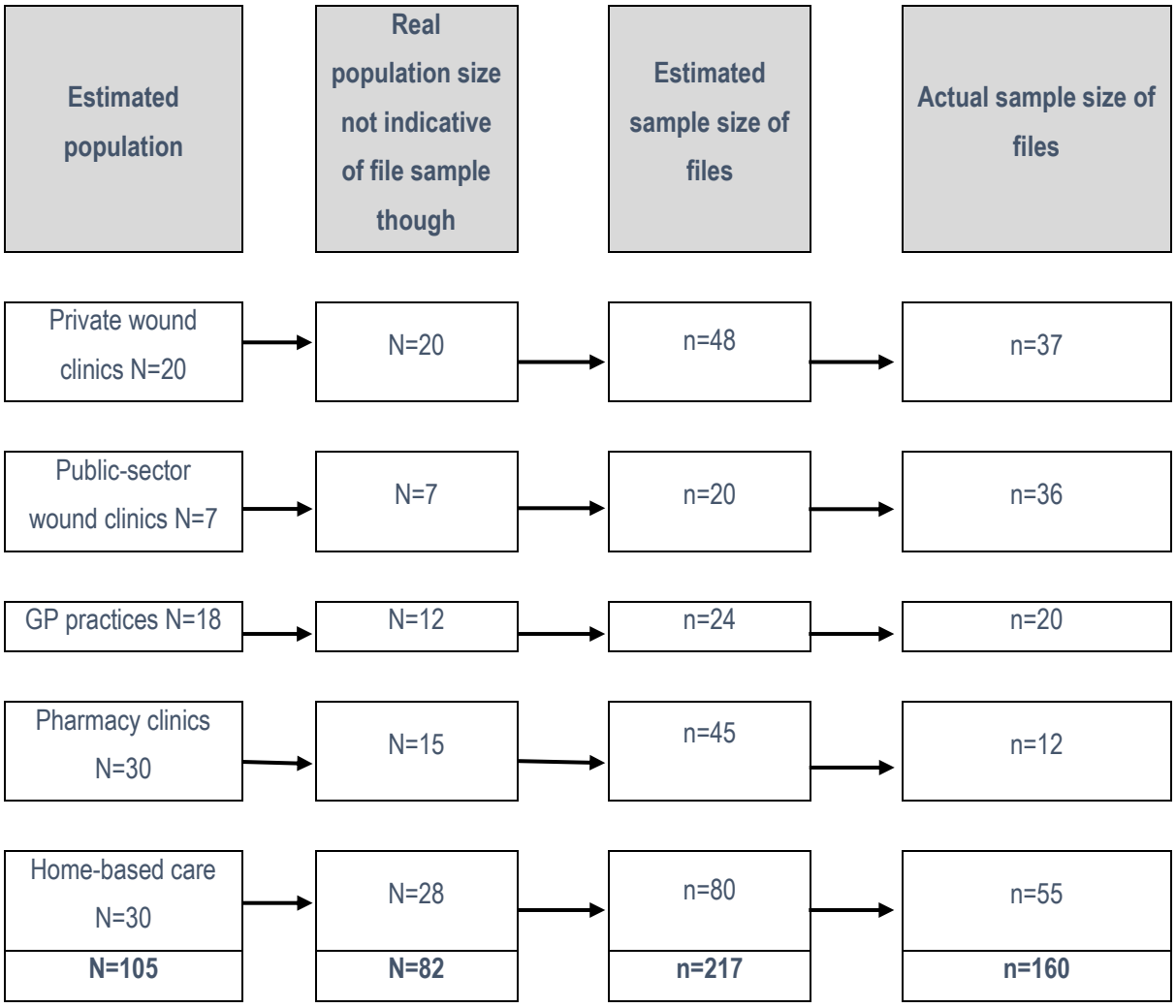


Figure 3.3 Schematic representation of the file sampling process

Initial estimates for file samples were calculated according to the data available to the researcher. The researcher manages a private wound clinic that treats between 25 and 30 patients per day, with cumulative consultations of between 400 and 600 per month of which 65% presents with venous lower leg ulcers. De Vos *et al.* (2011: 225) note the inverse relationship between sample size and population: the larger the population, the smaller the sample and vice versa. Accordingly, the researcher calculated that, if 65% of patients present with lower leg ulcers of venous origin, the other private clinics which consisted of eight clinics in the initial sample, might have attended to approximately 128 patients or more in the last six months (eight clinics attending to 16 patients each equals 128 patients).

De Vos *et al.* (2011: 225) suggest a 45% sample for 100 participants; hence, the initial 48 file estimate sample for a possible 128 participants (files). However, the sample size of the private wound clinics had to be increased to 17 clinics to obtain a more representative file sample, because on average only three files per facility met the inclusion criteria. Finally, only 37 files were sampled, which still calculated to about 20% per facility.

In the public sector, patients with lower leg ulcers far exceeded the initial estimate. After consultation with the biostatistician the sample size was increased to acquire a more representative sample of the public-sector wound clinic strata.

Obtaining a representative sample from the pharmacy group proved a challenge, as the big pharmacy groups declined to participate. Thus, the final sample was much smaller than anticipated and only nine files met the inclusion criteria. Also, despite a long list of general practitioner practices in the area, the final sample comprised six practices of which only six files fit the inclusion criteria for the file audit. Finally, obtaining data from the home-based care nurses were also challenging, since the final sample included only 16 nurses, and an average of four files per site were the only files that fit the inclusion criteria – which still calculated to about a 30% sample of the facilities. Many of the home-based care nurses declined to participate for reasons undisclosed.

Ultimately, 160 files from the 48 facilities were included, averaging about 3,3 files per facility. This constitutes about a 30% sample per facility and a 74% sample from the total estimated file population.

3.5.2.3 Data collection by means of audit

The fieldworkers selected the files and completed the audit checklist on site. No identifiable data were collected. On completion the fieldworkers placed the signed informed consent and Access to Facility forms and the completed interview questionnaire and audit checklist in an envelope, wrote the strata and number allocated to the clinic on the envelope and sealed it.

Finally, the fieldworkers returned the files to the facility manager or receptionist and thanked them for their time and cooperation. The facility manager signed the fieldworkers' log, after which they delivered the sealed envelope to the researcher.

After access was granted to the public-sector clinics, the CEO instructed the manager of the wound clinic to complete the questionnaire and retrieve files from the archives of patients who fit the inclusion criteria. Files were then collected from the relevant departments and file audits conducted at the site. The same process was followed as with the private institutions.

3.6 Data coding

Coding involves converting data to numerical values that can be interpreted by a computer and analysed using computer software (De Vos *et al*., 2011: 196, 252). Before data capturing could commence, the researcher and the data capturer liaised with the biostatistician regarding the coding of questions that had options listed. The biostatistician instructed the researcher and data capturer on how to code the data and assign numerical values to the answers. The data capturer coded the data by allocating a numerical value to the answer of each question and the researcher checked the coding (De Vos *et al.*, 2011: 196)

3.7 Data capturing

Data were captured on an MS Excel spreadsheet by an independent data capturer. All the questionnaires completed during the structured interviews and the file audits were numbered (De Vos *et al.*, 2011: 196). Question numbers appeared in vertical columns and file numbers and data in horizontal rows. Data indicated as not completed by site were distinguished by two legends with different colours as "included in assessment form but not recorded" and "not recorded by site". The coding sheet was attached to the data sheet and the biostatistician analysed the data accordingly. The data capturer checked and edited the data under supervision of the biostatistician.

3.8 Data analysis

Descriptive statistics was used to describe numerical data (De Vos *et al.*, 2011: 251). Descriptive statistics summarizes a data set and presents the results in a visual format that is easy to understand (Botma *et al.*, 2010: 149). Frequency distributions summarize the distribution of a variable and report on the number of cases contained in each category of the variable (Fowler, Jarvis and Chevannes, 2009: 2227). Thus, descriptive statistics is used to summarize the data, rather than to generalize the data to the population. Rovai *et al.* (2014: 41) refer to discrete variables or categorical variables that are non-metric, while continuous data or variables can take on a value between two specified values. All the data collected in the study were based on frequencies and whether the occurrence took place or not. Continuous data collected included years of clinical wound care experience of the practitioners attending to the patients, age of the patients, size of the wounds, the period the wounds have been treated before, and the time to healing. All the other data collected were categorical data and measured in frequency and percentage of the different variables.

3.9 Limitations

Limitations mainly pertained to sampling. As mentioned previously, the bigger pharmacy groups in South Africa declined participation, resulting in the pharmacy strata consisting only of small independent pharmacies that were willing to participate. The sample from the general practitioner strata was also limited, as only three from the potential participant list were willing to participate and, as mentioned, from these participants only a limited number of files could be audited. Thus, the full sample could not be collected.

Further limitations included the fact that the recordkeeping of the files collected at the sites was often incomplete and that some of the files had not been bound in sequence. Also, the handwriting in the files was illegible at times. Inaccurate and incomplete documentation could influence the quality of the data collected (Gebrekidan *et al.*, 2014: 4).

3.10 Ethical considerations

Ethical principles were applied to all aspects of the study. These principles included autonomy, beneficence and justice. Table 3.5 provides a summary of the principles and how they were adhered to in the study.

Table 3.5 Descriptions of ethical principles (Polit and Beck, 2017, p. 155)

Ethical principle	Description	Application to study
Autonomy	Based upon a person's right to self-determination and voluntary choice to participate in the study.	The information leaflet contained details about the study and allowed participants to make an informed decision. No-one coerced participants to participate and they could withdraw from the study without retribution. The researcher and fieldworkers treated participants with respect by keeping to the scheduled appointment times and places.
Beneficence	Based upon the right to protection from discomfort and harm; to "do good".	The participants did not directly benefit from the study; however, quality of care might improve once the researcher disseminates the results.
Nonmaleficence	Above all, "do no harm".	The researcher limited potential reputational harm by de-identifying data, maintaining confidentiality, and reporting aggregate data. The questionnaire was short and did not take up much time; thus, physical harm was limited. The questionnaire was also conducted during lunchtime or after hours to reduce possible economic harm. No other type of harm was foreseen.

Ethical principle	Description	Application to study
Justice	The responsibility for the equitable treatment of all individuals and organizations involved in the research process.	Randomization ensured equal chance to be included in the study. The researcher and the fieldworkers treated all participants equally and acted according to the research proposal.

The Belmont Report stipulates four ethical principles for research, namely autonomy, beneficence, nonmaleficence, and justice (Pera & Van Tonder, 2011:53; Polit & Beck 2012: 152). As described in Table 3.5, "autonomy" refers to the expression of respect for the absolute worth of an individual and is demonstrated when participants are allowed to make informed decisions and given a choice to participate or not, which amounts to voluntary participation (Long & Johnson, 2007: 50). Appendix B is the information letter that supports the upholding of the participants' right to full disclosure. Therein the researcher fully explained the purpose of the study, the data collection process, the option to participate or not, no punishment if the participant chooses not to participate, the researcher's responsibilities, as well as the risks and benefits. Informed consent, the right of refusal to participate, transparency regarding the aims and objectives of the study, as well as privacy and confidentiality, form part of the principle of autonomy (Pera & Van Tonder, 2011: 54). The right to self-determination also includes freedom from coercion, which might include penalties or rewards (Polit & Beck, 2012: 153). The right to self-determination and the right to full disclosure form part of informed consent which was obtained from each participant before participating in the study.

Another ethical principle is beneficence, which means "to do good" (Pera & Van Tonder, 2011: 55). Polit and Beck (2012: 153) view beneficence as the duty of the researcher. In this study, the researcher is the only person who will benefit directly from the study by obtaining her master's degree. The wound care community will benefit indirectly from the knowledge generated from the research (Gray *et al*., 2017: 8346). Dissemination of the results may raise awareness about practice gaps that could be addressed to improve quality of care.

“Nonmaleficence” pertains to the researcher’s responsibility to protect participants against foreseeable physical, psychological, social, economic, or dignitary or legal harm or suffering that may be experienced in the course, or as a result, of the research (Botma *et al.*, 2010: 23; Gray, Grove & Sutherland, 2017: 8296). In this study reputational harm was limited by numbering the sites and de-identifying data, maintaining confidentiality and reporting aggregate data, as described in Table 3.5. With regard to potential harm, the researcher, firstly, foresaw the temporary disruption in the practitioners’ daily routine due to their participation in a structured interview and observation. However, this could be justified by the fact that the data collected could assist in identifying a “practice gap” and encourage change in practice and clinical behaviour (De Vos *et al.*, 2011: 115). Secondly, many of the practitioners work in a “no work no pay” reimbursement structure; thus, occupying their time could be seen as financially harmful. The researcher addressed this issue by scheduling appointments at the participants’ convenience, i.e., after hours or during lunchtime. Long and Johnson (2007: 15) point out that the participant has no right to payment or benefit. The right to be protected from exploitation is another aspect of nonmaleficence that needs to be addressed; thus, the researcher ensured participants that any information provided would not be used against them (Polit & Beck, 2012:153). This confirmation was included in the informed consent form.

In order to avoid harm, qualified people conducted the research (Polit & Beck 2012: 153). The fieldworkers were registered nurses and trained in accordance to GCP guidelines. After the initial pilot study, the researcher retrained the fieldworkers in the use of the amended measurement tool. In an effort to prevent untoward use of information or any unprofessional conduct and ensure confidentiality (Pera & Van Tonder, 2011: 55), the fieldworkers signed a non-disclosure agreement.

Approval to conduct the research was obtained from the Health Sciences Research Ethics Committee of the UFS (Appendix A). All the relevant authorities of the facilities granted written permission for entrance to the facilities (Appendix L).

The fourth principle of research ethics is justice, which refers to the participant's right to fair treatment and right to privacy (Polit & Beck, 2012: 155). Every precaution was taken to protect the privacy of participants and the confidentiality of their personal information, as well as to minimize the impact of the study on their physical, mental and social integrity (Polit and Beck, 2012, p. 156). "Justice" is concerned with the equitable distribution of benefits and burdens and involves the adherence to the study protocol (Botma *et al*., 2010: 20). The concept also implies that the participants have an equal chance to participate. In this regard, the study applied random sampling on both the facilities and the files that were audited.

All data were gathered with the knowledge of the participants and with their consent. Participants were informed that their anonymity would be ensured, as a number would be allocated to each participant and no names of any provider, hospital or patient would be mentioned (De Vos *et al*., 2011: 114). In this way, the participants' right to privacy was ensured and protected (Long & Johnson, 2007: 16).

All data captured were password protected and had firewall, anti-virus and spyware protection. Information was available only to the researcher and fieldworkers with appropriate authorization. Hard copies of the data, as well as portable data, were stored in locked, fire-proof cabinets, and will be kept safe for a minimum of five years (Botma *et al.*, 2010: 19).

3.11 Methodological rigour

"Rigour" refers to the "truth value" of the outcome of the research and pertains to the validity of the research (Botma *et al.*, 2010: 84). Limiting errors, applying discipline and adhering to details in the study contribute to excellence and, thus, to the rigour of the research (Botma *et al.*, 2010: 84). In this regard, the fieldworkers carefully documented every step in the research process, and care was taken not to make errors. The fieldworkers kept a copy of the research protocol with them at all times to refer to the procedures if necessary. The researcher checked every data sheet for accuracy and comprehensiveness. Any missing data were addressed immediately and, where necessary, the fieldworker was retrained and instructed to return to the site and collect the data (De Vos *et al.*, 2011: 202).

Only two fieldworkers could be sourced, which affected the speed of data collection negatively. However, with only two fieldworkers, there was more control over the data collection. Furthermore, this contributed to consistency in data collection, and improved consistency contributed to the rigour of the study. Data clearance was done under the supervision of the biostatistician, who also performed the data analysis. The biostatistician verified the researcher's data interpretation and recommendations based on the study results.

"Validity" refers to the "extent to which an empirical measure adequately reflects the real meaning of the concept under consideration" (De Vos *et al.*, 2011: 202). As explained previously, the questionnaire and checklist were designed to assess and describe current practice regarding structure, process and outcome. The file audit entailed that files were checked at assessment, then at intervals of three weeks post assessment, and then on completion, either upon healing of the wound or patient referral. According to Donabedian (1966: 166), quality of health care can be measured by assessing the three elements of structure, process and outcome, and the measuring tools were designed to do exactly that. A panel of wound care experts currently in practice assessed the instrument for content and face validity (De Vos *et al.*, 2011: 175).

3.12 Chapter summary

Exploring the quality of care could be instrumental in the standardization of care and improvement of outcomes (Morton *et al.*, 2013: 553). The quality of wound management cannot be evaluated unless there are standards against which to measure it (Andrews & Langley, 2015: 59). A challenge in this study was all the restrictions encountered in the government sector and the fact that it was very difficult at times to get hold of the CEOs of some of the hospitals. The fieldworkers had to return several times, regardless of having made appointments, which proved to be very costly. Fortunately, this did not influence data collection.

Donabedian (1988: 66) described the measurement of quality according to the structure-process-outcome model. The researcher utilized this model to describe the current level of practice concerning venous lower leg ulcer care according to structure, process and outcome.

Chapter 4: Data analysis of structure

4.1 Introduction

This chapter provides an analysis of the data collected as described in Chapter 3. The data collected and analysed will be used to describe the structure of the facilities with regard to professional and organizational resources associated with the provision of care, i.e. equipment available, human resources and treatment modalities available in the care facility. Descriptive statistics will be used to summate and present the data (Rovai *et al.*, 2014: 34).

4.1.1 Structure

As mentioned previously, structure is concerned with the physical setting of the facility (Donabedian, 1966: 166). A total of 48 (n=48) facilities were included in the study, comprising 17 private wound clinics, four public health care clinics, six pharmacy clinics, five general practitioners and 16 home-based care nurses. Hereafter, n=48 unless stated otherwise.

For purposes of the study, private wound clinics are described as facilities in the private funding sector, either stand-alone clinics or within a hospital setting, which attend to patients with wounds. Public health care clinics, on the other hand, are sections of outpatient clinics at public hospitals dedicated to outpatient wound care. In this study, pharmacy clinics include pharmacies that indicated that they deliver a wound care service and have a separate area where patients with wounds are attended to. Similarly, general practitioners are seen as those who indicated that they attend to patients presenting with chronic wounds. Finally, private nursing practitioners are those stationed at home but delivering wound care services to patients at their homes. Figure 4.1 shows the number of facilities per strata (blue) and the final sample of files per strata (green).

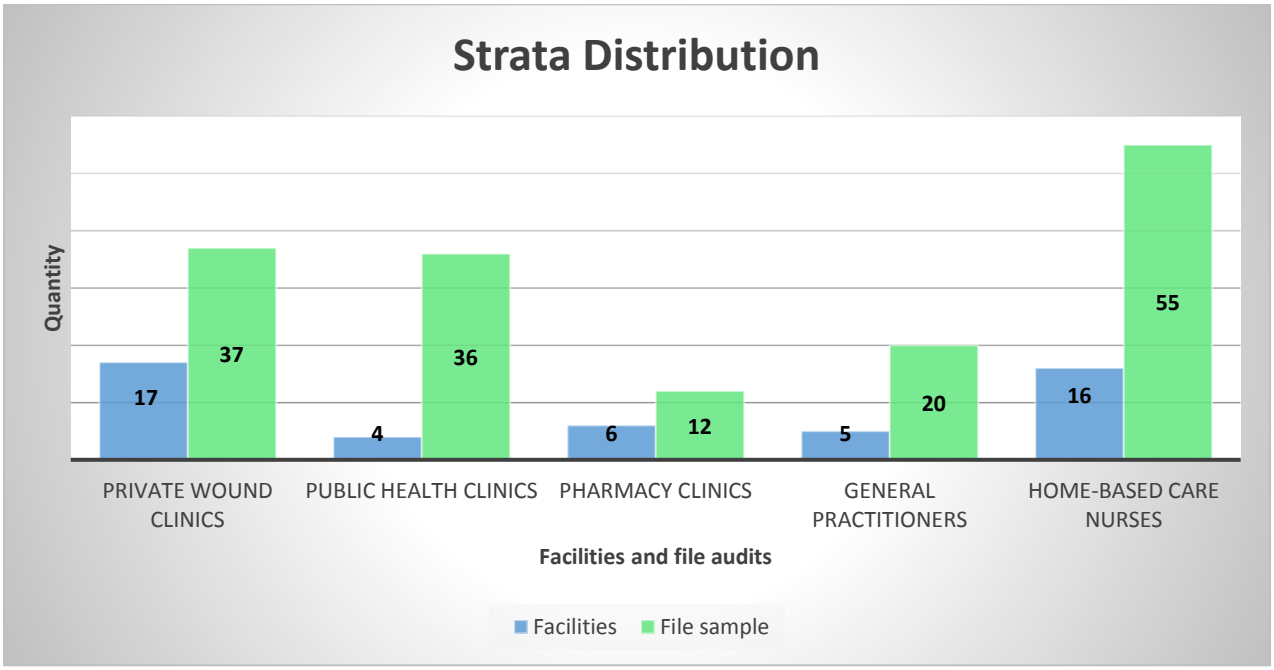


Figure 4.1 Distribution of strata and file sample

A total of 17 private wound clinics were included and 37 files were audited at the different sites, whereas four outpatient clinics were included from the public health sector of which 36 files were audited. Although the initial estimated pharmacy population was much bigger, the larger pharmacy groups declined to participate; thus, the pharmacy group consisted only of a few (six) independent pharmacies that had a clinic and were willing to participate. From these pharmacies, 12 files were identified that fit the inclusion criteria (as discussed in Chapter 3). In the general practitioner group, only five facilities were willing to participate of which 20 files were audited. In the home-based care strata 16 facilities were included of which 55 files were audited. The private wound clinics and home-based care nurses were the largest strata in the population, hence the bigger sample. Fewer public hospitals were part of the initial population. This resulted in a smaller sample of facilities but a larger sample of files in order to be representative of the estimated number of patients. Final strata distribution and sampling were discussed in Chapter 3.

Another pertinent concept with regard to structure is “accessibility”. Accessibility is concerned not only with the location and reachability of the clinic, but also the space available within the clinic, operating hours and specifically access for special needs patients, for example, wheelchair access (Wiersema-Bryant & Ward, 2012: 143).

The different facilities were assessed regarding accessibility, which included whether the facility had a physical address, clear signage, wheelchair access, and secure parking (if applicable). Sixty-four percent of the facilities have wheelchair access (64%, n=48). Thirty six percent of the facilities did not indicate wheelchair access as they were home based care nurses that visit patients at their own homes. A total of 62% (n=48) of the facilities had clear signage, within limitations according to legislation as set out in Allied Health Professions Act, No. 63 of 1982 (South Africa, 2015) and 64% (n=48) had secure parking. Once again, this discrepancy could be because 36% of the facilities consisted of home-based care nurses who only need an office and room for storage of equipment and dressings as patients are visited at their homes. All the facilities had a physical address.

4.1.2 Equipment available

An evaluation of structure included the equipment available at the facility (Donabedian, 1966: 167). Hanefeld *et al*. (2017: 368) point out that the availability of equipment cannot be used as an isolated criterion to determine whether patient health will improve as a result of the care given. The minimum equipment requirements for delivering a basic level of service, namely a hand-held Doppler with 8 MHz probe, a blood pressure monitor and a digital camera, were deduced from various guidelines (Wiersema-Bryant & Ward, 2012: 148; Di & Clark, 2016: 748).

From the data collected, 100% (n=48) of the facilities had a baumanometer and 94% (n=48) a digital camera, but only 60% (n=48) of the facilities had a hand-held Doppler. Figure 4.2 indicates the percentage of equipment in the facilities. An ABPI machine is an automatic, digital ABPI system, a very costly item and thus not expected to be available in all facilities. Monofilaments and infrared thermometers are utilized more in the care of the diabetic foot (Sibbald, Armstrong *et al*., 2015: 38), but were included in the questionnaire to assess their availability, as suggested by the panel of experts. Another reason for inclusion was that wound care facilities do not attend only to lower leg ulcers, but also to various other chronic wounds, and need to be equipped to assess and manage these wounds appropriately. A basic blood glucose monitor is utilized as a risk assessment tool and aids in a thorough assessment of the patient.

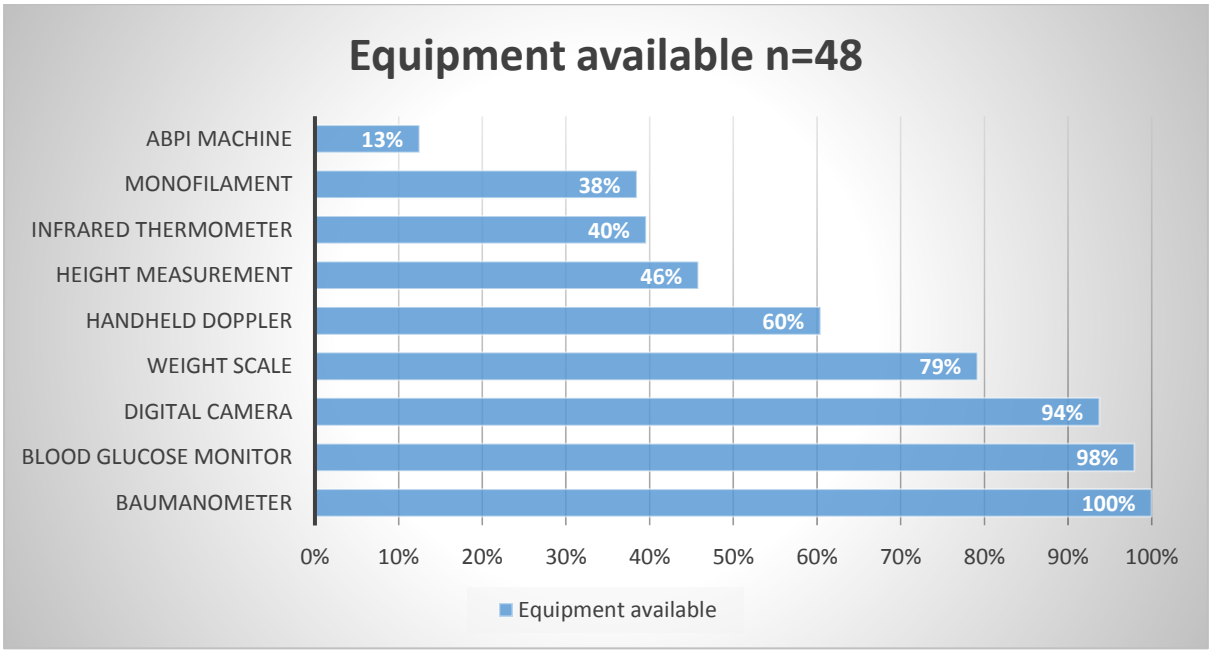


Figure 4.2 Equipment available in the facilities

Height measurements and weight scales are used to collect data on patient body mass index, which is indicative of nutritional status and an important measure for wound healing potential. Hanefeld *et al.* (2017: 369) argue that the availability of certain equipment is not an indication that the care will be delivered. According to Donabedian's model, the relationship between structure, process and outcome implies that an effective structure would promote effective processes and, in turn, result in advantageous outcomes (Soter *et al.*, 2017: 3).

Consensus documents and guidelines state that all clinicians involved in the management of patients with lower leg ulcers should have direct access to a hand-held Doppler with 8 MHz probe. With this piece of equipment, arterial flow can be established, and treatment options determined. This is essential, because the application of compression without assessing the ABPI, and in the presence of peripheral arterial disease, could result in limb threatening situations and, ultimately, amputations with legislative consequences (Weir *et al.*, 2015: 8).

4.1.3 Human resources

Structure also includes managerial ability and staff competence and experience (Willumsen, Ahgren & Ødegård, 2012: 199). Managerial ability as such was not included in the measurement, as the survey focused on assessing the field of practice of those in charge of the facility, level of education and years of clinical experience. Figure 4.3 provides an outline of the field of practice of the health care providers in charge of the facilities.

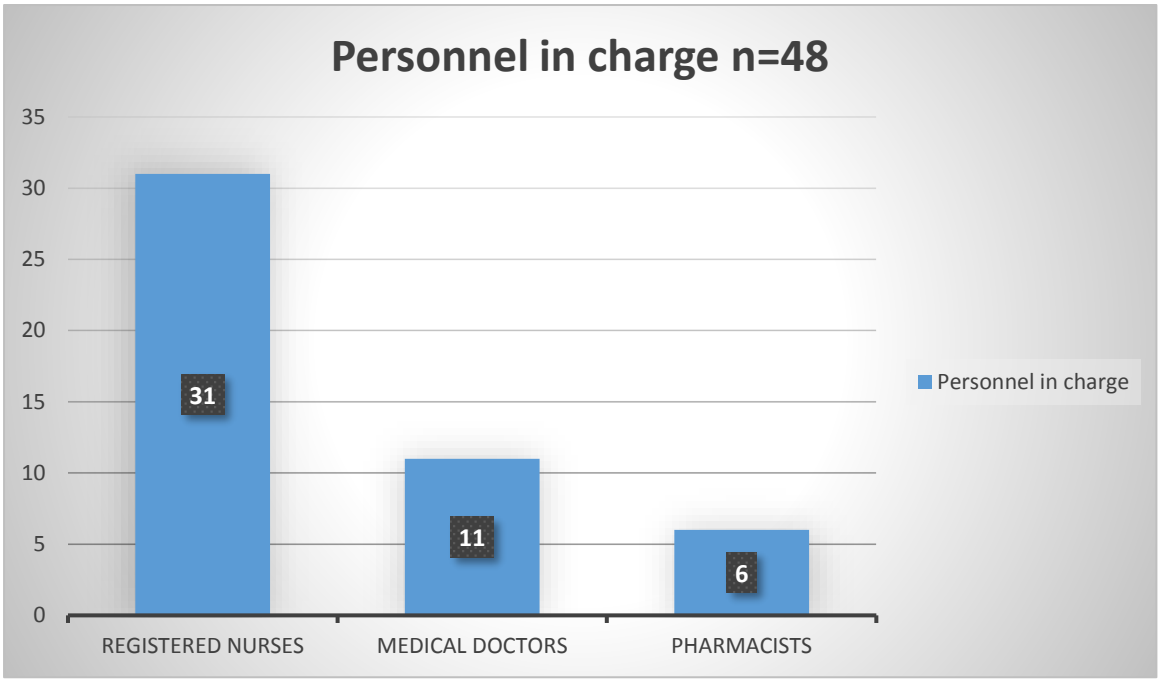
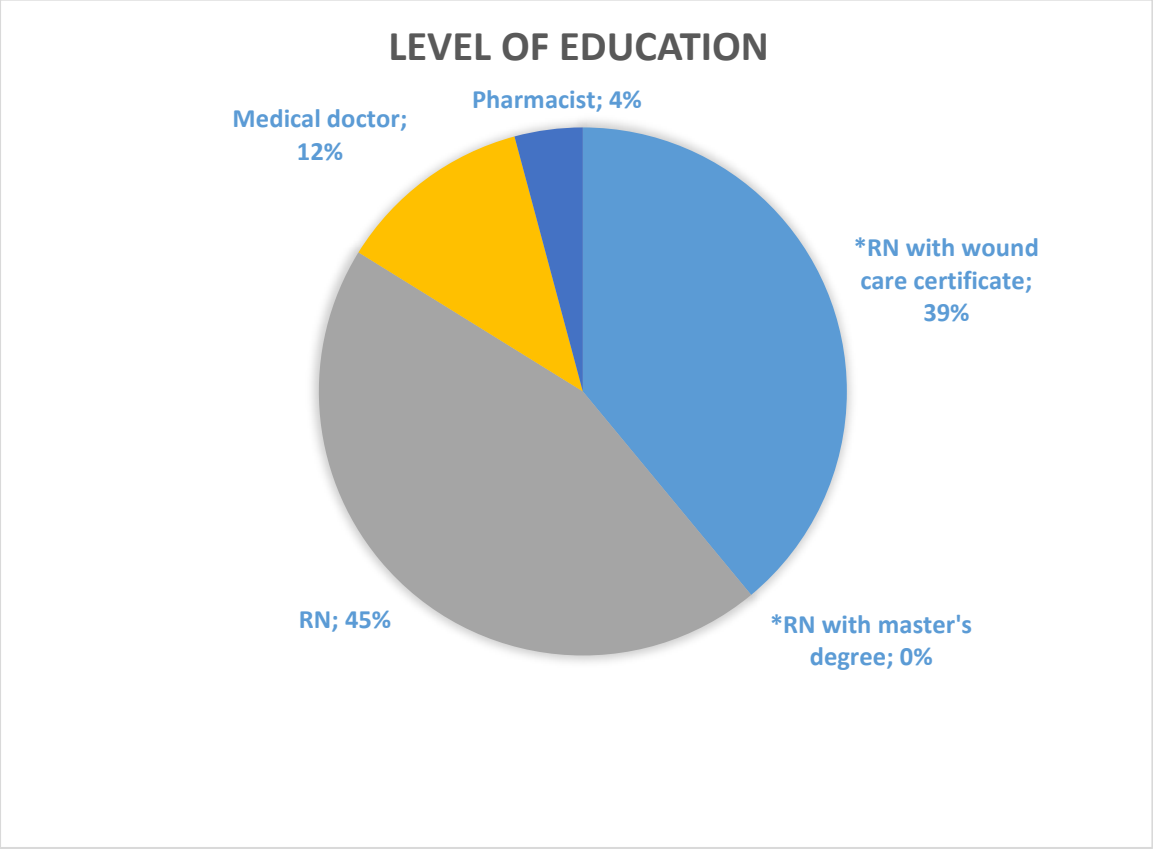


Figure 4.3 Personnel in charge of the facilities

From the data collected it seems registered nurses managed the facilities in 31 of the facilities, which calculates to 65% (n=48) of the facilities. Although 11 (23%, n=48) of the facilities were managed by medical doctors, of those facilities which included general practitioners and public health care hospitals, registered nurses attended to the patients in 85% of the cases. This finding concurs with UK and European statistics which indicates that up to 80% of lower leg ulcers are treated within the community by home-based care nurses and nurses in wound clinics (Templeton & Telford, 2010: 72).

Woo (2013: 538) notes that nurses are central to delivering wound care, but that there is a general lack of wound care knowledge and training among nurses, healthcare professionals and clinicians. In a study, Fourie (2013: 21) concluded that medical professionals, specifically general practitioners, had limited knowledge regarding wound care and that 77% of medical practitioners "felt uncertain about what wound care treatment should be prescribed". Donabedian (1988: 1746) includes attributes such as the level of education of staff in the assessment of structure. Woo (2013: 538) points out that knowledge about wound care has a direct impact on the quality of care delivered. Figure 4.4 depicts the level of education of the personnel attending to the patients in the participating facilities.



*RN – "Registered nurse" means a person registered as a nurse under section 16 of the Nursing Act as amended.

Figure 4.4 Level of education of personnel attending to patients in the facilities (n=48)

Of the sample population, 39% (n=48) of the practitioners attending to patients were registered nurses with an accredited wound care qualification. Accredited qualifications were:

- Post Basic Certificate in wound care obtained from the University of the Free State, Bloemfontein, South Africa;
- International Interdisciplinary Wound Care Course (IIWCC), University of Toronto, Canada; and
- Advanced wound care course from the University of Hertfordshire, UK.

Up to 45% (n=48) of the practitioners were registered nurses with no formal wound care training. None of the registered nurses had a master's degree. Twelve percent of the facility staff were Medical doctors who indicated that they had no formal wound care training. Pharmacists (4%, n=48) who attended to patients had no formal wound care training. Only one private practice indicated that they made use of nursing assistants to attend to the patients. Figure 4.5 shows the distribution of years of experience of the practitioners attending to patients in the participating facilities.

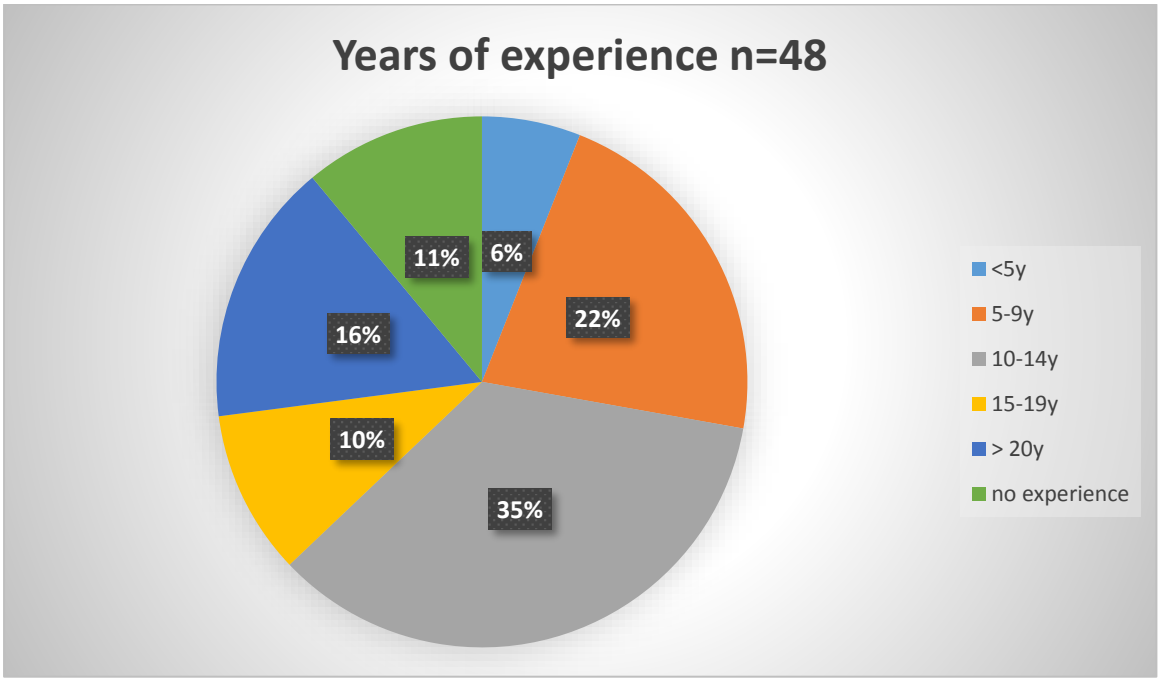


Figure 4.5 Clinical wound care experience of practitioners in years

Clinical experience is pivotal in learning how to apply theory to practice, but continuous, self-directed learning is vital for advanced wound management in order to improve effective clinical decision making and quality of care (Weller, 2012: 335).

The clinical wound care experience of personnel as measured in years revealed that 11% of the practitioners had no clinical wound care experience, with the median years' experience measured at 10 years (35%), with minimum and maximum years of experience being four months and 40 years respectively.

4.1.4 Policies and protocols

It is estimated that only about 20% of clinical decisions are evidence based (Hughes, 2012: 2565). Many efforts in improving health care delivery are focused on and involve the development and implementation of standards, guidelines and protocols as part of evidence-based practice (Hughes, 2012: 2568). Clinical guidelines seem to be one of the most effective ways to apply evidence to practice and improve quality of care (Weller, 2013: 7).

The item in the questionnaire regarding the use of guidelines was an open-ended question to assess the type of guidelines being followed. Wiersema-Bryant and Ward (2012: 149) suggest that facilities develop their own policies and procedures to suit the specific type of service to be delivered. From the practitioners, 37% (n=48) indicated that they follow guidelines in their practice. Of the 37% of practitioners, about 50% indicated that they use the WHASA consensus documents. The rest is divided equally between following international guidelines (EWMA and Wounds International) and using their training (IIWCC) as guideline.

Standard operating procedures (SOPs) are documents that describe activities to be performed to complete a task or procedure in accordance with industry-specific regulations or standards for running a business (Hensall, 2017: online). Standard operating procedures ensure efficacy and consistency and reduce errors by serving as a guide for processes (Hensall, 2017: online). Policies and procedures should be clinic- and service-specific and developed as such (Wiersema-Bryant & Ward, 2012: 5718). The quality of wound management cannot be evaluated without standards against which to measure it (Andrews and Langley, 2015: 59).

An SOP provides a starting point for a general consultation, in other words, it ensures that patients and/or their families are aware of the nature of the diagnosis, the prognosis, the nature and duration of treatment, the time course of treatment response, possible adverse effects of treatment, and related issues. Some of these topics addressed during health dialogue may need to be repeated at follow-up visits, because patients are not expected to remember all that has been conveyed at the first meeting (Bromley, 2011: online). Consultations can be structured based on an SOP comprising aspects such as the duration of consultation, social behaviour, agreement, rapport and partnership building, giving directions and information, asking questions, and counselling.

By using SOPs, aspects of treatment which are not highlighted in guidelines or which are part of different guidelines can be incorporated into consultations. Thus, SOPs are guideline based, and 37% (n=48) of the practitioners did indicate that they use guidelines in their practice. However, SOPs should be updated or reviewed at least every two years (Castronova, 2014: online). Table 4.1 shows the SOPs expected to be in place at the sampled facilities and the percentage facilities that actually had these SOPs in place.

Table 4.1 Expected SOPs and actual percentages of clinics with SOPs in place (adapted from Franks *et al.*, 2016: S20; Harding *et al.*, 2015; Moffatt, Cutting *et al*., 2005)

SOPs expected to be in place in an outpatient wound clinic	**Percentage of facilities with SOPs in place (n=48)**
SOP regarding assessment of patient with lower leg ulcers	52%
SOP regarding application of compression	50%
SOP regarding management of infection	56%
SOP regarding measurement of ABPI	52%
SOP regarding referral protocol	54%
SOP regarding treatment of recurrent infection	52%
SOP regarding pain management	56%
SOP regarding wounds that have become stagnant	52%

All SOPs should be prominently available in the clinician's consulting chamber, in the outpatient department, in the hospital wards, and in any zone related to patient care. Availability, however, does not guarantee implementation into practice (Weller, 2013: 12). Weller (2012: 332) found in a survey regarding management of venous leg ulcers in general practice that up to 72% of the practitioners do not utilize SOPs in practice. Thus, although there are many guidelines available, implementation thereof remains a challenge (Barker & Weller, 2010: 62; 2013: 6).

To achieve optimal results or a favourable outcome, the practitioner needs to make an accurate assessment, implement an adequate intervention and communicate effectively with other stakeholders to maintain continuity of treatment (Willumsen, Ahgren & Ødegård, 2012: 200). Collaboration between the different health professions are critical in improving the quality of care delivered (Willumsen, Ahgren & Ødegård, 2012: 201; Scarborough, 2013: 3). A referral structure should form part of the policies and procedures of any practice. Figure 4.6 outlines the types of specialists to which the participating facilities indicated they refer patients.

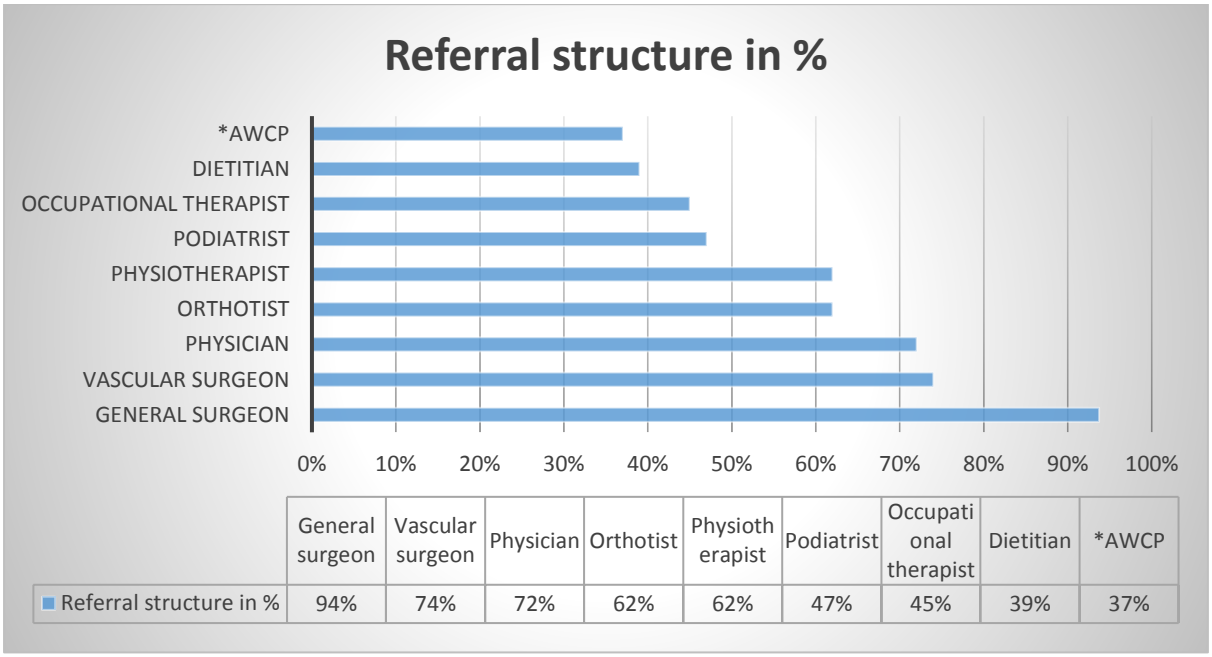


Figure 4.6 Referral structure utilized in the facilities

A multidisciplinary team approach is vital to improve outcomes for the patient and forms an important part of evidence-based medicine (Abrahamyan, Wong, Pham, Trubiani, Carcone, Mitsakakis & Rosen., 2015: 22). A team approach has been shown to improve healing rates and reduce overall cost for both the patient and funder (Abrahamyan *et al.*, 2015: 23). This study did not collect data with regard to the reason for referral, but with regard to the types of specialists' patients were referred to. General surgeons, vascular surgeons and physicians were referred to the most, but there seems to be a reluctance to involve ancillary health care professionals such as podiatrists, occupational therapists, dieticians and even AWCP. Advanced wound care is, in fact, not recognized as a specialty as yet and there is a definite need to define this field of practice. Further studies are needed to evaluate the collaboration of different disciplines and their effect on improving outcomes for patients suffering from venous lower leg ulcers.

4.1.5 Treatment modalities available

Factors that influence clinical decision making include the type of clinical setting, availability of certain treatment modalities, scope of practice and individual skills (Weller, 2013: 7). In this study, the facilities were assessed according to the availability of different treatment modalities, as this contributes to the quality of care delivered (Hanefeld, Powell-Jackson & Balabanova, 2017: 369).

When assessing the wound bed according to the TIME guideline, once devitalized tissue has been identified, the clinical action is to decide on a method of debridement to remove the devitalized tissue and obtain an outcome that results in a well vascularized, clean wound bed (Dowsett *et al*., 2015: 5). The presence of devitalized tissue protracts the healing time (Gethin, Cowman & Kolbach Dinand, 2015: 4). The facilities were, therefore, assessed according to the different types of debridement agents they have at their disposal. Figure 4.7 indicates the different debridement agents available in percentage.

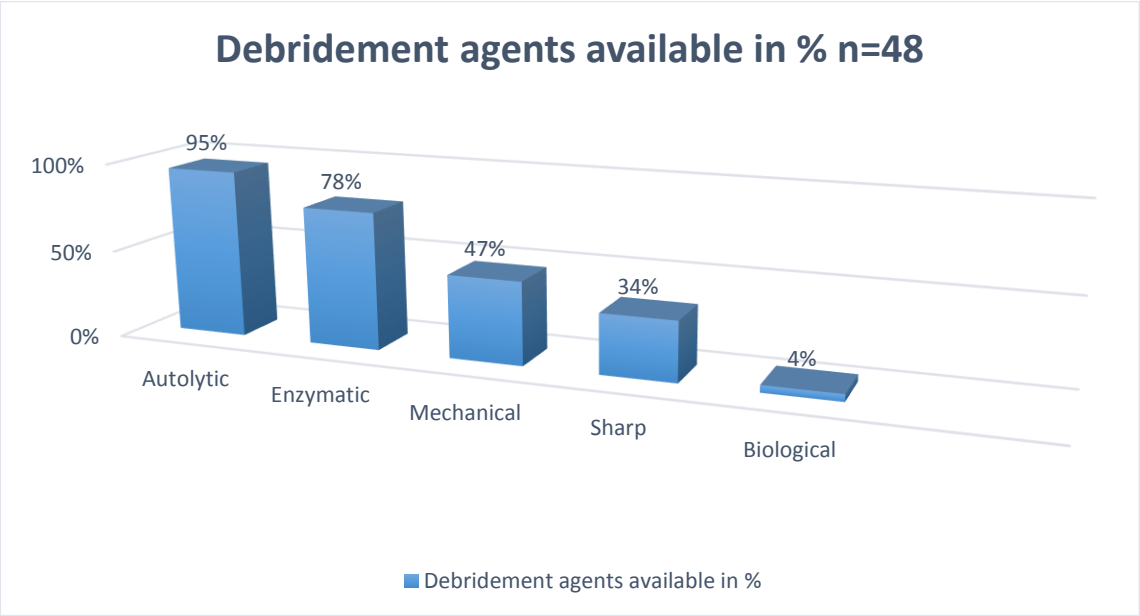


Figure 4.7 Debridement agents available in the facilities

From the data collected it seems autolytic debridement is favoured at 95%. Autolytic debridement is selective and requires minimal clinical training and thus seems to be a safer option as well (Ayello, Baranoski, Sibbald & Cuddigan., 2016: 5819; Gethin *et al*., 2015: 6). However, the EWMA position document on wound bed preparation published in 2004 states that utilizing autolytic debridement agents like hydrogel and hydrocolloids is not as effective under compression (Moffatt, Flanagan & Shuttleworth, 2004: 12).

Only one enzymatic debridement agent is available in South Africa, namely Iruxol®, and 78% of the facilities indicated that it is available in their facility. Enzymatic debridement is also selective and indicated for sloughy tissue that adheres to the wound bed (Moffatt, Flanagan & Shuttleworth, 2004: 12). Although it might be a better alternative to autolytic debridement, enzymatic debridement requires daily application which could pose logistical challenges in outpatient settings.

Being non-selective and often painful, mechanical debridement is not favourable because of its possible detrimental effects on the wound (Gethin *et al*., 2015: 5). However, 47% (n=48) of the practitioners indicated that they do mechanical debridement. This could be due to a misinterpretation by the practitioner of what mechanical debridement entails and might need further scrutiny.

Sharp debridement should only be done if the practitioner has the necessary training. In this study 80% (n=48) of the practitioners, which included doctors and nurses, at the various facilities stated that they had been trained to do sharp debridement. However, 34% (n=48) of the nursing practitioners indicated that they utilize sharp debridement in everyday practice. A 2015 Cochrane review found a lack of evidence to conclude that debridement improves healing rates and that one specific product is superior to another; in contrast, expert consensus states that debridement is necessary to promote wound healing (Gethin *et al*., 2015: 21).

A total of 4% (n=48) of practitioners indicated that they use biological debridement. This could, however, be ascribed to patient refusal, practitioner preference or availability, as maggot therapy has only been coded and made available for commercial use in the last few months.

With delayed wound healing and an increased risk of antibiotic resistance and mortality and morbidity associated with wound infection, the IWII released a consensus document on principles of best practice regarding diagnosis and treatment of wound infection (Swanson *et al.*, 2016: 3). It is vital for health care professionals to implement effective strategies to prevent, diagnose and manage infection in the wound. Infection and the diagnosis thereof were discussed in Chapter 2. A few pertinent points regarding practice were deduced from the consensus documents:

- Antiseptics should be used at their lowest effective concentration to reduce cytotoxicity.
- Topical antimicrobials should be used for superficial infection and not in the absence of infection.
- Topical antibiotics are not recommended for general management of wound infection.
- Systemic antibiotics should be reserved for treatment of deep tissue infection or systemic infection if not controlled by a local intervention, i.e. topical antimicrobial and debridement (Sibbald, Ayello, Elliot *et al*., 2015: 10; Swanson *et al*., 2016: 22).

The facilities were assessed regarding the availability of topical antimicrobials to treat wound infection. Figure 4.8 is a chart of the available antimicrobials at the various facilities.

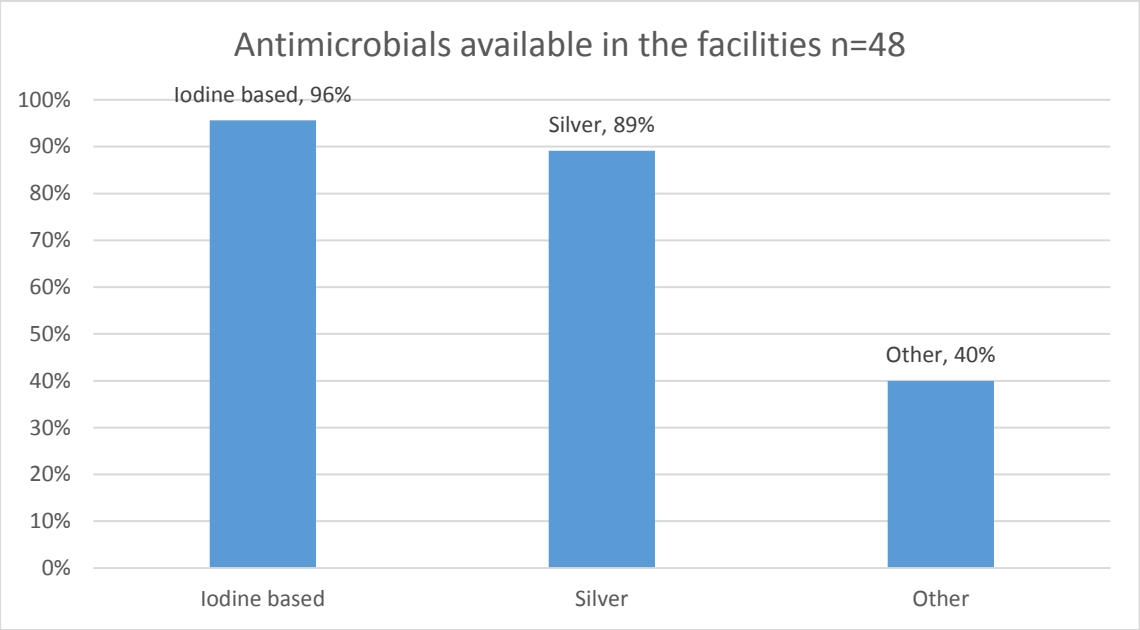


Figure 4.8 Availability of topical antimicrobials at the facilities

Iodine-based products had the highest level (96%) of availability at the facilities. Iodine in all forms significantly reduces the bioload in infected wounds and could inhibit biofilm development but might be cytotoxic in high concentrations. It is also contra-indicated in individuals with a sensitivity to iodine, renal failure or thyroid dysfunction (Schultz *et al*., 2017: 744; Swanson *et al*., 2016: 19).

Leaper, Ayello *et al.* (2012: 6) argue that silver should be used only to reduce bioburden in chronic or acute wounds that are clinically infected or at high risk of infection. Silver (specific types not indicated) was available in 89% of the facilities. The general misconception is that silver is more expensive than other antimicrobials, hence its patient-specific use and limited availability in some of the facilities, i.e. only upon request (Swanson *et al.*, 2016: 19).

Although hydrophobic dressings seem to have a low risk for resistance, low toxicity, no endotoxin release and reduction in surface bioburden due to bacterial adherence and hydrophobicity (Anon, 2016: 17), these dressings were available in 69% of the facilities. Further research might be needed on where these dressing products fit into the “antimicrobial hierarchy”.

Under the “other” category the practitioners listed honey and chlorhexidine-based products to treat infection. According to the WHASA consensus document, honey is listed as an antimicrobial, but a 2014 Cochrane review points to a lack of evidence to support the use of honey as an antimicrobial (The Cochrane Collaboration, 2014: 77; Weir *et al*., 2015: 14).

Moisture management is the third component of the TIME guideline. Regarding venous ulcer care, exudate and the management thereof are seen as an outcome measure, because excessive exudate associated with chronic oedema has a detrimental effect on both body image and quality of life (Hunter, 2015: S8). The goal of treatment of venous lower leg ulcers is to treat the underlying cause, i.e. venous hypertension and the effects thereof (Kirsner & Vivas, 2015: 173). For this reason, most of the guidelines refer to the use of a “basic non-adherent, but absorbent” dressing in conjunction with compression (Widener, 2015: 63). Moisture management is an important part of moist wound healing principles; therefore, the facilities were assessed according to the availability of different absorbent dressings. Absorbent dressings were discussed in Chapter 2. Table 4.2 provides a list of absorbent dressings and the percentage of their availability in the facilities.

Table 4.2 Availability of moisture management dressings in the facilities

Type of dressing	% of availability (n=48)
Foam	97%
Film dressings	89%
Hydrocolloids	87%
Alginate	75%
Superabsorber	72%
Hydro fibre	70%
NPWT	68%
Hydro capillary	45%

Foam dressings were available in 97% of the facilities. However, specific foams were not evaluated, as the utilization of the different treatment modalities were assessed during the file audit.

Film dressings and hydrocolloids were available for use in 87-89% of the facilities. These types of dressing retain moisture and are thus not indicated for use in lower leg ulcers with a high exudate level, because they could contribute to peri-skin maceration (Sibbald, Ayello, Elliot *et al*., 2015: 470).

Alginates, superabsorbers and hydro fibre dressings form part of the available treatment modalities of moisture management (Sibbald, Ayello, Elliot *et al*., 2015: 13), but this study assessed the availability and not the utilization of dressings. The different types of moisture management dressings and the utilization and appropriateness thereof were assessed in the file audit.

Negative pressure wound therapy is not necessarily kept on the premises of facilities, but 68% of the practitioners in this study indicated that they utilized it in their facilities. The utilization of negative pressure as a treatment modality was assessed during the file audits.

A possible reason why hydro capillary dressing seems to be utilized the least might be because these dressings often require daily dressing changes and cannot be used under compression. Furthermore, it transfers exudate horizontally in the dressing and has a high risk of per-wound maceration if not changed regularly (McGuire & Sumpter, 2014: online). Moisture addition with water-based gels is often redundant due to the characteristically high exudate level of venous lower leg ulcers. The use of water-based gels was evaluated as part of debridement choices as demonstrated in Figure 4.7.

Compression therapy is the cornerstone of treatment for lower leg ulcers of venous origin and the following statements are widely accepted:

- Compression improves healing trajectories when compared with no compression.
- Multicomponent systems seem to be more effective than single component systems.
- High compression is more effective than lower compression.

- A high stiffness index (high working pressure, low resting pressure) is associated with improved venous haemodynamics (Harding *et al.*, 2015: 13; Stücker, Link, Reich-Schupke, Altmeyer & Doeler, 2013: 68).

Facilities were assessed according to the availability of various compression systems. Figure 4.9 shows that 40% (n=48) of the facilities make use of four (4) layer or multilayer compression systems. There seems to be an even distribution of different compression bandages available at the facilities, which could be contributed to practitioner skill or preference. It is generally accepted that multicomponent compression is more effective when compared with no compression and that high compression is better than low compression (Stücker *et al.*, 2013: 68). Forty-five per cent (n=48) of the facilities had no compression bandages available. Compression stockings are not a stock item kept by the facilities. They either refer patients to an orthotist or measure patients and order stockings as per individual requirement, because medical funders do not reimburse private nurse practitioners for the supply of compression stockings.

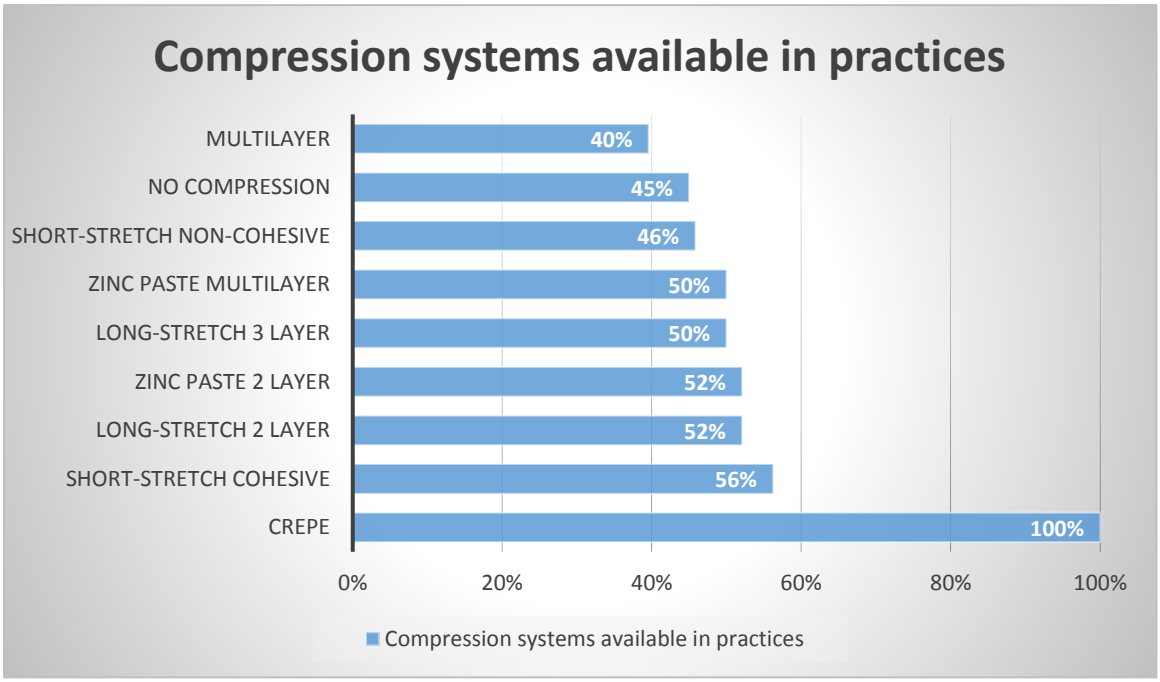


Figure 4.9 Compression systems available in the facilities

Compression is the cornerstone of the treatment of venous lower leg ulcers and forms part of the wound bed preparation paradigm's "treating the cause" (Sibbald *et al.*, 2011: 418). By non-application of compression bandaging, the patient is not receiving the best possible care with the best possible outcome. The facilities were assessed according to the availability of the different types of compression. Compression should be, when indicated, applied according to the clinical need of the patient (Carr, Shadwell, Regan & Hammett., 2015: 538). Different compression systems and their indications were discussed in Chapter 2. The utilization of the different compression systems came under scrutiny in the file audit, which involved the assessment of the process and outcomes reached.

4.1.6 Summary of structure

In this study, the participating facilities were surveyed to collect information on the discipline of personnel in charge of the facility, their level of education and the years of clinical experience of the personnel attending to the patients. Clinicians attempting wound care should be trained in this regard (Franks & Barker, 2016: 83). Wound care as a specialty has evolved over the last 10 to 15 years and requires clinicians who can effectively apply evidence-based care in practice, make effective clinical decisions and are committed to delivering a high standard of care through continuous self-directed, lifelong learning (Weller, 2013: 8). However, there are several barriers to implementing evidence-based practice, most notably a lack of skill and knowledge among health care practitioners (Flanagan, 2005: 73). Ideally, all clinicians attending to patients with wounds should be appropriately trained, which does not seem to be the case unfortunately. Only a limited percentage seems to have appropriate training.

It became clear that the availability of equipment does not necessarily indicate that high quality of care is being delivered (Hanefeld, Powell-Jackson & Balabanova, 2017: 370). Furthermore, there seems to be a significant shortage of equipment vital for basic assessment and care in some of the facilities.

Another important point came to the fore, namely that many policies and procedures are available to aid clinicians in making ethical and evidence-based clinical decisions (Weller, 2013: 4). However, in practice, clinicians do not always seem to consult these guidelines.

Chapter 5: Data analysis of process and outcome

5.1 Introduction

This chapter reports on the results of the wound care processes and outcomes reached. Two trained fieldworkers audited the files according to the checklist. Data were recorded at first visit, three weeks, and at completion or termination of treatment. The data were analysed and described in frequency of occurrence and percentages and are presented in tables and graphs. The presentation follows the sequence of the checklist. The reported data will be accompanied by discussions on the main findings. Conclusions, recommendations and limitations are discussed in Chapter 6.

5.2 Process

The behaviour of the health care provider contributes directly to the clinical processes being applied (Hanefeld, Powell-Jackson & Balabanova, 2017: 368). Measurement of these processes provides a critical starting point in the development of methods to improve the care supplied to patients (Hanefeld, Powell-Jackson & Balabanova, 2017: 368). The data capturing sheet processes were derived from best practice guidelines and consensus documents as outlined in Chapters 2 and 3.

5.2.1 Assessment: History taking

In 2008 WHASA developed and endorsed a patient assessment form (Appendix G) in support of holistic patient assessment (Naudé, 2008: 20). There is no recent update available of this form, but in 96 files (60%, n=160) the practitioners indicated that they use this form when **assessing the patient**. Thirteen (13) files (8%, n=160) did not contain any formal assessment documentation, only clinical notes, and 51 files (32%, n=160) contained various other assessment forms. Flanagan (2013: 2704) found that, in a 2011 UK survey, up to 73% of practitioners did not use any type of formal assessment documentation. Use of a comprehensive assessment tool aids in developing a holistic treatment plan (Van Rijswijk & Eisenberg, 2012: 3789).

A large portion of the data could not be captured due to incomplete record-keeping by practitioners. Good quality care can be achieved only when records are kept and sufficient information is available (Geyer, 2005: 5). Health care practitioners, especially nurses, have a legal obligation to keep accurate and complete records as stipulated in the Nursing Act (Act 50 of 1978).

The files revealed that 153 patients (96%, n=160) signed an **informed consent** form for the treatment as it. This is an ethical and legal requirement. However, seven (7) files (4%, n=160) had no consent form.

Regarding referral structures, 138 files (86%, n=160) indicated that the patient was referred from another health care practitioner, whereas 22 files (14%, n=160) did not indicate whether the patient was referred. A total of 87 files (63%, n=138) indicated that the patient was referred from a general practitioner (GP). Templeton and Telford (2010: 76) reported that GPs tend to refer up to 83% of patients with venous ulcers to nurses for treatment. Health care practitioners who referred patients for wound care include surgeons and specialists, and 51 files (37%, n=138) indicated referral from various specialists.

In 56 files (35%, n=160) it was recorded that patients were referred within the first three weeks of treatment to other specialists or back to the referring doctor. Patients were not referred according to 99 files (62%, n=160), and five (5) files (3%, n=160) contained no information on referral. According to Franks *et al*. (2016: S15), there is no consensus regarding when patients should be referred; however, non-healing as measured by a lack in wound size reduction is stipulated in four guidelines as a measure for “when to refer”, as this is an indication that the treatment plan might need to be reviewed. Regarding specialist referral, 14 (25%, n=56) of the wound care practices indicated that they referred patients to vascular surgeons regularly. Research indicates that 15-30% of all vascular wounds could have an arterial component (Mosti, Labichella & Partsch, 2012: 34). Eight (8) files (14%, n=56) indicated that patients were referred to general practitioners and the other 34 files (61%, n=56) indicated that the patients were referred to different ancillary health care personnel (dieticians, occupational therapists and podiatrists).

In 96 files (60%, n=160) the **gender of the patient** was specified as female, supporting the fact that lower leg ulcers of venous origin has a higher incidence amongst women (Sibbald, Williamson *et al*., 2012: 429).

History taking is an essential part of assessment (Van Rijswijk & Eisenberg, 2012: 3801) and should address a number of aspects. **Type of gait** was recorded as normal in 39 files (24%, n=160) and abnormal in 66 files (41%, n=160), whereas in 55 files (35%, n=160) no mention was made of the type of gait. **History of previous DVT** was recorded in 65 files (40%, n=160), but 95 files (60%, n=160) did not have any information in this regard. **Calf muscle functioning** was indicated as normal in 46 files (28%, n=160) and abnormal in 57 files (36%, n=160), but 57 files (36%, n=160) did not contain any information of the assessment of calf muscle functioning. **Family history of varicose veins** was recorded in 40 files (25%, n=160), whereas 120 files (75%, n=160) had no indication on whether this information was collected during history taking. A total of 124 files (78%, n=160) had information on the presence of varicose veins, but 36 files (22%, n=160) had no information. History of **vein stripping** was indicated in 12 files (8%, n=160), whilst the other 148 files (92%, n=160) had no information. **History of sclerotherapy** was recorded in seven (7) files (4%, n=160), but 153 files (96%, n=160) had no information in this regard. Although the tool did not measure whether the symptoms were in fact present at assessment, information was collected on how thorough history was recorded. According to Vuylsteke *et al*. (2015: 432), these above-mentioned symptoms are to be expected in up to 61% of patients who present with lower leg problems.

Obesity causes outflow obstruction in groin and popliteal areas, as well as changes in the venous haemodynamics that contribute to chronic venous insufficiency and increased risk of ulceration (Davies *et al.*, 2016: 5). Obesity has a direct correlation to lower limb venous disease and does not only exacerbate the symptoms thereof, but also delay wound healing, and is thus a critical factor to consider during treatment and health dialogue (Davies *et al.*, 2016: 4).

The least documented aspect was **body mass index** (BMI), as only two (2) (1%, n=160) files contained information in this regard, whilst the other 158 files (99%, n=160) had no information on BMI. In 34 files (21%, n=160) weight was recorded.

Table 5.1 gives the mean weight calculated from the data of 34 files. **Length measurements** were indicated in 32 files (20%, n=160), with the minimum length 1,5 m and maximum length 1,94 m. Unfortunately, weight or length measurement on its own is not useful unless both measurements are recorded, and the BMI calculated.

Table 5.1 Data recorded on weight measurements

Variable	n	Mean	Median	Minimum	Maximum
Weight in kg	34	94,32	93	45	149

Pregnancy, or rather multiple pregnancies, is indicated as a risk factor for chronic venous insufficiency (Eberhardt & Raffetto, 2014: 333). One pregnancy was recorded in six (6) files (6%, n=96), two pregnancies in 16 files (17%, n=96), three pregnancies in 11 files (12%, n=96) and four or more pregnancies in seven (7) files (7%, n=96). Unfortunately, 56 files (58%, n=96) that recorded female gender did not indicate the number of pregnancies. Pregnancy also influences venous haemodynamics due to increased intra-aortic pressures which result in increased femoral vein pressure, lower shear stress, possible inflammation and increased risk of ulceration (Rabe & Pannier, 2017: 3080).

Pain is listed as a “patient-centred concern” that needs to be addressed, as it has a detrimental effect on patients and their quality of life (Woo, Krasner & Sibbald, 2012: 3366; Akesson & Forsseli, 2014: S6). Instances where practitioners mentioned that patients experienced pain were marked as a positive response. Pain assessment at first consultation was recorded in 146 files (91%, n=160); however, the type of pain scale used was indicated in only 126 files (79%, n=160). A total of 94 files (75%, n=126) indicated the use of the analogue scale to measure pain on a scale from 0-10. Use of the Wong-Baker Faces Scale was indicated in 25 files (20%, n=126). This scale measures pain by utilizing facial expressions associated with pain. Seven (7) files (5%, n=126) did not specify the type of pain scale used.

Although 126 files indicated the use of a pain scale, values were only indicated in 121 files (96%, n=160). Pain is a predominant factor for patients, and 116 files (96%, n=121) indicated pain scores between 2/10 and 10/10 on the Analog scale. Pain is subjective and influenced by many factors, but pain assessment is vital to determine the most therapeutic treatment modality (Schechter, 2018: 14). According to Franks *et al.* (2016: S15), guidelines are not clear on how pain should, in fact, be managed once assessed.

Eberhardt and Raffetto (2014: 333) mention that the prevalence of chronic venous insufficiency increases with **age** and is greater in people over the age of 50 years. Patient age recorded in the 160 files indicated a mean age as 63 years, with 20 years the youngest and 91 years the oldest.

Smoking is a risk factor for the development of venous lower leg ulcers, as well as for delayed wound healing (Michael & Maier, 2016: 174). (See Section 2.4 for a detailed description of the effects of smoking on the vascular system.) A total of 34 files (21%, n=160) indicated that patients smoke, and 16 (47%, n=34) indicated that patients smoke up to 20 cigarettes per day. A total of 121 files (76%, n=160) indicated that patients did not smoke, and five (5) (3%, n=160) contained no information regarding smoking. Duration of smoking ranged from three (3) to 40 years. None of the files indicated that the patients attempted to reduce smoking or had ceased smoking at either the three-week or completion intervals, and no mention was made of health dialogue regarding smoking and the effects thereof.

Surgical history aids the clinician in identifying underlying pathology or risk factors for developing lower leg ulcerations (Hess, 2013: 823). Surgical history in general was indicated in 78 files (49%, n=160). However, surgical history relevant to the risk of lower leg ulcer formation, such as knee surgery, hip surgery or vein stripping, was indicated only in 27 files (35%, n=78). A total of 82 files (51%, n=160) did not contain any information on surgical history.

Medication could influence wound healing; therefore, it is vital to collect information about medication use as part of history taking in order to identify factors that might impair wound healing (Benbow, 2016: 42).

In 48 files (30%, n=160) there was no medication use recorded. From the remaining 112 files 48 files indicated the use of only one (1) medication type, 38 indicated the use of two (2) medications, 26 indicated the used of three (3) or more different medications.

Ninety (90) files (80%, n=112) indicated the use of **non-steroid anti-inflammatory drugs (NSAIDs**). These drugs could inhibit proliferation, delay epithelization and, ultimately, reduce wound tensile strength, thus increasing risk of recurrence (Guo & Dipietro, 2010: 224).

Corticosteroids increase the risk of infection and inhibit wound repair (Guo & Dipietro, 2010: 224; Swanson *et al.*, 2016: 12). Of the 90 files that indicated the use of NSAIDs, the use of corticosteroids was indicated in 33 files (37%, n=90) as used in conjunction with the NSAIDs. Owing to the detrimental effects of these drugs on wound healing, it is important for the clinician to do a comprehensive assessment (Benbow, 2016: 40).

The use of **anti-coagulants** was recorded in 76 files (68%, n=112), which could correlate with the fact that cardiovascular disease was recorded as a co-morbidity in 76 files (47%, n=160).

In 21 files (19%, n=112) the use of **chemotherapeutic agents** was indicated in conjunction with other medication. Chemotherapeutic agents could influence wound healing negatively, as they suppress protein synthesis and delay fibroblast proliferation, resulting in decreased collagen synthesis. This, in turn, increases the patient's risk of infection and reduces granulation tissue formation and contraction (Mulder *et al.*, 2002: 39).

In 19 files (12%, n=160) it was recorded that the patients had been exposed to radiation before. Radiation could delay wound healing, as it causes skin hypoxia due to the disruption of cell mitosis and obliteration of arteries; therefore, it is an important consideration when assessing the patient (Stotts, Wipke-Tevis & Hopf, 2012: 7767).

Malnutrition could contribute to wound chronicity (Marston *et al.*, 2016: 139). Notes about diet or daily food intake were recorded only in 50 files (31%, n=160) at assessment, and none indicated that dietary issues were addressed at any point in care. The nutritional health of the individual could determine the wound management outcome and is often overlooked in assessment (Quain & Khardori, 2015: 327). Nutritional requirements are multifaceted and a lack of nutrition could contribute to weakened immune response, substandard collagen synthesis and reduced wound tensile strength (Quain & Khardori, 2015: 327). Malnutrition is not only seen in patients with a low BMI, but extremes of BMI are indicative of malnutrition and should be addressed (Quain & Khardori, 2015: 328). Both macro- and micronutrients play an important role in nutrition and support of sufficient nutrition to aid wound healing (Quain & Khardori, 2015: 329). It is critical to involve members of the interdisciplinary team, such as the dietician, to address these concerns in an attempt to reduce any detrimental effect on wound healing (Scarborough, 2013: 3).

Co-morbidities such as diabetes and cardiovascular or pulmonary diseases were mentioned only in 85 files (53%, n=160), 74 files (46%, n=160) and 33 files (21%, n=160) respectively. None indicated anaemia as a contributing factor and none indicated that a haemoglobin level was measured. Anaemia reduces oxygen delivery to the wound site, increases risk of infection and could delay wound healing (Quain & Khardori, 2015: 333). Failure to record haemoglobin levels could result in misdiagnosis or overlooking a risk factor, which could contribute to a non-healing or maintenance wound (Woo, 2013: 540).

Duration of the wounds varied between one (1) month and 12 years, with a mean duration of six (6) months. Recurrent wounds were indicated in 103 files which calculated to 64% (n=160). Recurrence rates, as indicated by Sibbald, Williamson *et al*. (2012: 429), were estimated at about 72%.

Previous treatment, and the efficacy thereof, should form part of history taking, as it aids in future dressing choices and identifying underlying causes not previously addressed (Mulder *et al.*, 2002: 285; Hess, 2013: 824). Figure 5.1 shows the frequency of previous treatment recorded.

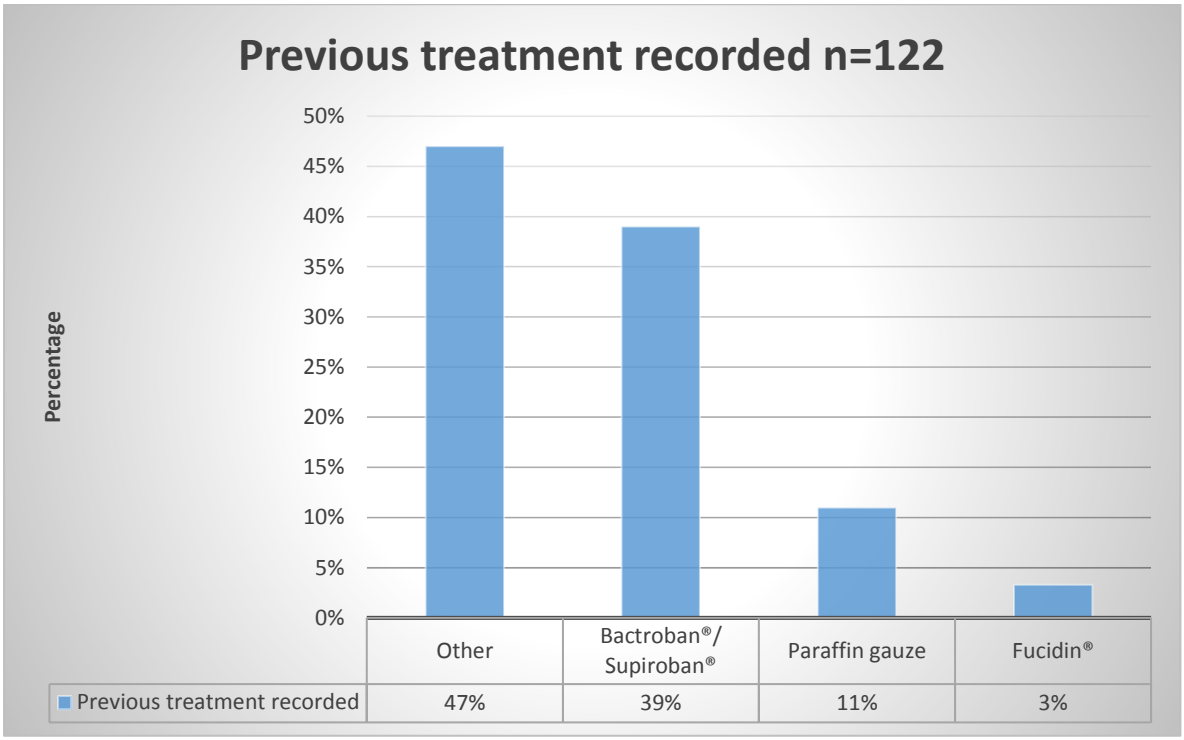


Figure 5.1 Percentage of previous treatment recorded (n=122)

A total of 122 files (76%, n=160) indicated which previous treatments were used, whereas 38 files (24%, n=160) made no mention of previous treatment. Bactroban®/Supiroban® (Mupirocin) was used according to 47 files (39%, n=122) and Fucidin® according to five (5) files (3%, n=160) which recorded previous treatment. International consensus states that topical antibiotics are not recommended for use in managing wound infection due to the risk of microbial resistance (Swanson *et al.*, 2016: 21; Schultz *et al.*, 2017: 21). Other treatments included Comfrey Ointment®, home-made preparations (not specified), Germoline®, Betadine® and dry gauze, and were indicated in 57 files (47%, n=122). These ointments are topical antiseptics and may be cytotoxic and cause allergic reactions. Tickle (2013: S20) points out that when choosing an appropriate antiseptic or antimicrobial one should consider duration of efficacy and frequency of dressing changes. The above types of applications require frequent dressing change, which is not conducive to an optimal healing environment and increases the risk of wound contamination (Martin, 2013: 36). Paraffin gauze that is impregnated with a petroleum base hydrates and protects the skin and is not designed to absorb moisture. Furthermore, paraffin gauze requires a secondary dressing and can also adhere to the wound bed and cause trauma when removed (Moffatt, Harding *et al*., 2008: 14). Use of paraffin gauze was indicated in 13 files (11%, n=122).

Dry gauze cannot manage exudate efficiently, thus increasing the risk of maceration, as well as the risk of inflammation of the wound bed due to shed fibres (Broussard, 2007: 251).

Duration of previous treatment varied from one (1) week to about 10 years, with treatment between four (4) and eight (8) weeks being the most prevalent. However, this aspect was indicated only in 115 files (72%, n=160). In 45 files (28%, n=160) there was no indication of duration of previous treatment.

A summary of the data collected regarding history taking and patient assessment is provided in Table 5.2.

Table 5.2 Summary of data on history taking

Aspects recorded in ≥70% (112 files)		**Aspects recorded in 69-31% of the files**		**Aspects recorded in ≤30% (48 files)**	
Age	160	Calf muscle function	103	Smoking	34
Informed consent	153	Gait	105	Pulmonary disease	33
Assessment tool utilized	147	Recurrent wounds	103	Vein stripping	12
Pain assessed	146	Medication	90	History of sclerotherapy	7
Varicose veins	124	Diabetes	85	BMI	2
Previous treatment	122	Surgery	78	Anaemia	0
Duration of previous treatment	115	CVD	74		
		DVT	65		
		Pregnancy (n=96)	40		

Aspects recorded in 112 files or more calculate to 70%. Table 5.2 highlights that the aspects of age, informed consent, use of an assessment tool, assessment of pain, varicose veins, and previous treatment were recorded in the majority of the files. Assessment of smoking, pulmonary disease, vein stripping, BMI and anaemia was omitted in 70% or more files. All of these omitted factors play important roles in wound healing and can contribute to slow or no wound healing.

5.2.2 Physical assessment

Measuring wound size and the reduction thereof is a measure for healing (Pudner, 2015: 32). To determine a reduction or not, baseline data need to be collected. A total of 130 files (81%, n=160) indicated length and width measured. Thirty (30) files (19%, n=160) did not contain any information on wound measurement. Mean length was calculated at 5,5 cm and mean width at 4,8 cm. Wound depth was indicated in 99 files (62%, n=160), with a mean depth of 0,6 cm. Lower leg ulcers of venous origin are characteristically shallow wounds; thus, depth is not easily calculated (Franks *et al.*, 2016: S20).

Location of the wound was indicated in 149 files (93%, n=160), with the highest frequency in 66 files (44%, n=149) being only indicated as “lower leg”. Eleven (11) files (7%, n=160) did not have any indication of location of the wound. Location of the wound aids in differentiating between wounds of arterial or venous origin, as venous lower leg ulcers are most likely located around the medial malleolus or gaiter area (Franks *et al.*, 2016: S24).

Several best practice guidelines and consensus documents state that all patients with a chronic lower leg ulcer should have an **ABPI** measured prior to commencing treatment with compression to establish arterial flow and determine type of treatment required (Rai, 2014: 408; Harding *et al.*, 2015: 8; Di & Clark, 2016: 748; Franks & Barker, 2016: 84). The measurement of an ABPI was indicated in 48 files (30%, n=160). It is alarming that in 112 files (70%, n=160) of the practitioners did not perform or record an ABPI on assessment.

In this regard, an association could be established between level of education and the utilization of a hand-held Doppler. When associating the level of education (i.e., RN with an accredited wound care qualification) with the availability of a hand-held Doppler, the p-value was calculated at <.0001 by means of the chi-square probability test, which indicates a significance. Thus, health care practitioners who are adequately trained are more likely to use the correct equipment.

Weller (2012: 335) states that practitioners do not routinely use Doppler assessment due to a lack of confidence and that there is a general underutilization of ABPI measurement, over-reliance on dressings and a lack of understanding of compression therapy amongst practitioners. Weller (2012: 335) also mentions time constraints and remuneration issues as reasons for the underutilization of ABPI measurements. Currently, medical schemes do not reimburse practitioners in South Africa for ABPI measurements. The risk of complications such as amputation and pressure damage increases when compression is applied without measuring ABPI (Weir *et al.*, 2015: 8).

The ABPI represents a mathematical ratio, with the denominator being the highest systolic pressure in the brachial artery and the numerator the highest systolic pressure in the ankle artery (dorsalis pedis or posterior tibial) of the specific leg (Crowell & Meyr, 2017: 52). The ABPI values recorded in the files ranged from 0,5 to 1,49. Of the 48 files (30%, n=160) in which an ABPI was recorded, 21 (44%, n=48) recorded the readings on both legs and 39 (24%, n=160) indicated that both legs were inspected as part of the leg inspection.

Of the 48 patients for whom an ABPI was recorded (30%), only 44 of the ABPI measurements were within the range of 0,8 to 1,3. Therefore, only 92% (n=48) of the patients for whom an ABPI was measured qualified for high compression (35-40 mmHg) or a multi-layered system containing an elastic bandage. Of the four (4) patients (8%, n=48) of whom the ABPI was not within range, three (3) were indicated to have received compression therapy. Compression therapy applied when the ABPI is not known or not within range could have detrimental consequences for the patient, such as amputation due to aggravation of the ischemia (Gordon, Widener & Heffline, 2015: 58).

Re-assessment of the ABPI was recorded in 48 files (30%, n=160) at the three-week interval. Furlong (2015: S22) recommends that the ABPI be re-evaluated according to the patient's risk profile, i.e., age, diabetes, smoking, increased BMI and immobility. Therefore, these are important aspects to assess. High-risk patients should be re-evaluated every 12 weeks or when any change in symptoms is noted (Furlong, 2015:S20). An ABPI reading of 0,8-1,3 is generally accepted as being an indication that the ratio of peripheral arterial disease is high enough to merit the use of compression bandaging in the treatment of venous lower leg ulceration (Harding *et al.*, 2015: 8; Franks *et al.*, 2016: S28). Table 5.3 is a summary of the data collected on physical examination.

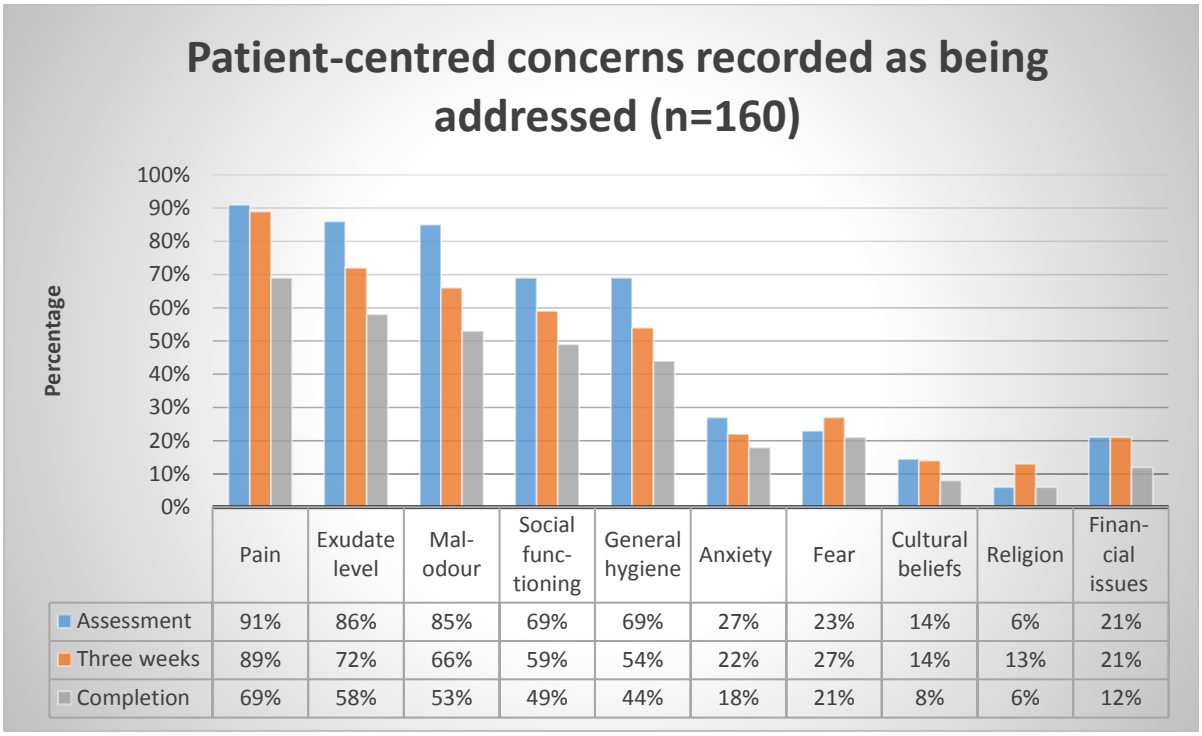
Table 5.3 Summary of data on physical assessment

Aspects recorded in >70% of files		**Aspects recorded in ≤30% of files**	
Wound size	130	ABPI	48
Wound location	149		

The ABPI was recorded in ≤30% of files, which is in contradiction with all guidelines available. Without an ABPI measurement, and if PAD is not excluded before compression is applied, the patient runs the risk of limb ischemia and amputation.

5.2.3 Patient-centred concerns

Sibbald *et al.* (2013: 47) updated the wound bed preparation paradigm to include treatment of the cause and addressing patient-centred concerns which include pain, malodour, exudate level, social functioning, general hygiene, cultural belief and religion. Figure 5.2 is a representation of the patient-centred concerns that were recorded in the audited files.



	Pain	Exudate level	Mal-odour	Social func-tioning	General hygiene	Anxiety	Fear	Cultural beliefs	Religion	Finan-cial issues
Assessment	91%	86%	85%	69%	69%	27%	23%	14%	6%	21%
Three weeks	89%	72%	66%	59%	54%	22%	27%	14%	13%	21%
Completion	69%	58%	53%	49%	44%	18%	21%	8%	6%	12%

Figure 5.2 Percentage of how often patient-centred concerns were addressed according to data collected from audited files (n=160)

When addressing patient-centred concerns, pain is the most significant factor that influences quality of life and functional ability (Franks *et al.*, 2016: S30). During history taking at initial assessment, pain was assessed according to 146 files (91%, n=160).

Vandenkerkhof, Hopman, Carley, Kuhnke & Harrison (2013: 3) found an 82% prevalence of the symptom of pain in lower leg ulcers. In the current study the files were assessed for records on whether patient-centred concerns were addressed. Therefore, the 142 files (89%, n=160) that assessed pain at three weeks and the 111 files (69%, n=160) indicating that pain was addressed at completion cannot be seen as an indication of whether the patients experienced pain, but whether the files contained information about the practitioners' addressing pain. Indications of "patient verbalized that he/she had no pain" in the file were viewed as a positive response for addressing pain. The same applies to the other aspects of patient-centred concerns: The frequency is not an indication that the patient had a concern, but whether the practitioner recorded having addressed the concern. No information was collected on patient perceptions or beliefs, as questions did not involve collecting data on those aspects, but only whether the practitioner recorded any aspects in that regard.

Psychological consequences of living with unmanaged **exudate** include stress, depression, social isolation and sleep deprivation (Tickle, 2015: S38). Addressing the concern of exudate management is not only vital for the patient's quality of life, but also influences wound healing, because unmanaged exudate could result in peri-wound maceration and excoriation, as well as an increase in wound dimensions. In 137 files (86%, n=160) practitioners recorded that they addressed the exudate level at assessment, with a general decline from three weeks (115 files, 72%, n=160) to completion (92 files, 58%, n=160).

Malodour and the presence of pain could be indicative of infection and, although chronic wound fluid tends to have an odour, the presence of malodour should be assessed, because it has a detrimental effect on the patient's quality of life (Tickle, 2013: S16; 2015: S38). Malodour was recorded as being addressed in 136 files (85%, n=160) at assessment, although it was not specified how the malodour was addressed. A decline in recordings regarding addressing malodour was noted, from three weeks (106 files, 66%, n=160) and at completion (85 files, 53%, n=160). But once again, if the file indicated "no odour present", this was marked as a positive response to addressing malodour.

Both **social functioning** and **general hygiene** were recorded in 111 files (69%, n=160) at assessment. Once again, no information was provided on how these aspects were addressed, and more information is needed to deduce whether they were, in fact, addressed sufficiently. Social functioning was recorded as being addressed in 95 files (59%, n=160) at three weeks, and 78 files (49%, n=160) at completion. General hygiene was addressed in 87 files (54%, n=160) at three weeks and 70 files (44%, n=160) at completion.

Cultural belief and religion were not addressed as frequently. At assessment 23 files (14%, n=160) recorded having addressed cultural beliefs, and 10 files (6%, n=160) recorded religion. A slight increase was noted in the recording of addressing religion at three weeks (21 files, 13%, n=160), but decreased at completion (7 files, 6%, n=160) of treatment. Cultural beliefs were recorded as being addressed in 22 files (14%, n=160) at three weeks, which reduced to 12 files (8%, n=160) at completion.

This could be due to various reasons, for example, clients and health care practitioners might take a while to build a trust relationship, and some patients might have been more forthcoming with information.

Overall, there seemed to be a general decline in the frequency of addressing patient-centred concerns at three weeks and completion.

Anxiety and fear are two important patient-centred concerns that need to be addressed, as they could contribute to non-adherence to treatment (Brown, 2017: 4). A total of 43 files (27%, n=160) recorded having assessed the anxiety of the patient. The most prevalent form of anxiety seemed to be anxiety about pain, as 18 files (42%, n=43) indicated fear regarding pain. Recording of anxiety reduced to 35 files (22%, n=160) at three weeks, and 28 files (18%, n=160) at completion.

In 36 files (23%, n=160) that mention fear at assessment, the most prevalent type of fear seemed to be fear of amputation, as this was indicated in 30 files (83%, n=36). This type of fear seems to become less at the three-week interval, as 20 files (56%, n=36) reported this type of fear. Fear was recorded in 34 files (27%) at the three-week interval and 33 files (21%, n=160) at completion.

Another patient-centred concern that was not addressed sufficiently was **financial issues**, which was indicated only in 33 files (21%, n=160). Of the 33 files, eight (8) (24%, n=33) indicated the most prevalent financial issues to be the fear of depletion of medical aid. At the three-week interval, 34 files (21%, n=160) reported on financial issues, and 16 patients (47%, n=34) expressed fear about financial issues. This fear is a reality, because funders often allocate only a small portion of funds towards wound care, and protracted healing times and complications due to chronicity are not considered. Although this aspect was documented, the frequency seems too low, as patient-centred concerns should form part of a standardized assessment form to improve the quality of data collected and, in turn, improve quality of service delivery and outcome (Vishwanath, 2014: 29).

There seemed to be a general decline in addressing patient-centred issues at three weeks and termination of care. Pain, exudate level and malodour were addressed in most cases (>70%), but aspects such as anxiety (27%), fear (23%), financial issues (21%), cultural beliefs (14%), and religion (6%) were addressed in less than 30% of cases.

5.2.4 Classification of chronic venous insufficiency

The CEAP (Clinical, Etiologic, Anatomy and Pathophysiology) classification system is used to classify chronic venous insufficiency and the clinical appearances thereof (Kistner & Eklöf, 2017: 2657). The CEAP classification was included in the checklist for the file audit, as it is a standardized classification system utilized to communicate the severity of chronic venous disease (Kistner & Eklöf, 2017: 2657). None of the files indicated the use if the complete CEAP classification. Instead, certain clinical signs identified as being indicative of chronic venous disease were followed to record different manifestations of chronic venous insufficiency on assessment of the patient. These signs were indicated in 94 files in groups with 36 different variables, for example the combination of varicose veins, oedema, eczema, pigmentation and lipodermatosclerosis, being indicated in 79 files (84%, n=94).

Atrophie blanche is a rare clinical sign and easily overlooked (Kistner & Eklöf, 2017: 2659). This could have serious implications, because in the presence of this clinical sign compression should be modified to prevent pressure damage. Nineteen (19) files (20%) recorded atrophie blanche as a sign, of which seven (7) (37%, n=19) indicated to have used short-stretch compression, seven (7) (37%, n=19) the African Bandage System and three (3) (16%, n=19) four-layer compression. Four-layer compression gives continuous pressure of between 30 and 40 mmHg and should not have been used on these patients. Although none of these files indicated serious consequences due to the application, it still is not safe practice. One (1) file (5%, n=19) indicated no compression used. Application of high compression is contra-indicated and not safe practice in the presence of atrophie blanche, Short-stretch bandages are, however, safer to use if there is an arterial component present, but caution should be taken to prevent complications such as skin necrosis.

A reduction in oedema can be measured by measuring the leg circumference and, thus, evaluating a component of the effectiveness of the care (Partsch & Mortimer, 2015: 359). Leg circumference measurement was recorded in 51 files (32%, n=160) at assessment, which remained the same at three weeks, but increased to 61 files (38%, n=160) at completion. Leg circumference measurements are used to measure patients for compression stockings, hence the possible increase.

The assessment of leg circumference was not recorded in 109 files (68%, n=160) neither at assessment nor three weeks. A positive “Stemmer sign” is indicative of lymphoedema, but not frequently used, as it is not part of any assessment form used in South Africa. The Stemmer sign was noted in five (5) files (3%, n=160), whereas the other 155 (97%, n=160) files had no information on assessing the Stemmer sign.

Although a clear guideline exists in determining the severity of venous insufficiency, none of the files indicated use of the existing classification system.

5.2.5 Assessment of the wound bed

The WHASA wound assessment form (Appendix H) developed in 2008 incorporates the TIME wound assessment. This form was used according to 87 files (55%, n=160) as baseline information. The TIME (Tissue viability, Infection and Inflammation, Moisture and Edge) guideline was initially developed in 2000 as part of the wound bed preparation concept to aid clinicians in assessing the wound and making treatment decisions (Flanagan, 2013: 2678). The TIME guideline on its own was used in 18 files (11%, n=160).

Sixteen (16) files (10%, n=160) contained amendments to the TIME guideline of “colour assessment” which described the wound bed according to the colour identified on the wound bed, i.e., black for necrotic tissue, yellow for slough, green for infection, red for granulation tissue, and pink for epithelization. The colour assessment was initially developed in 2005 for descriptive purposes, but has developed over the last few years to include combinations thereof (Benbow, 2016: 44). In 29 files (18%, n=160) there was evidence that the practitioners designed and used their own invalidated wound assessment forms. In 10 files (6%, n=160) no formal wound assessment form was used. Benbow (2016: 40) argues that accurate wound

assessment provides clinical information that could guide treatment choices. In turn, effective treatment could ensure continuity of care and improve outcomes. Hence, this 6% might not have reaped the benefits that come with accurate wound assessment.

Wound progress can be measured by a reduction in devitalized tissue, reduction in infection or inflammation (as seen by a reduction in erythema), changes in moisture balance (as seen by a reduction in maceration or desiccation) and epithelial advancement (Baranoski, Ayello & Langemo, 2015: 4138). These features can be captured and stored using digital photography (Flanagan, 2013: 2713; Baranoski, Ayello & Langemo, 2015: 4138). Using digital photography can facilitate better diagnosis, enhance clinical documentation, help monitor the progress of wound healing, help prevent litigation in wound management, and allow interdisciplinary communication among the wound care team members and with medical insurance companies (Rennert, Golinko, Kaplan, Flattau & Brem, 2009: 32; Baranoski, Ayello & Langemo, 2015: 4154). It is, however, a legal requirement for the patient to give consent for photographs to be taken and stored for clinical record-keeping and communication purposes. This consent formed part of the consent forms that patients signed on commencement of treatment; however, not all the files indicated compliance in this regard. Digital photography was utilized in 137 files (86%, n=160). Of the 137 that indicated the use of a camera, 135 files (99%, n=137) combined digital images with disposable rulers. Twelve (12) files (8 %, n=160) indicated that wound tracing was used, whereas 11 files (7%, n=160) did not indicate any form of wound assessment by either digital photography, rulers or tracing. Without any form of measuring the wound surface, progress towards healing cannot be determined. If progress cannot be determined, treatment efficacy cannot be measured.

The majority of the files indicated that the wound bed (96%) and the wound size (81%) were assessed and recorded, which aids the clinician in assessing progress or the lack thereof.

5.2.6 Diagnosing wound infection

Wound infection is the single most prevalent cause of delayed wound healing (Leaper, Assadian & Edmiston, 2015: 351). Sibbald, Woo and Ayello (2007: 25) introduced the use of the NERDS and STONEES mnemonics in 2007 as a guide to clinicians to identify superficial and deep infection in wounds. Although some aspects of the symptoms described in the mnemonics were utilized at assessment according to the files, superficial infection was not specifically identified, as these symptoms were indicated as “infection” and the practitioners did not distinguish between superficial and deep infection.

The files that indicated three (3) or more positive NERDS, which is indicative of superficial infection, were calculated at 68 (42%, n=160). Of these files, 31 (46%, n=68) indicated systemic antibiotics as choice of treatment, which is in violation of various guidelines (Swanson *et al.*, 2016: 22). Antimicrobial dressings contain antiseptics such as silver, cardexomer iodine, PHMB and honey, and were indicated as choice of treatment for superficial infection in 77 files (48%, n=160) at assessment. Therefore, in nine (9) files (12%, n=77), the use of antimicrobials was redundant. Consensus documents state that antimicrobials should be used only in the presence of superficial or deep infection (Swanson *et al.*, 2016: 21). Antimicrobials could control bioburden and, due to their mode of action, have a low risk of antibiotic resistance. However, they are non-selective and could be cytotoxic, influencing tissue cells involved in healing when applied in the absence of infection (Swanson *et al.*, 2016: 21).

In 49 files (31%, n=160) the signs of infection recorded resulted in three (3) or more positive STONEES. This is indicative of deep tissue infection at assessment, but from the files it seemed as if the practitioners were not able to distinguish between superficial and deep infection, seeing that it was not stated as such. According to Tickle (2013: S16), it is vital for health care professionals to understand the different levels of bioburden, i.e., colonization, superficial infection and deep wound infection.

A total of 64 files (40%, n=160) indicated the use of wound swabs at assessment, yet 49 files (31%, n=160) recorded signs and symptoms that could be indicative of deep infection and perhaps require systemic treatment. Wound swabs could be utilized to direct infection management, but not to diagnose infection (Leaper, Ayello *et al*., 2012: 10; Tickle, 2013: S16). Although a wound bed swab is generally the most used technique, this technique, when applied incorrectly, often collects surface bacteria only and is not indicative of the pathogens causing infection (Swanson *et al.*, 2016: 12). A wound bed swab can be performed utilizing the Levine technique to give a semi-quantitative estimate of bacterial numbers and identify bacterial species for susceptibility (Sibbald, Woo & Ayello, 2007: 28). Using swabs when there are no clinical signs of deep infection adds to already exorbitant costs and is a waste of resources. Wound swabs need to be done correctly, after the wound has been adequately cleaned with saline or sterile water, and not on devitalized tissue (Sibbald, Woo & Ayello, 2007: 28; Swanson *et al*., 2016: 12). This study did not collect data on how swabs were performed, but on whether practitioners utilized swabs. Unfortunately, no data was collected on the use of swabs at the three-week interval. In 43 files (27%, n=160) there were no signs and symptoms of infection recorded.

The use of systemic antibiotics was indicated in 80 files (50%, n=160) at assessment, but in 49 files (31%, n=160) three or more positive STONEES were recorded, which is indicative of deep tissue infection. Therefore, 31 patients who presented with superficial infection were treated with systemic antibiotics. Consensus documents state that systemic antibiotics should be reserved for treatment of deep tissue infection and not as a stand-alone treatment, but in conjunction with topical antimicrobials and wound bed preparation principles such as appropriate debridement and wound cleansing (Swanson *et al.*, 2016: 22). A total of 102 files (64%, n=160) also indicated the use of antimicrobials for deep tissue infection, even though only 49 files indicated signs of deep tissue infection.

The use of systemic antibiotics was reported in 48 files (30%, n=160) at the three-week interval, but 39 files (24%, n=160) reported an incident of infection at three weeks, with no distinction between superficial and deep infection. According to the WHO (2018: online), antibiotic resistance is the biggest threat to global health, and the overuse or incorrect use of antibiotics contributes to resistance.

Antibiotics should be reserved for deep tissue infection as confirmed by clinical signs (Swanson *et al.*, 2016: 22). After scrutinizing the data, it seemed that only 20 files (13%, n=160) reported symptoms that resulted in three or more positive STONEES signs, an indication of deep tissue infection. Thus, 28 patients received systemic antibiotics for a superficial infection.

Although topical antibiotics are not recommended for use in treating wound infection (Swanson *et al.*, 2016: 21), they were used according to 19 files (12%, n=160). Topical antibiotics contain a low dose of an antibiotic, and incorrect use increases the risk of bacterial resistance (Swanson *et al.*, 2016: 22). Eighty (80) files (50% n=160) indicated the use of systemic antibiotics for infection at assessment.

Owing to the increased tissue pressure that could be the result of the swelling with acute infections, compression could compromise the limb and is, therefore, not recommended for use in the presence of infection (Hanson, Langemo, Thompson *et al.*, 2018: online). Increased exudate levels associated with infection could also contribute to peri-skin maceration if compression is used during infection. At the three-week interval 34 files (21%, n=160) indicated that compression was discontinued due to infection, yet 39 files (24%, n=160) reported an incident of infection within the first three weeks.

Table 5.4 provides a summary of the data collected on the diagnosis and treatment of infection.

Table 5.4 Summary of data collected regarding diagnosis and treatment of infection

Superficial infection at assessment (3 or more + NERDS	**Use of antimicrobials**	**Use of systemic antibiotics**
68 files	77 files	31 files
Deep infection identified at assessment (3 or more + STONEESS)	Use of antimicrobials	Use of systemic antibiotics
49 files	77 files	80 files
Wound swabs done: 64 files		
Superficial infection at three weeks (3 or more + NERDS)	**Use of antimicrobials**	**Use of systemic antibiotics**
19 files	36 files	48 files
Deep infection at three weeks (3 or more + STONEESS)	Use of antimicrobials	Use of systemic antibiotics
20 files	19 files	48 files

Health care practitioners in this study seemed unable to distinguish between superficial and deep infection, as well as the correct treatment thereof. There is a general tendency of between 40% and 60% overuse of antimicrobial and systemic antibiotics.

5.2.7 Wound cleansing

Wound irrigation at between 8 and 15 psi with a non-toxic solution effectively removes surface contaminants, debris and microbes, thereby improving the wound environment (Shetty *et al*., 2012: 590; Tariq *et al*., 2016: 3). Wound cleansing was mostly done using spray bottles (113 files) (71%, n=160), a practice that is not standardized and of which the psi is unknown. The use of running water to cleanse wounds was indicated in 15 files (9%, n=160). The use of Jet-ox® was indicated in 10 files (6%, n=160). Jet-ox® is a wound cleansing system that uses compressed air/oxygen and cleansing fluid to deliver a psi of between 4 and 9. In 22 files (14%, n=160) it was not indicated how wounds were cleansed.

With regard to cleansing solutions listed, 39 files (24%, n=160) indicated the use of Saline solution to cleanse the wounds, whereas 26 files (16%, n=160) indicated the use of Prontosan® solution. Prontosan® contains PHMB and the irrigation bottle is designed to deliver 10-15 psi (Davis *et al*., 2017: 1). A total of 69 files (43%, n=160) did not indicate the type of cleansing solution that was used. Solutions such as Hibiscrub® and Betadine®, and Savlon®, were listed under “other” and were utilized according to 26 files (16%, n=160). These antiseptics could lower the bacterial burden, but be cytotoxic in higher concentrations and impair wound healing (Tariq *et al.*, 2016, p. 3). Although they could aid in lowering the bioload, antiseptic solutions could impair healing due to the effect they have on normal tissue cells (Swanson *et al.*, 2016: 22). Antiseptics have a lower risk of bacterial resistance than topical antibiotics, but the use of antiseptic solutions should be evaluated every two weeks during treatment (O'Meara *et al*., 2014: 5).

A total of 84 files (53%, n=160) indicated the use of antiseptic wipes to cleanse the legs and surrounding skin prior to application of a moisturizer. Antiseptic wipes contain 2% chlorhexidine and is indicated for use as a skin disinfectant, but not recommended for routine use on peri-wound skin due to possible allergic reaction and risk of contact dermatitis (Anderson & Stewart, 2017: online).

5.2.8 Wound debridement

A Cochrane review on debridement methods used for venous lower leg ulcers found no evidence that one debridement method is superior to another, but acknowledged that debridement is the first step in wound bed preparation (Gethin *et al*., 2015: 21).

Figure 5.3 represents the percentage of different debridement methods utilized according to the data collected.

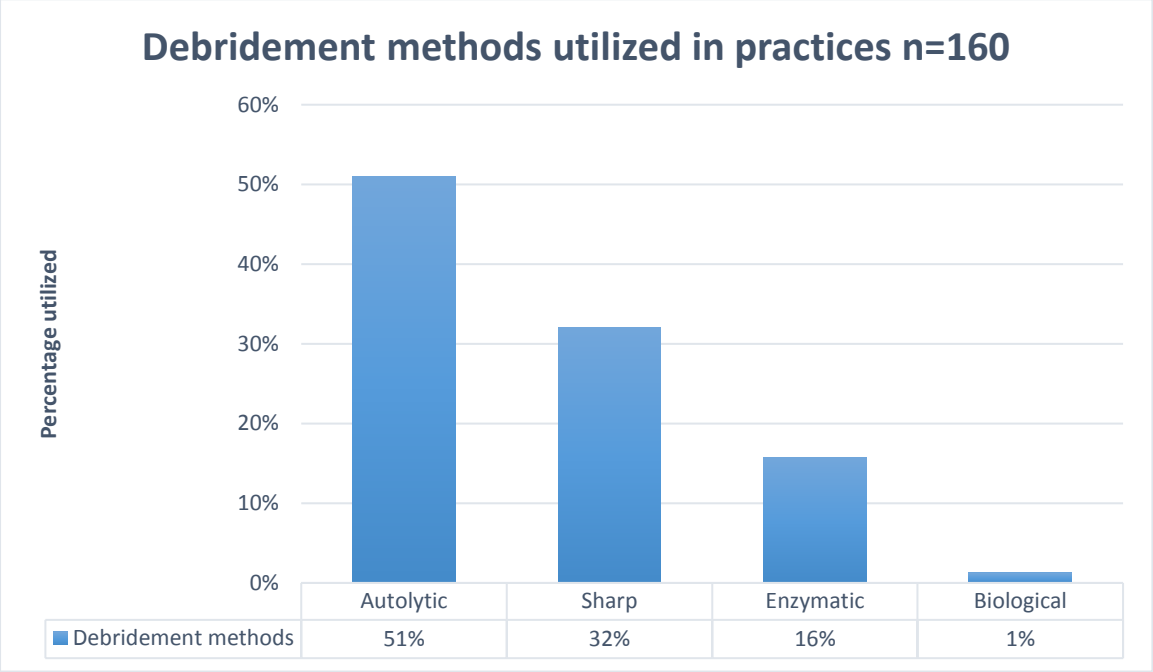


Figure 5.3 Debridement methods utilized according to data collected from file audits (n=160).

Autolytic debridement methods were used most frequently in 82 cases (51%, n=160) and biological debridement the least (2 cases, 1%, n=160), possibly due to costs and a lack of availability. Until recently, biological debridement was not available outside of Gauteng. Therefore, logistical challenges could also have contributed to the low numbers, as the larvae had to be collected.

Autolytic debridement is possibly the safest method to choose, but due to venous lower leg ulcers having a characteristically high exudate level, adding moisture by utilizing hydrogels or occlusive dressings such as hydrocolloids could, in fact, contribute to peri-wound maceration.

By law, the patient needs to sign consent for debridement procedures, and 130 files (81%, n=160) indicated that the practitioners were compliant in this regard. Non-compliance is a medico-legal risk, because patients must sign an informed consent form prior to any invasive procedure or treatment. In evaluating structure, it was determined that 80% (n=48) of the practitioners claimed to be trained in sharp debridement. However, sharp debridement was utilized only in 51 cases (32%, n=160). Patient preference or practitioner confidence levels could also have played a role in this low percentage.

Although 78% (n=48) of the facilities indicated that they have an enzymatic debrider available, usage was recorded in only 25 files (16%, n=160).

5.2.9 Compression therapy

Compression therapy is seen as the gold standard treatment of venous lower leg ulcers, because compression has been proven to favourably affect the haemodynamics of the venous system in the lower leg (Partsch & Mortimer, 2015: 359; Nazarko, 2017: S8). Compression therapy was applied for 114 patients (71%, n=160) on assessment. But in 112 cases (70%, n=160) the practitioners did not perform or record the patient's ABPI. Of the 48 patients whose ABPI was calculated, 44 (28%, n=160) met the criteria for receiving compression as discussed under 5.1.2.2. Therefore, compression was applied to 66 patients (41%, n=160) without their ABPI value being known, and the four (4) for whom compression was contra-indicated also received compression. This violates various guidelines (Harding *et al.*, 2015: 10; Kelechi, Johnson & Yates, 2015: 36; Franks *et al.*, 2016: S34). A total of 46 files (29%, n=160) did not indicate the use of any compression therapy at assessment. Without compression, the underlying cause cannot be addressed, which could result in impaired wound healing and a maintenance wound (Sibbald *et al.*, 2011: 420).

The various compression systems were discussed in Chapter 3. Figure 5.4 is a diagram of the percentages of the different bandaging systems utilized.

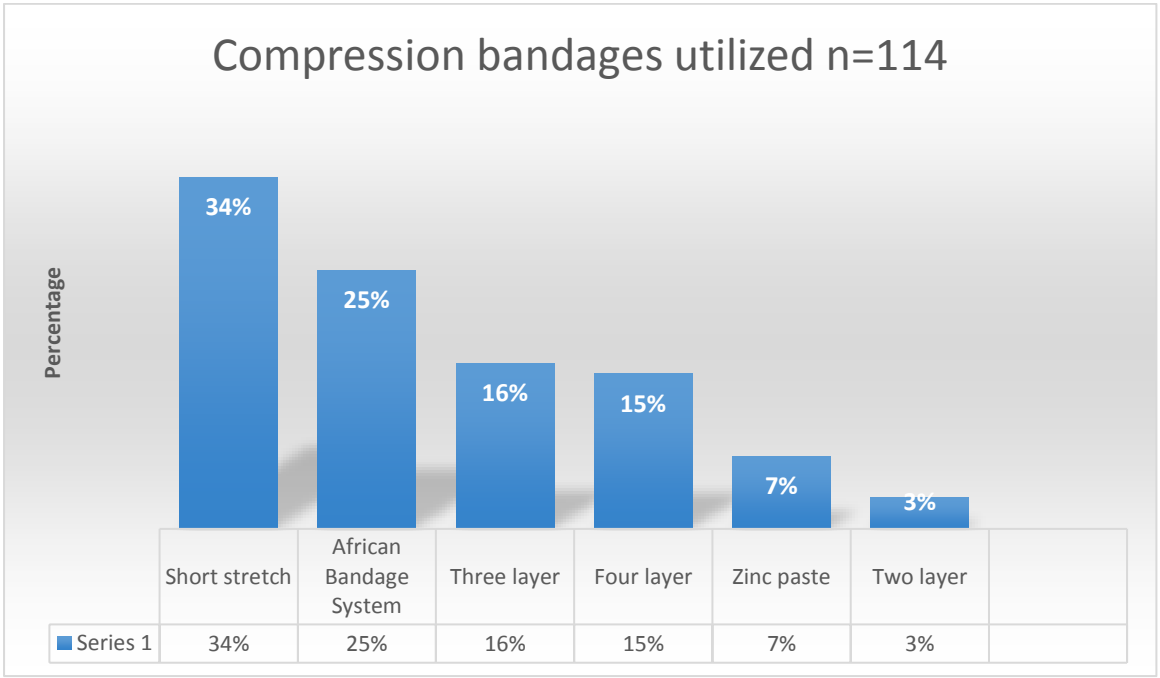


Figure 5.4 Compression bandages utilized at assessment (n=114)

Short-stretch bandages were chosen as treatment in 39 files (34%, n=114). Short-stretch bandages are available in a re-usable system, and therefore more cost effective, which could have contributed to their frequent use. Partsch (2017: 8) also concluded that, when applied correctly, short-stretch bandages are safer to use even if there is a slight arterial component present in the dynamics of the venous system, i.e., an ABPI of between 0,6 and 0,8.

The African Bandage System comprises two rolls of knitted 100 mm bandage and 100 mm orthopaedic wool and gives a mean ankle interface pressure of 22,3 mmHg (Smart, 2014: 14). The African Bandage System is based on the premise that low compression is better than no compression, as multilayer systems are designed to give pressures of between 40 and 60 mmHg (Fletcher *et al.*, 2013: 11). The African Bandage System is a low-cost system and could explain why practitioners used it more frequently, seeing that some of the medical aid schemes do not cover compression bandages, and knitted crepe is often the only bandages available. The African Bandage System was utilized in 29 files (25%, n=114).

Three-layer bandages consist of a long-stretch bandage and a short-stretch bandage and were utilized in 18 files (16%, n=114). The use of four-layer bandaging systems was recorded in 17 files (15%, n =114). Three- and four-layer bandages give continuous high pressures of between 30 and 40 mmHg (full compression).

Zinc paste bandages, which are also classified as short-stretch bandages, were utilized in eight (8) files (7%, n=114). Zinc paste bandages are impregnated with zinc ointment, and zinc aids in treating skin irritation and inflammation due to eczema. Three (3) files (3%, n=114) indicated the use of two-layer bandages. Two-layer bandages are classified as long-stretch bandages, consisting of one long-stretch bandage and a cotton wool layer. Long-stretch bandages give continuous pressure of 30-40 mmHg and require skill to apply.

The use of the different types of bandages varied over the period from assessment to completion. This could be ascribed to funding issues or patient or practitioner preference. The compression systems used at three weeks are outlined in Figure 5.5.

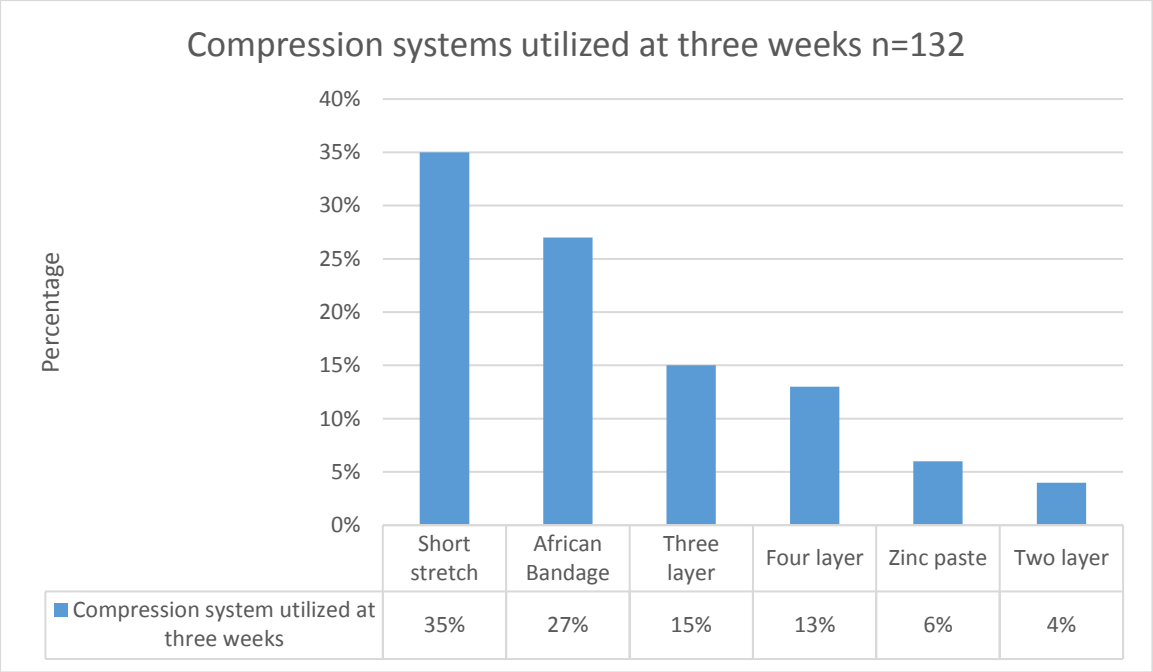


Figure 5.5 Compression systems utilized at week 3 (n=132)

Short-stretch bandages were indicated as being used the most frequent in 46 files (35%, n=132), and use of the African Bandage System was reported in 36 files (27%, n=132). Three-layer bandage systems were reported in 20 files (15%, n=132), and 17 files (13%, n=132) indicated the use of the four-layer system. Zinc paste was indicated in eight (8) files (6%, n=132) and the two-layer system in five (5) files (4%, n=132). Use of compression bandages increased slightly from assessment to three weeks, as 132 files (83%, n=160) indicated the use of compression, although only 48 files (30%, n=160) indicated a re-assessment of the ABPI at three weeks. Therefore, 84 files (53%, n=160) indicated the use of compression, but with no ABPI being recorded. Table 5.5 provides a summary of the data collected on the utilization of compression systems and shows that best practice guidelines regarding ABPI are not being implemented and that. In such cases, the wound care practitioners might be liable in case of litigation.

Table 5.5 Summary of data collected regarding utilization of compression therapy

Compression applied	ABPI measured	Patient who fit criteria for compression	Compression applied to patient without assessing ABPI
114 files	48 files	44 files	66 files

Short-stretch bandages were utilized in more than 30% of files that indicated the use of compression. Using short-stretch bandages is a safer option, because these bandages can be utilized in the presence of moderate PAD (ABPI of 0,6-0,8) – but the ABPI must be assessed (Mosti, 2014: 17). Inappropriate application of compression bandaging in patients with undiagnosed PAD could potentially result in distal gangrene and limb loss (Vasudevan 2014: 396). A Cochrane review of 2011 highlighted improved healing rates comparing compression with no compression (Marston *et al.*, 2016: 619).

5.2.10 Health dialogue

"Concordance" is a term used to describe the process of shared decision making and the relationship amongst the team members to reach a common goal (Brown, 2017: 1). Thus, health dialogue forms an integral part of the mutually agreed upon treatment plan. In this regard, 130 files (81%, n=160) indicated that the patient and the practitioner engaged in health dialogue regarding the following aspects: reason for therapy, signs of increased pressure, possible complications from treatment, and mobility. On average, 140 files (88%, n=160) indicated that health dialogue occurred regarding leg elevation, exercise, diet and risk factors, i.e., smoking, mobility and weight at assessment, with a decline to 122 files (76%, n=160) at three weeks and completion. Health dialogue was not recorded in 20 files (13%, n=160) at assessment, 38 files (24%, n=160) at three weeks, and 47 files (29%, n=160) at completion. Failure to record discussions with the patient and the patient's response could have medico-legal implications as per the acts and omissions of the Nursing Act (Act 50 of 1978).

Good clinical practice guidelines state that all dialogue with the patient should be recorded as such. Nurses are obligated to keep clear, accurate records of all actions performed concerning the patient (Geyer, 2005: 5).

5.2.11 Adjunctive therapy

Adjunctive therapy, such as topical negative pressure, intermittent pneumatic compression, skin replacement and the use of protease modulators, were utilized very infrequently. This could be ascribed to a lack of availability, funding, or knowledge and training. Figure 5.6 shows the utilization of adjunctive therapies.

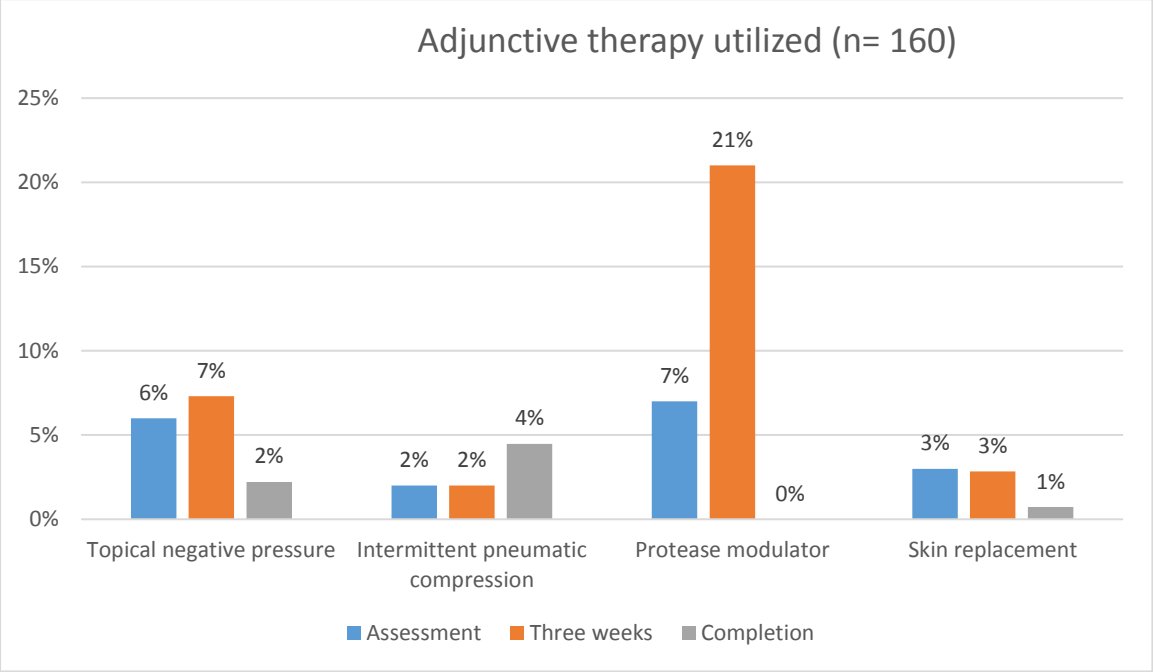


Figure 5.6 Utilization of adjunctive therapy (n=160)

The cornerstone treatment for venous lower leg ulcers is compression therapy which aims at treating the underlying cause, although the use of topical negative pressure for the treatment of ulcers could be beneficial in managing exudate. Once again, a 2015 Cochrane review found limited clinical effectiveness of NPWT as a primary treatment of lower leg ulcers; thus, more evidence is needed (Dumvill *et al.*, 2015, p. 3). Currently, this would imply that the use of negative pressure has no merit and only adds to the cost of treatment.

The use of NPWT was recorded in 10 files (6%, n=160) at assessment, which increased to 11 files (7%, n=160) at three weeks and three (3) files (2%, n=160) at completion. In the case of the latter three (3) files, NPWT could have been used for skin graft fixation, as negative pressure is indicated for this purpose. Currently, funders require a signed script/motivation from a medical doctor to authorize negative pressure therapy.

Intermittent pneumatic compression is a dynamic pressure applied using sleeves with air chambers that inflate and deflate (Alguire, 2016: online). This treatment modality is not readily available and often not covered by funders. The effect of the treatment lasts only a few hours and should be applied in conjunction with other modalities such as compression stockings (Sieggreen & Kline, 2015: 12342). Intermittent pneumatic compression was indicated in four (4) files (3%, n=160) at assessment and three weeks, and in six (6) files (4%, n=160) at completion, but the data collected were not clear on how this treatment was being utilized.

Chronic wounds are characterized by an increase in MMPs, which degrade and damage extracellular matrix proteins (Daughty & Sparks, 2016:64). Protease modulating dressings are indicated to alter the effect of proteolytic enzymes in the wound (Treadwell, Walker *et al.*, 2016: 1). Lower leg ulcers of venous origin are classified as chronic wounds with high levels of proteases (Daughty & Sparks, 2016: 64). There seemed to be an increase in the use of protease modulating treatment modalities at the three-week interval (34 files, 21%, n=160) compared with 12 (8%, n=160) at assessment. The reason for the increase could be that efforts were made to reduce the effects of chronic inflammation (Daughty & Sparks, 2016: 78). A Cochrane review found no substantial evidence that protease modulating dressings or applications significantly influence wound healing; thus, more research is needed (Westby *et al.*, 2015: 3).

Skin replacements refer to “bio-engineered epidermal or dermal grafting” and is currently mostly used in cases where conventional therapy has failed (Broussard and Powers, 2013: 455). These applications are unfortunately very costly. Five (5) (3%, n=160) files indicated skin replacements at assessment and three-week interval, specific types not specified. The utilization of advanced modalities is not cost effective if the underlying cause is not being addressed.

5.2.12 Primary dressing applied

Consensus documents advocate the use of “basic non-adherent primary dressings”. Primary dressing was recorded in 154 cases (96%, n=160) at assessment. Many of the dressings were utilized in conjunction with other dressings, thus a total of 268 dressings were utilized in 160 files. Figure 5.7 is a breakdown of the different types of dressings used.

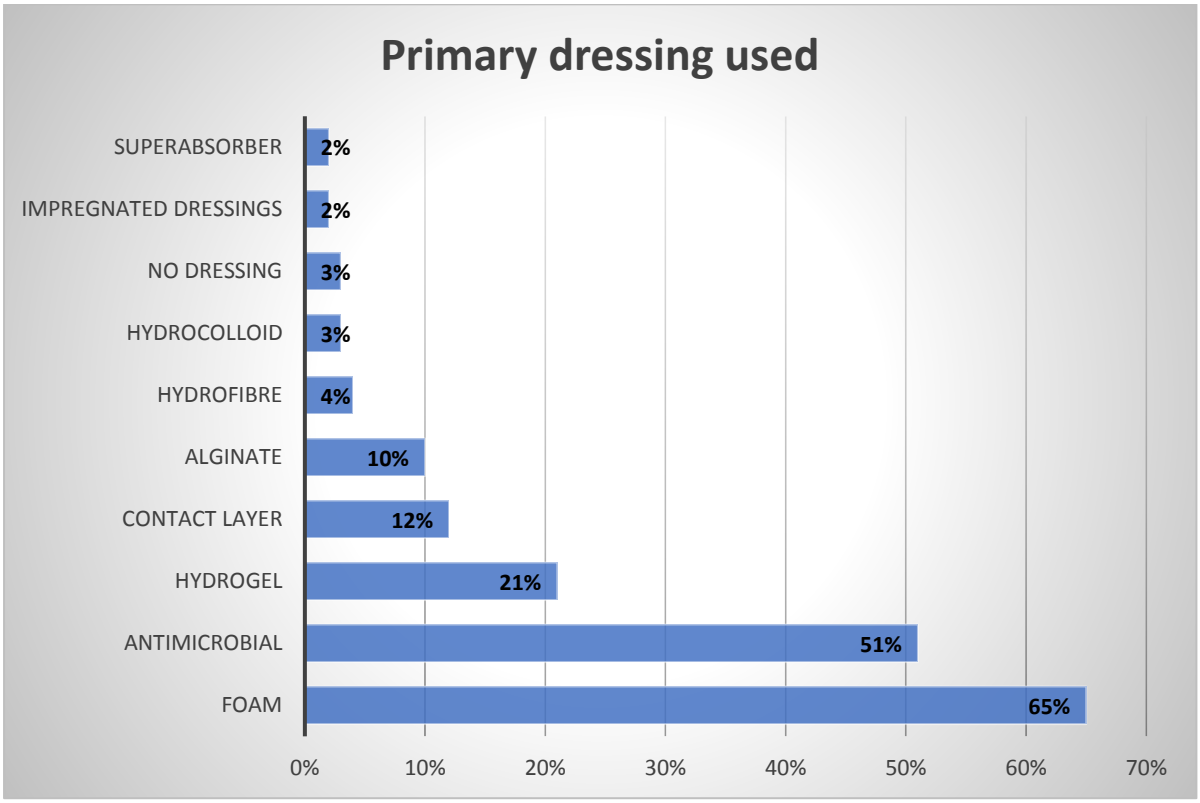


Figure 5.7 Utilization of primary dressings

Foam dressings were utilized most frequently, indicated in 104 files (65%, n=160). Dressing choice should be goal directed, namely to manage moisture and optimize the moist wound environment (Broussard and Powers, 2013: 451). Foam dressings are indicated for moisture management of lower leg ulcers of venous origin that are characterized by high exudate levels. Only 15% of the foams utilized were not utilized in conjunction with other products (16 cases). The different foam dressings used as indicated in 104 files (65%, n=160) were specified in 96 files (92%, n=104). Allevyn® was indicated as dressing choice in 25 files (24%, n=104) and Mepilex® in 19 files (18%, n=104). Allevyn® has a tri-layer fluid management system that is indicated for use under compression (Broussard & Powers, 2013: 415). Mepilex® is a foam dressing with Safetac® technology to reduce trauma to the wound bed. It can be used under compression, but clinical data have shown a reduction in absorption capacity when interface pressure is 40 mmHg. Cutimed Siltec®, a polyurethane foam that contains superabsorbent pockets to lock away fluid, was recorded in 12 files (12%, n=104). The mechanism of fluid locks and wicks the fluid in one direction to prevent peri-skin maceration (Broussard, 2007: 251; Broussard and Powers, 2013: 451). In 33 files (32%, n=104) the foam of choice was indicated as various polyurethane-based foam types available in South Africa (Permafoam®, Askina®, Biatain®, Hydrotac®), all of which function the same, hence their being grouped. Exudate is absorbed into hollow polyurethane pores, but can also be donated back to the wound bed, hence the risk of peri-wound maceration (Sibbald, Ayello, Elliot *et al.*, 2015: 13). This "moisture donating" effect could be exacerbated under compression. Seven (7) files (6%, n=104) indicated the use of Tielle®. Tielle® is a hydropolymer foam that also has liquid lock technology and is indicated for use under compression. In eight (8) files (8%, n=104) the foam type was not specified but recorded only as "foam dressing".

Although foams were recorded in 104 files, in 80 of these files (77%, n=104) foams were indicated to have been used in conjunction with other dressings. Table 5.6 gives a list of variations of other dressings used with the foam dressings.

Table 5.6 Frequency of dressings used in conjunction with a foam dressing

Dressings utilized in conjunction with foams	Utilization frequency
Antimicrobial	58 cases
Alginate	12 cases
Contact layer	6 cases
Hydro fibre	6 cases
Hydrogel	20 cases

Antimicrobials were recorded in 79 cases (51%, n=154), of which 58 (38%, n=154) indicated that they were utilized in conjunction with a foam. Antimicrobials should be utilized only when infection is diagnosed (Swanson *et al.*, 2016: 22). The use of composite dressings that incorporate a foam dressing with an antimicrobial was not specified and could have influenced accuracy of data. The use of antimicrobials as a prophylactic measure in the absence of signs of infection is not recommended and is not cost effective (Swanson *et al.*, 2016: 22).

Alginate dressings are made from seaweed or kelp and are designed to absorb medium to high levels of exudate, as well as maintain a moist wound bed by converting into a gel when in contact with exudate. They could, however, require a secondary dressing (Broussard and Powers, 2013: 455). Alginates were indicated in 15 cases (10%, n=154), of which 12 indicated usage in conjunction with a foam and three (3) usage in conjunction with a contact layer. Guidelines recommend that exudate level be monitored, because when these dressings dry out, they might adhere to the wound bed and cause trauma on removal (Broussard and Powers, 2013: 455).

Contact layers included Adaptic®, Mepitel® and Adaptic Touch®. Contact layers were recorded in 18 cases (12%, n=154), of which six (6) indicated usage with a foam dressing, three (3) usage as a primary dressing and nine (9) usage in conjunction with an antimicrobial. Contact layers are designed to reduce trauma to the wound bed and protect delicate tissues by providing an interface between the fragile new epithelium and the dressing. However, a secondary dressing might be required, and contact layers are more expensive than traditional tulle gras (Green, 2012: 16).

Hydro fibre dressings are made from woven sodium carboxymethylcellulose that turns into a gel when coming into contact with wound exudate, similar to alginates (Green, 2012: 16; Broussard & Powers, 2013: 455). Hydro fibre dressings could aid in autolytic debridement and have greater absorption than alginate dressings, but they are also slightly more expensive than other dressings. Hydro fibre dressings were utilized in six (6) cases (4%, n=154), mostly by private wound clinics and home-based care nurses. All the hydro fibre dressings were used in conjunction with a foam dressing. Caution should be taken in applying more than one application, as more layers could result in increased interface pressure and add to the cost of the treatment.

Hydrogel dressings are 60-90% water based and aid autolytic debridement by donating moisture to the wound bed (Green, 2012: 16; Sibbald, Ayello, Elliot *et al.,* 2015: 11). Lower leg ulcers tend to have a high exudate level, thus adding moisture could contribute to peri-wound maceration and skin breakdown and should be used with caution. The use of a hydrogel was indicated in 32 cases (21%, n=154), of which 20 indicated usage together with a foam dressing. In 10 cases (7%, n=154) hydrogel was indicated as the primary dressing, and in two (2) cases used in conjunction with an antimicrobial.

Hydrocolloids, indicated in five (5) cases (3%, n=154), could be useful to aid autolytic debridement, but due to their inability to absorb moisture, these dressings have the risk of peri-skin maceration and increasing the wound size in wounds with high exudate levels. They are thus not recommended for use in the treatment of lower leg ulcers (Broussard and Powers, 2013: 451). In one (1) case an alginate was utilized with the hydrocolloid. This could aid fluid management, but peri-wound maceration remains a risk.

Impregnated dressing included honey-impregnated tulle and Bactigras®. These dressings were indicated in three (3) files (2%, n=154). No secondary dressing was utilized with these dressings. As primary dressing, these dressings cannot absorb any exudate and run the risk of adhering to the wound bed and causing trauma.

Superabsorbers, which can absorb a larger amount of fluid and have fluid lock technology (Sibbald, Ayello, Elliot *et al.*, 2015: 11), were recorded in three (3) files (2%, n=154). Superabsorbers tend to expand whilst absorbing fluid, and there is evidence that interface pressure increases (Cook, 2011: 542). An untoward increase in interface pressure might influence the effect of the bandage on venous haemodynamics and could have a detrimental effect on healing, but evidence is lacking on the effect on wound healing (Cook, 2011: 542). Increased pressure in the wound bed is shown to have a negative effect on wound healing (Broussard, 2007: 255).

The absorbent layer of the compression system could also be utilized for absorption and could be the reason why four (4) files (3%, n=154) indicated the use of no dressings. Cotton wool directly on the wound bed could be detrimental to wound healing, as the cotton fibres adhere to the wound bed, cause trauma on removal and are not sterile. This practice is not beneficial to the patient.

Layers of the bandages and the size, thickness or bulkiness of the dressing should be considered when choosing a dressing, as these aspects might interfere with sub-bandage pressures (Cook, 2011: S40). The dressing decision should depend on the exudate management properties, performance under compression, ability to lock and retain fluid, cost and availability (Saco, Howe & Nathoo, 2016: 16). In a systematic review, Saco *et al.* (2016: 16) concluded that a basic non-adherent dressing is just as effective as an alginate, hydro fibre or foam, when used in conjunction with compression.

Several of the consensus documents and guidelines refer to the use of a non-adherent, absorbent dressing (Broussard & Powers, 2013: 456; Di & Clark, 2016; 745; Harding *et al*., 2015: 12). The nature of the wound bed determines the type of primary dressing to be used and requires that the practitioner have the necessary knowledge and skill to choose an appropriate treatment. Ultimately, it is not the primary dressing that determines the outcome of the care, but addressing the cause, addressing patient-centred concerns and then addressing local wound care concerns (Sibbald *et al*., 2013: S13).

The findings from the files indicate that the utilization of appropriate primary dressings was not optimal. Application of several layers of dressings could change interface pressure and could affect wound care negatively. There seemed to be a general tendency to overuse antimicrobials and hydrogels. In only 15% of cases only a foam was utilized, which could constitute a simple non-adherent dressing as recommended by several guidelines.

5.2.13 Treatment of the surrounding skin

Treatment of the surrounding skin, especially in lower leg ulcers, merits just as much attention as the wound itself, because there is a risk of injury or skin breakdown with subsequent ulcer formation (Sieggreen & Kline, 2012: 363). Figure 5.8 represents the use of four different types of skin moisturizers indicated in the files.

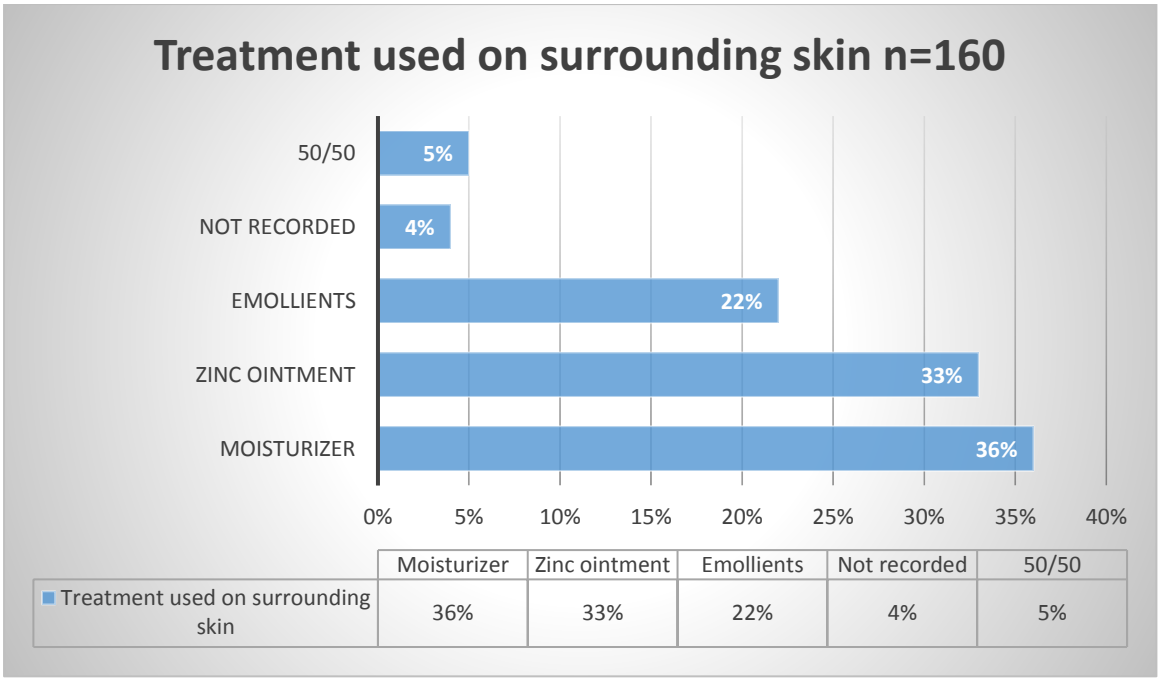


Figure 5.8 Topical applications indicated as being used on the surrounding skin (n=160)

Moisturizers (water based) were indicated in 58 files (36%, n=160). There seems to be no consensus about what a moisturizer comprises (Sethi, Kaur, Malhotra & Gambir , 2016: 280). The mode of action of humectants and emollients aids moisture retention and absorption in the skin, whereas water-based or aqueous moisturizers might contribute to even more dryness due to evaporation of moisture (Sethi *et al.*, 2016: 280).

Zinc is a trace element naturally found in the body and could aid in wound healing (Tippett, 2017: online). Zinc paste can be used as a barrier to protect the surrounding skin and was indicated in 53 files (33%, n=160).

Emollients are humectants that help the epidermis retain moisture (Sibbald, Alvari *et al.*, 2012: 207). Emollients could aid in the repair of the skin's natural barrier and also help protect against irritation and infection (Sibbald, Alvari *et al.*, 2012: 207). A total of 35 files (22%, n=160) indicated the use of emollients as a treatment for the surrounding skin.

In eight (8) files (5%, n=160) the 50/50 application (liquid paraffin and soft paraffin) was used. However, 30% (n=160) noted that they did not know what emollients, or 50/50 ointments are (not in questionnaire, notes made by fieldworkers). In six (6) files (4%, n=160) nothing was recorded about whether the patient's skin was treated or what was utilized.

5.3 Outcomes measured

Outcomes could provide information about the health care delivered, but seem to be a crude measure for quality due to the inherent unpredictability of patients' responses to the care they receive (Hanefeld, Powell-Jackson & Balabanova, 2017: 369). **Outcome** measures were determined to be the following:

- Reduction in devitalized tissue;
- Reduction in oedema;
- Reduction in pain;
- Reduction in wound size;
- Advancement in wound edges;
- Reduction in malodour;
- Reduction in exudate level;
- Increase in daily activities; and
- Improvement in the surrounding skin condition.

Outcome measures are based upon the functional aspects of care such as the absence of complications or the reduction in disease, as well as patient satisfaction (Soter *et al.*, 2017: 3). Patient satisfaction was not measured in this study, whereas changes in health status were assessed and whether practitioners recorded the change. Figure 5.9 represents the percentage of outcomes recorded in the files audited.

	Reduction in devitalized tissue	Reduction in odour	Reduction in oedema	Improvement in wound edges	Reduction in pain	Improvement in skin condition	Reduction in exudate	Reduction in wound size	Improvement in ADL	Nothing recorded
Completion	65%	63%	81%	63%	61%	65%	59%	63%	56%	20%
Three weeks	84%	83%	80%	78%	80%	75%	75%	74%	63%	23%

Figure 5.9 Percentage of outcomes recorded in the files audited (n=160)

A reduction in devitalized tissue is a measure for healing. As devitalized tissue reduces, so does the risk of infection. It is vital for the clinician to record the amount of devitalized tissue on the wound bed, because this could direct the treatment plan and choice of dressing and evaluate the outcome of the treatment. A reduction in devitalized tissue was recorded in 134 files (84%, n=160) at the three-week interval.

No information was collected on the percentage of reduction, but on whether the practitioner recorded a reduction. In 26 files (16%, n=160) no information on a reduction in devitalized tissue recorded. At completion, 104 files (65%, n=160) recorded a reduction in devitalized tissue, but “no devitalized tissue visible on the wound bed” was also marked as a positive response.

A reduction in oedema could be an indication that therapy is effective, 128 files (80%, n=160) and 130 files (81%, n=160) noted a “reduction of oedema” at three weeks and completion respectively. A total of 51 files (32%, n=160) recorded a measurement of leg circumference, thus the reduction mentioned in the files does not seem to have been be clinically verified with a circumference measurement (Partsch & Mortimer, 2015: 359).

Changes in pain were recorded in 128 files (80%, n=160) during the three-week follow-up, and 98 files (61%, n=160) reported a decrease in pain on completion. Once again, the percentage is not a reflection of whether the patient had pain, but whether any information about pain was recorded; in other words, a reduction in or no pain was seen as a positive response. The percentage only reflects whether any recording was done on the aspect of pain reduction and does not reflect pain intensity. Pain assessment at dressing changes was unfortunately not assessed.

A reduction in wound size was recorded in 119 files (74%, n=160) at three weeks, which correlates with the fact that 79% of the practitioners recorded having measured the wound size at assessment. The exact size reduction was not considered. A total of 100 files (63%, n=160) recorded a reduction in wound size at completion, but “wound has healed” was also marked as a positive response.

Information about the wound edge was recorded in 124 files (78%, n=160). However, the information was limited, since it was only indicated with a yes or no and did not give details regarding the characteristics of the wound edges, for example, rolled or senescent. A total of 100 files (63%, n=160) recorded data on the wound edge at completion, but “wound bed has epithelialized” or “wound edges seem viable” was noted as a positive response.

Malodour and exudate levels that result in strikethrough on bandages affect the patient's quality of life. Although subjective, a reduction in these symptoms has been shown to improve patients' social well-being and functioning (Sibbald, Goodmam and Reneeka, 2013: S12). A reduction in odour was recorded in 133 files (83%, n=160) at three weeks, and in 101 files (63%, n=160) at completion. These figures represent the quality of recording, as data were collected on whether the practitioner recorded a reduction or not.

A reduction in exudate level was recorded in 120 files (75%, n=160) at the three-week interval, and 94 files (59%, n=160) recorded changes in exudate level at completion. Once again, the assessment recorded only whether an inscription was made in the file regarding exudate levels and whether any changes were noted by the practitioner and recorded as such.

Activities of daily living are assessed by determining patients' functional status, i.e., how well they can manage their own hygiene requirements, dressing, feeding, mobilizing and continence care. Chronic wounds that cause pain, restrict mobility and cause depression and social isolation can influence activities of daily living negatively (Sibbald, Goodmam and Reneeka, 2013: S15). The files were assessed regarding whether the practitioners noted any changes in the patient's activities of daily living. At the three-week interval 101 files (63%, n=160) recorded changes in activities of daily living, which decreased to 90 files (56%, n=160) at completion.

Improvement in skin condition is an important factor to record, because patients suffering from lower leg ulcers have a high risk of peri-wound maceration due to high exudate levels, skin excoriation due to pruritis, and contact dermatitis (Sibbald, Alvari *et al*., 2012: 215). An improvement in skin condition was recorded in 120 files (75%, n=160) at the three-week interval, but this reduced to 65 files (40%, n=160) at completion.

There was a general decline of recording changes at completion regarding desired wound care outcomes. All of the mentioned measurements should be reported on at completion, as they depict level of successful treatment.

5.3.1 Assessment intervals

Continuous re-assessment is key to improvement of care (Marston *et al.*, 2016: 134). In 150 files (94%, n=160) the practitioners re-assessed the wound at every consultation which, in the case of lower leg ulcers, could be weekly or twice weekly, as compression bandages have to be changed weekly or, if needed, twice weekly. In 10 files (6%, n=160) there were no information on assessment intervals.

In 71 files (44%, n=160) it was indicated that patients were followed up 24 hours after initial assessment, whereas 89 files (56%, n=160) did not record any follow-up after 24 hours. The consensus documents state that patients should be followed up after 24 hours with the use of inelastic or short-stretch bandages (Moffatt, Harding *et al*., 2008: 10) As oedema reduces, the sub-bandage pressure also reduces due to the stiffness index. Hence, the bandage should be re-applied after 24 hours to maintain correct interface pressure, to be effective and to prevent friction damage due to ill-fitting bandages (Moffatt, Vowden *et al*., 2008: 24).

Best practice guidelines regarding follow-up after the application of compression were poorly followed, as the majority of cases (56%) were not followed up after 24 hours.

5.3.2 Healing rates

According to Sibbald *et al*. (2013: S12), the healing trajectory of a healable wound could be estimated at 12 weeks, but only if the wound surface area has reduced by 30% at week four. This study was not designed to measure healing times, but to collect information on the period the wounds were treated at the facilities. Figure 5.10 is a representation of the time to healing in weeks.

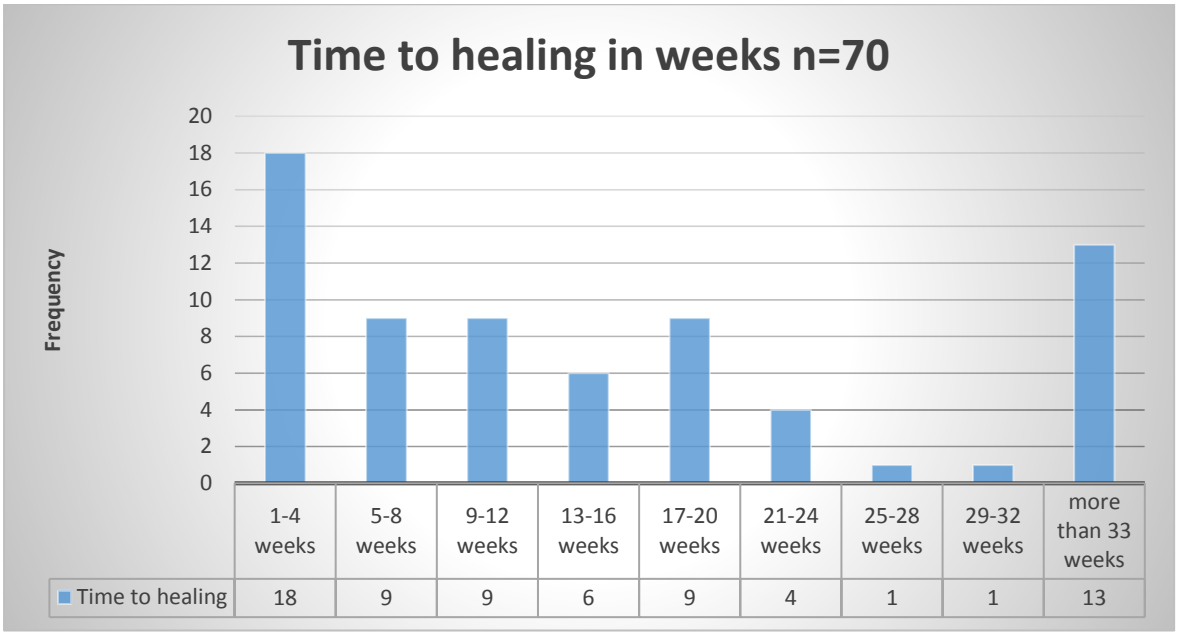


Figure 5.10 Time it took for wounds to heal (n=70)

Time to healing was recorded in 70 files (44%, n=160). Time to healing in 36 files (51%, n=70) was 12 weeks, which is aligned with the expected healing trajectory mentioned by Sibbald *et al.* (2013: S12). In 19 files (27%, n=70) the time to healing was between 13 and 24 weeks. However, 15 wounds (21%, n=70) took 25 weeks or more to heal. Twenty-five (25) weeks calculate to about six (6) months; thus, 21% of the wounds took six (6) months or longer to heal. This has a serious socio-economic implication for the patient (Woo, Van Den Kerkhof & Jimenez, 2015: 311). Although significant for the patient, time to healing cannot be used as a measure for quality of care, because there are many factors, both intrinsic and extrinsic, that could contribute to a protracted healing time i.e. age of the patient, initial size of the wound, arterial impairment (Stotts, Wipke-Tevis & Hopf, 2012: 7583; Martin, 2013: 37; Young & McNaught, 2014: 376; Bryant & Nix, 2016: 76).

Of the 160 files audited, 61 (38%, n=160) indicated that the wounds did not heal. Figure 5.11 is a representation of the actions taken when the wounds did not heal.

Figure 5.11 Actions taken when wounds did not heal (n=61)

From personal experience, the researcher has learned that patients often choose to take over care of their wounds or fail to keep appointments in the following circumstances: when all the symptoms are under control, medical aid schemes deny further funding, patients experience financial constraints, and/or work responsibilities make it difficult for them to visit the facility. In six (6) files (10%, n=61) it was indicated that the patients had taken over their own care. In 18 files (30%, n=61) it was indicated that the patients were referred for a second opinion. In twenty-seven (27) files (44%, n=61) it was indicated that the patients had amputations. This rate is high and might need further scrutiny, as only one (1) file indicated PAD with an ABPI measurement of 0,5, and one (1) file indicated moderate PAD with an ABPI of 0,62, whereas 66 patients received compression without an ABPI. Of the 27 cases that had amputations, 13 cases (48%, n=27) were identified as being diabetic. Diabetes-related ulcers tend to have a higher amputation rate due to presence of PAD (Karavan *et al.*, 2015: 745).

Lower leg ulcers have a protracted healing time and a high risk of infection, and nine (9) files (15%, n=61) indicated that the patients were admitted, without reasons being specified. One file (1) (1%, n=61) indicated that the patient did not return for treatment. In 29 files (18%, n =160) there was no record of what action was taken when the wound did not heal. A lack of proper record-keeping is a medico-legal risk (Geyer, 2005: 5).

5.3.3 Prevention of recurrence

Once the wound has epithelialized and healed, maturation could take up to two years, because the newly formed skin has potentially only 70% tensile strength of undamaged skin, thus increasing the risk of breakdown (Young & McNaught, 2014:477). To decrease the risk of recurrence, consensus documents recommend compression even if the wound has healed (Franks & Barker, 2016: 84). In 69 files (43%, n=160) it was indicated that compression was continued for two weeks after the wound had epithelialized.

Patients were referred for compression stockings post treatment according to 58 files (36%, n=160). A total of 93 files (58%, n=160) indicated that the patients were not referred for stockings, and nine (9) files (6%, n=160) had no information of referral for stockings. Guidelines state that all patients with healed ulcers should use compression stockings as a lifelong intervention for prevention of recurrence (Franks & Barker, 2016: 84; Marston *et al.*, 2016: 144). Thus, compliance with best practice guidelines regarding prevention of recurrence was poor.

5.4 Conclusion

Practice guidelines are designed to guide evidence-based practice (Tomson & Van der Veer, 2013: 19; Weller, 2013: 10) and promote high quality care. Conversely, poor guideline implementation contributes to practice variation and substandard quality of care (Tomson & Van der Veer, 2013: 19).

The survey conducted in this study aimed at collecting data regarding structure, processes followed and outcomes reached in order to define possible “causal linkages” (Donabedian, 1988: 1743). Despite the availability of guidelines, practice variations seem inevitable (Hanefeld, Powell-Jackson & Balabanova, 2017: 396).

Consensus documents recommend that assessments be “conducted by a healthcare professional with appropriate clinical skill and knowledge” (Franks & Barker, 2016: 83). Thus, appropriate skill, knowledge and experience are needed to interpret data collected during history taking, assessment and physical examination to be able to draw the correct conclusions about the findings and choose appropriate treatment (Weller, 2013: 8). A total of 61% of the practitioners in the sample did not have any accredited wound care training.

The results in general indicated that record-keeping was poor and history taking was incomplete. Furthermore, the main concern with physical examinations is that only 30% of the files indicated that an ABPI was performed. Patient-centred concerns such as pain, odour and exudate seemed to have been addressed, but religion, cultural beliefs and financial issues were not addressed sufficiently.

Other areas of concern include the fact that the diagnosis of superficial and deep infection seemed to be deficient, and that antimicrobials and systemic antibiotics appeared to be overutilized in general. Compression therapy also seemed either underutilized and not helpful in treating the underlying cause, or applied when the ABPI is not known, which is a medico-legal risk. The required follow-up 24 hours after application of compression was not done routinely. Finally, record-keeping of health dialogue is lacking. Health dialogue performed with the patient should be recorded.

Guidelines, protocols and algorithms could guide practice when implemented or applied correctly and consistently, but the patient as an individual must never be removed from the equation.

Chapter 6: Conclusion, recommendations and limitations

6.1 Introduction

Venous lower leg ulcers have, due to their chronicity and associated symptoms, a debilitating effect on patients and place a huge socio-economic burden on both the patient and the health care system. A lack of data on the prevalence of lower leg ulcers in South Africa makes it difficult to establish the extent of this burden. Furthermore, the lack of standardization of care for these patients exacerbates the situation.

The researcher sought to describe the quality of care received by patients with venous lower leg ulcers by utilizing the Donabedian quality of care model of structure, process and outcome. Structure refers to the physical setting, human resources, policies, protocols and treatment modalities available. Process assesses the actions implemented whilst delivering the care, and outcomes evaluates the result of the care. Outcomes as a measure of quality of care can be divided into technical aspects, which include the reduction in disease or symptoms or the absence of complications, and patients' level of satisfaction with the care or their perception as to the improvement of their quality of life. The latter was not evaluated, as patient quality of life was not addressed in this study.

A randomized, descriptive quantitative design was followed to evaluate current levels of venous leg ulcer care with regard to BPGs in wound care practices in Gauteng. The research was conducted in two phases: a structured interview using a questionnaire to assess structure, and a file audit according to a checklist to assess process and outcome. The population comprised five strata, namely public health clinics, private wound clinics, pharmacy clinics, general practitioners and home-based care nurses. A total of 48 facilities were sampled and 160 files were audited in order to describe current levels of care.

The objectives were to explore and describe the:

- Structures available in the facility;
- Processes being implemented at the facility; and
- Outcomes being reached at the facility.

6.2 Factual conclusions

Factual conclusions are based on the evidence that emerged from the data and are described according to the research objectives.

6.2.1 Main results regarding structure

A hand-held Doppler with 8 MHz probe and a baumanometer are basic equipment required to assess patients with lower leg ulcers in order to exclude PAD. Most facilities (60%) had a Doppler available and all facilities had a baumanometer. The majority (61%) of the health care personnel had no formal wound care training and more than 60% did not follow any guidelines in making treatment decisions. Advanced treatment modalities with regard to primary dressings, debridement agents and antimicrobials were available in 70% of the facilities. Although compression is the key therapy for venous lower leg ulcers, 45% of the practices had no compression bandages available. Consequently, all patients with venous lower leg ulcers will receive suboptimal care at these facilities.

6.2.2 Main results regarding process

File audits were conducted to assess processes. The results indicated that record-keeping was very poor in general. The overall conclusion is that available BPGs were not enacted in practice. The following serves as evidence:

- Important aspects such as smoking, history of vein stripping and sclerotherapy, BMI and anaemia were indicated in less than 30% of the files (see 5.2.1). These aspects are vital because they affect wound healing and should be noted and addressed accordingly.
- An ABPI measurement was done in only 30% of the files (see 5.2.2). Wound care practitioners are not reimbursed by medical aid schemes for this procedure and may be a reason why it was underutilized, albeit to the detriment of the patient. Moreover, compression was applied to 71% of patients without their ABPI value being known, and in 29% of cases no compression was utilized (see 5.2.9). These actions, and lack of appropriate action, can be construed as negligence, and the relevant health care practitioners could be liable in case of litigation.

- Patient-centred concerns such as pain, exudate and malodour were addressed in more than 70% of the files at assessment, whereas culture, religion, fear, anxiety and financial issues were addressed in less than 30% of the files. Recording of patient-centred concerns declined over the period from assessment to termination of care. (See 5.2.3.)
- Wound bed preparation was not optimal, but there were no glaring issues.
- Assessment and classification of wound infection were done inaccurately and not according to international standards. In general, there was an overuse of between 40 and 60% of topical antimicrobials and systemic antibiotics, which contributes to unnecessary costs and might lead to resistance.
- Appropriate primary dressings were used in 18% of cases and the surrounding skin was appropriately cared for in 60% of cases.

6.2.3 Main results regarding outcomes

Once again, record-keeping of outcome measures, i.e., reduction in devitalized tissue, oedema, pain and exudate and improvements in ADL, wound edges and surrounding skin, was incomplete. However, between 60 and 80% of the files did record positive changes and improvements or positive outcomes. There was a general decline of record-keeping of these aspects toward completion of care.

According to the files, approximately one-third of the wounds did not heal and in 27 cases amputation was performed. This number of amputations is high and could be linked to inadequate assessment and/or suboptimal or incorrect treatment due to a lack of knowledge.

Record-keeping

As deduced from the data, record-keeping was poor. A more comprehensive, standardized method of assessment and history taking could aid not only in more useful data collection and improved and cost-effective treatment planning, but also in legal defence when necessary. Accurate and complete record-keeping is a legislative requirement. The clinical record is the most important piece of evidence in a negligence case. It also serves as the supporting basis for treatment decisions and delivery of evidence-based care, and as a communication tool and a tool to evaluate treatment modalities.

Incomplete records and the absence of documentation related to observations and treatment outcomes are strong evidence of negligence. Documenting the patient's response to care and treatment outcomes is in itself an evaluation of the quality of care. Without careful, comprehensive documentation of treatment, outcomes and treatment modifications are impossible to justify in a court of law.

6.3 Recommendations

The recommendations are presented below per stakeholder group. The stakeholders include WHASA, SPNP, SANC as regulatory body, nursing education institutions, wound care practitioners and medical aid schemes.

6.3.1 Wound Healing Association of South Africa

WHASA could negotiate with medical aid schemes on behalf of wound care practitioners to fund practices which are based on best available evidence, for example, taking an ABPI. This could increase the use of an assessment that differentiates between venous and arterial disease and promote appropriate care.

Furthermore, WHASA should endeavour to promote standardized care of patients with venous lower leg ulcers, considering the finding that approximately half of patients in this study received suboptimal care.

6.3.2 Society of Private Nursing Practitioners

The Society of Private Nursing Practitioners (SPNP) could negotiate on behalf of their members with the Medical Aid Schemes to fund care modalities that are based on best available evidence. Furthermore, they should strengthen their efforts to promote standardisation of care. It would be beneficial to the patients receiving the care that SANC, the DOH and originations like SPNP increase their efforts to work together in terms of regulation and funding for Prescribed minimum benefits (PMB).

6.3.3 South African Nursing Council

The purpose of the SANC is to licence practitioners and accredit training programmes and clinical facilities for training to ensure quality of services and training. Therefore, regulations should be formulated and promulgated that only nurses who have the specialist training in the specific field may practice as a private practitioner.

The SANC needs to acknowledge “Wound management” as a speciality and better legislation is required to govern private practice. It would be to the benefit of patients in all sectors, both public and private if SANC, DoH and the practitioners could work together to improve levels of service through training and regulations. SANC has been authorised to register specialists, but they have not yet set out the requirements. Different levels of registration might be required according to level of training and skill i.e. wound care specialist and advanced wound care specialist.

6.3.4 Nursing education institutions

In the absence of regulations regulating nurses and clinicians in both public and private sectors, all NEI should train their preregistration students in the science and best practices of the dynamic field of wound care. There is a definite need to reduce the knowledge gap and improve skill with intensive training as 61% of the nurses and clinicians attending to patients did not have formal training in wound care.

Continuous professional development programmes on all aspects pertaining to wound care are of paramount importance.

6.3.5 Wound care practitioners

Wound care practitioners should ensure that they keep up to date with research and apply the available BPGs. They should also improve their assessment skills and be aware of malpractices, such as applying compression when it is contra-indicated, and of the risk of litigation, such as not applying compression when it is indicated.

A knowledge gap regarding assessment, classification and treatment of superficial and deep wound infection clearly exists and should be addressed through continuous professional development.

6.3.6 Medical aid schemes

Medical aid schemes need to engage with wound care specialist or representative organisations of wound care specialist to negotiate funding systems or items based on best practice guidelines. The management of Lower Leg Ulcers should be considered for inclusion in the list of PMBs, which would then require all schemes to cover their treatment. The patient will ultimately benefit by receiving optimal care and the medical aid schemes will find it less costly because better wound care outcomes could be achieved in a shorter time.

6.3.7 Further research

The large number of amputations reported in this study warrant further investigation. Possible areas of further research would include development of care pathways for the impovemnt of leg ulcer care, specifically within the South Africn context.

6.4 Limitations

The study had several limitations. One limitation was the fact that practitioners answered the questions during the interview and the physical clinic setting was not inspected for availability of standard operating procedures or equipment. Standard operating procedures were not scrutinized for comprehensiveness or whether they were appropriate for the practice. The availability of treatment modalities in the facilities does not necessarily ensure good quality treatment, but unfortunately the physical practice setting was not evaluated.

With hindsight, a different methodology, for example, a prospective study under direct observation, might have resulted in better data collection, as poor record-keeping resulted in missing data. But direct observation also has limitations (Hawthorne effect) and might not be feasible.

Outcome measures such as wound size was not quantified at the three-week interval, which limited the quality of data collected regarding outcomes reached. Associations could not be made between the process implemented, i.e., compression, and the reduction in wound size.

Although some files indicated a reduction, the percentage of reduction was not collected. The exact quantity of reduction in devitalized tissue was also not collected. Owing to incomplete records, outcome measures such as reduction in oedema could also not be measured.

6.5 Conclusion

This study has highlighted the need for regulations or legislation that govern clinicians and nurses who deliver a wound care service, as the majority of the nurses and clinicians practicing wound care, in both private and public sector were not a specialist in the field of wound care. Consequently, suboptimal and/or incorrect care were provided and BPGs were not implemented.

The role of medical aid schemes was highlighted because they do not remunerate essential and differentiating assessments that should be performed in order to optimally treat patients with lower leg ulcers. The lack of reimbursement for, for example, an ABPI might contribute to the malpractice of applying compression without knowing the true nature of the ulcer.

The study revealed a dire need for training regarding the assessment and treatment of wound infections, seeing that the practitioners overused antimicrobial and systemic antibiotics and did not seem able to differentiate between deep and superficial infection. Continuous professional development regarding this aspect of wound care is of paramount importance due to the increasing risk of bacterial resistance to known antimicrobials and antibiotics.

Poor record-keeping and monitoring of wound care outcomes were highlighted in the study. The high number of amputations recorded in this study is worrisome and warrants further investigation.

This study provided evidence that advocates for patients as better-quality care wil result in better outcomes. Clinicians attending to wounds can utilized this in their endeavours to set regulations for wound management, negotiate with medical aid schemes, and direct attention to areas where the knowledge base of current practitioners is lacking.

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Appendix A: Ethics permission letter

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

30 November 2016

MS FEBE A BRUWER
SCHOOL OF NURSING
IDALIA LOOTS BUILDING
UFS

Dear Ms Febe A Bruwer

HSREC 146/2016
PROJECT TITLE: A SURVEY TOWARDS BEST PRACTICE REGARDING VENOUS ULCER CARE WITHIN WOUND CARE PRACTICES IN GAUTENG

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met at the meeting held on 29 November 2016.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | F: +27 (0)51 444 4359 | E: ethicsfhs@ufs.ac.za
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

Appendix B: Cover letter for questionnaire and checklist

Sr. F.A. Bruwer

B. Cur (Cum Laude) (UP) Cert. Wound Care (UOFS)

Cert. Wound Care (Univ. Hertfordshire, United Kingdom) IIWCC (Univ. Toronto, Canada)

Pr. Nr. 088 000 0044 954 Web: woundclinic.co.za Tel: (011)822-8508 Fax: 086-685-8353

DATE:

Dear Colleague

Thank you for confirming that you have agreed to participate in a **randomised, descriptive quantitative design study in the form of a survey** regarding venous ulcer care within wound care practices in Gauteng.

Please also be kind enough to advise which method of communication you would prefer, i.e. via e-mail or telephone to setup an appointment with our Field Worker to call on you in person at your facility to complete the questionnaire. You will be required to sign an Access to Facility and Informed Consent Form indicating your agreement to allow the Field Workers to conduct the study.

All the information collected at your facility will be kept confidential.

The patient's names will not be disclosed outside the study site nor will the facility name be made known. The patients will only be identified by a number on paper records that are taken from the study site and entered onto a computer. All data will be handled in the strictest confidence. Only the study personnel that have signed non-disclosure agreements might have access to the information and all information will be password protected.

Should you have questions or don't understand the study at some point, the Field Worker conducting the study will note this in his/her records of the visit to your site and report back to Sr. F.A. Bruwer who will attempt to answer your questions about the study and explain issues that you might not understand. You are also welcome to contact Sr. Bruwer on Telephone nr. (011) 822-8508. You may also withdraw from the study without prejudice and without reason at any point in time.

Thank you for your willingness to participate.

Regards

F. Bruwer

Appendix C: First draft of questionnaire

Questionnaire - Structure

1. Indicated what type of facility is being utilized (Chin et al., 2011:228)	
1. Clinic within a hospital	
2. Stand-alone clinic	
3. Home based care	
4. Mobile clinic	
5. Dr's rooms	
6. Clinic within a pharmacy	

2. Indicated accessibility of the facility (Chin et al., 2011:228)	Yes (1) No (2)
Has a physical address - can be found on a map	
Easy access	
Wheelchair access	
Clear signage within legal parameters	
Secure parking area	
Accessible to the community	

3. Indicate what Equipment is available in the facility (Chin et al., 2011:228)	Yes (1) No (2)
Blood pressure machine	
Hand held Doppler	
ABPI Machine	
Camera	
Visitrac/tracing material	
Weight scale	
Blood glucose monitor	

4. Indicated the level of education of staff attending to the patients (Chin et al., 2011:228)	
1. Registered Nurse	
2. Staff Nurse	
3. Medical Doctor	
4. Pharmacist	
5. Other - Specify	

5. Indicated the level of education of staff attending to the patients (Chin et al., 2011:228)	
1. RN with Master's degree	
2. RN with Accredited Wound Care Course	

3. RN

4. GP

5. Pharmacist with wound care cert

6. Other - Specify

6. How many years of wound care experience does the person in charge have? (Chin et al., 2011:228)

1. More than five (5)

2. Five (5) years

3. Three (3) to five (5) years

4. Less than three (3) years

5. None

7. How available is the care? (Chin et al., 2011:228)

1. Twenty-Four (24) hours per day

2. Only by appointment

3. Set clinic hours

4. Other

8. What Payment methods does the practice use? (Chin et al., 2011:228) Yes (1) No (2)

Cash only

Cash and Credit card	
Funders only	
Funders and WCA	
Other	

9. Does the practice make use of any type of Best practice guideline? (Chin et al., 2011:228)	Yes (1) No (2)
Specify if Yes (1)	

10. Which multidisciplinary team members are available at the facility? (Burrows et al., 2006:54)	Yes (1) No (2)
Surgeon	
Physician	
Occupational therapist	
Physio therapist	
Dietitian	
Other	

11. Does the practice have Standard Operating procedures in place? (Chin et al., 2011:229)	Yes (1) No (2)

If Yes (1) - Specify

12. Where are the standard operating procedures kept? (Chin et al., 2011:229)

1. Locked office
2. Open office
3. Clinical area
4. Off site
5. Other - Specify

13. Does the practice have access to advanced wound care products? (Burrows et al., 2006:54) Yes (1) No (2)

14. Does the practice have access to advanced wound care products? (Burrows et al., 2006:54) Yes (1) No (2)

15. Who performs the initial assessment on the patients? (Burrows et al., 2006:54)

1. Registered Nurse
2. Wound care Nurse
3. Pharmacist

4. GP

5. Other

16. Does the initial assessment include a physical examination? (Burrows et al., 2006:54)

Yes

No

Appendix D: Final questionnaire

F.A. Bruwer
2004190316
NVRT 7905

Questionnaire relating to Research Proposal; School of Nursing; Faculty Health Sciences, University of the Free State, South Africa

Version 4.2

A randomized, descriptive quantitative design study to evaluate venous leg ulcer care with regards to best practice guidelines within Wound Care practices in Gauteng

1		***Indicate what type of facility is being used:***	***YES***	***NO***	***Description (Where applicable)***
1.1		Wound Clinic (Private)	***YES***	***NO***	
1.2		Wound Clinic (Public Sector)	***YES***	***NO***	
1.3		GP Practice	***YES***	***NO***	
1.4		Pharmacy	***YES***	***NO***	
1.5		Home based care	***YES***	***NO***	
2		***Indicate how accessible the facility is:***			
2.1		Has Physical address	***YES***	***NO***	
2.2		Wheelchair Access	***YES***	***NO***	
2.3		Signage within legal parameters	***YES***	***NO***	
2.4		Secure Parking	***YES***	***NO***	
3		***Indicate what equipment is available at the facility***			
3.1		Blood Pressure Machine	***YES***	***NO***	
3.2		Hand held Doppler	***YES***	***NO***	
3.3		ABPI Machine	***YES***	***NO***	
3.4		Digital Camera	***YES***	***NO***	
3.5		Tracing Material	***YES***	***NO***	
3.6		Weight scale	***YES***	***NO***	
3.7		Blood glucose monitor	***YES***	***NO***	
3.8		HB meter	***YES***	***NO***	
3.9		Infrared thermometer	***YES***	***NO***	
3.10		Monofilament	***YES***	***NO***	
3.11		Height measurement	***YES***	***NO***	
4		***Indicate rank of person in charge of the facility***			
4.1		Registered Nurse	***YES***	***NO***	
4.2		Medical Doctor	***YES***	***NO***	

4.3		Pharmacist	***YES***	***NO***	
4.4		Other: Specify			
5		***Indicate level of education of person attending to patients***			
5.1		RN with accredited wound care certificate	***YES***	***NO***	
5.2		RN with master's degree	***YES***	***NO***	
5.3		Registered Nurse	***YES***	***NO***	
5.4		Medical Doctor	***YES***	***NO***	
5.5		Pharmacist	***YES***	***NO***	
5.6		Pharmacist with wound care training	***YES***	***NO***	
5.7		Other: Specify			
6		***Indicate how many years of clinical wound care experience the person attending to the patients has***			
6.1		Years			
6.2		None			
7		***Indicate if the practice makes use of a best practice guideline with regards to treatment of lower leg ulcers***			
7.1		If yes please specify	***YES***	***NO***	
7.1.1		Specify			
7.2		If no please indicate possible reason			
7.2.1		Reason			
8		***Indicate which specialist the facility refers to:***			
8.1		General Surgeon	***YES***	***NO***	
8.2		Physician	***YES***	***NO***	
8.3		Occupational Therapist	***YES***	***NO***	
8.4		Dietitian	***YES***	***NO***	
8.5		Podiatrist	***YES***	***NO***	
8.6		Advanced Wound care practitioners	***YES***	***NO***	
8.7		Vascular Surgeon	***YES***	***NO***	
8.8		Orthotist	***YES***	***NO***	
8.9		Physio Therapist	***YES***	***NO***	
9		***Indicate if the practice has Standard Operating Procedures with regards to lower leg ulcer treatment in place***			
9.1		SOP regarding assessment of patient with lower leg ulcers	***YES***	***NO***	
9.2		SOP regarding application of compression	***YES***	***NO***	
9.3		SOP regarding management of infection	***YES***	***NO***	
9.4		SOP regarding measurement of the ABPI	***YES***	***NO***	
9.5		SOP regarding referral protocol	***YES***	***NO***	
9.6		SOP regarding treatment of infection	***YES***	***NO***	

9.7		SOP regarding pain management	***YES***	***NO***	
9.8		SOP regarding wounds that have become stagnant	***YES***	***NO***	
10		***Indicate where the SOP's are kept***			
10.1		Locked office	***YES***	***NO***	
10.2		Open office	***YES***	***NO***	
10.3		Clinic area	***YES***	***NO***	
10.4		Off-site	***YES***	***NO***	
10.5		Other: Specify	***YES***	***NO***	
11		***Indicate what products are available in the clinic***			
11.1		**Debridement agents**:			
	11.1.1	Autolytic	***YES***	***NO***	
	11.1.2	Enzymatic	***YES***	***NO***	
	11.1.3	Biological	***YES***	***NO***	
	11.1.4	Conservative Sharp	***YES***	***NO***	
	11.1.5	Mechanical	***YES***	***NO***	
11.2		Foams	***YES***	***NO***	
11.3		Super absorber	***YES***	***NO***	
11.4		Antimicrobials	***YES***	***NO***	
	11.4.1	Silver	***YES***	***NO***	
	11.4.2	Iodine based	***YES***	***NO***	
	11.4.3	Hydrophobic	***YES***	***NO***	
	11.4.4	Honey	***YES***	***NO***	
	11.4.5	Other : Specify	***YES***	***NO***	
11.5		Alginate	***YES***	***NO***	
11.6		Hydrofibre	***YES***	***NO***	
11.7		Hydrocolloid	***YES***	***NO***	
11.8		Hydro capillary (Drawtex)	***YES***	***NO***	
11.9		Film dressings	***YES***	***NO***	
11.10		Protease modulators	***YES***	***NO***	
12.1		**Compression therapy**			
	12.1.1	Four-layer system	***YES***	***NO***	

	12.1.2	3-layer Systems	***YES***	***NO***	
	12.1.3	Long stretch bandages (Surepress®)	***YES***	***NO***	
	12.1.4	Short stretch cohesive	***YES***	***NO***	
	12.1.5	Short stretch non-cohesive	***YES***	***NO***	
	12.1.6	Zinc paste bandages	***YES***	***NO***	
	12.1.7	CREPE	***YES***	***NO***	
13.0		**If sharp debridement is done indicate if the person performing the sharp debridement has been trained**			
14.0		**Indicate what advanced modalities are available at the clinic**.			
	14.1.1	Topical negative pressure	***YES***	***NO***	
	14.1.2	Intermittent pneumatic compression	***YES***	***NO***	
	14.1.3	Other: Specify	***YES***	***NO***	

Appendix E: First draft of checklist

	File audit **Process and outcomes**				Official use
1	**Indicate the type of assessment tool being used with initial assessment**				
1.1	WHASA				
1.2	Own				
1.3	None				
1.4	Other, specify				
2.	Has the patient signed consent for treatment?	Yes	No		
3	**Indicate if the Assessment form contains information regarding factors that might influence wound healing**				
3.1	Age	Yes	No	Age in years	
3.2	Gender	M	F		
3.3	Family history of venous disease	Yes	No		
3.3	Smoking	Yes	No		
3.4	Body Mass Index	Yes	No		
3.5	Number of pregnancies (female patients only)				
3.6	Surgical history	Yes	No	List:	
3.7	Vein stripping	Yes	No		
3.8	Sclerotherapy	Yes	No		
3.9	Type of gait	Yes	No		
3.10	Muscle wasting of calf muscle	Yes	No		
3.11	Medication	Yes	No		
3.12	Nutrition	Yes	No		
3.13	Oedema	Yes	No		
4	**Indicate if the assessment form list Co-morbidities**				
4.1	Diabetes	Yes	No		
4.2	Cardio vascular disease	Yes	No		
4.3	Pulmonary diseases	Yes	No		
4.4	Previous DVT	Yes	No		
4.5	Varicose veins	Yes	No		
4.6	Anaemia	Yes	No		
5	Is a pain assessment done with the first consultation?	Yes	No	Name tool:	
6	**Is the Age of the wound**	Yes	No		
6.1	Please indicate period patient has had wound in months				
6.2	Recurrent wound	Yes	No		
6.3	Previous treatment	Yes	No		
6.4	Please indicate previous treatment				
7	**Has patient centred concerns with regards to proposed treatment been assessed?**				

7.1	Pain	Yes	No			
7.2	Odour	Yes	No			
7.3	Exudate level	Yes	No			
7.4	Social functioning	Yes	No			
7.5	General hygiene	Yes	No			
7.6	Cultural beliefs	Yes	No			
7.8	Religion	Yes	No			
7.9	Any fear or anxiety regarding treatment	Yes	No			
7.10	Financial issues	Yes	No			
	Other: Specify					
	Physical Assessment: Process					
8	Indicate if an ABPI was performed	Yes	No			
9	**Indicate what the value of the ABPI measurement was:**					
9.1	≥ 1.3	Yes	No			
9.2	> 9.0-1.3	Yes	No			
9.3	0.8 – 0.9	Yes	No			
9.4	0.6 - 0.8	Yes	No			
9.5	<0.5	Yes	No			
10	**If the patient's ABPI was below 0.5 was the patient referred to a vascular surgeon?**	Yes	No	N/A		
11	**Does the file indicate if both legs were assessed?**	Yes	No			
12	**Indicate what tool was used to assess chronic venous insufficiency**					
12.1	CEAP Classification	Yes	No			
12.2	Other: Specify	Yes	No			
12.3	Not done or indicated	Yes	No			
13	**If the CEAP classification was used a mentioned in question 13 was the following indicated?**					
13.1	CLINICAL:					
13.2	C0 No signs of venous disease	Yes	No			
13.3	C1 Telangiectasia's or reticular veins	Yes	No			
13.4	C2 Varicose veins	Yes	No			
13.5	C3 Presence of oedema	Yes	No			
13.6	C4a Eczema or pigmentation	Yes	No			
13.7	C4b Lipodermatosclerosis or atrophy blanche	Yes	No			
13.8	C5 Evidence of a healed VLU	Yes	No			
13.9	C6 Active VLU	Yes	No			
14	**Indicate how oedema was assessed:**					
14.1	Clinically	Yes	No			

14.2	Leg circumference measured	Yes	No			
14.3	Not done/indicated	Yes	No			
14.4	Differentiated between pitting and non-pitting oedema	Yes	No			
14.5	Stemmer sign indicated	Yes	No			
15	Does the file indicate from where the patient was referred?	Yes	No			
	If referred specify discipline of referring person					
	Wound assessment:					
16.	**Indicate what tool was used to do wound assessment:**					
16.1	WHASA	Yes	No			
16.2	TIME	Yes	No			
16.3	Colour assessment	Yes	No			
16.4	Other: Specify					
17.	**Indicate what was used to measure the size of the wound**					
17.1	Photo (Digital)	Yes	No			
17.2	Ruler	Yes	No			
17.3	Tracing	Yes	No			
17.4	Other: Specify					
18.	**Indicate if the Assessment tool assesses the wound according to: (TIME)**					
18.1	Tissue viability	Yes	No			
18.2	Infection	Yes	No			
18.3	Inflammation	Yes	No			
18.4	Moisture	Yes	No			
18.5	Edge	Yes	No			
19	**Indicate what method was used to diagnose superficial infection if present at assessment:**					
19.1	**NERDS:**	Yes	No			
19.2	Non-healing	Yes	No			
19.3	Erythema	Yes	No			
19.4	Red/Friable granulation	Yes	No			
19.5	Debris on the wound	Yes	No			
19.6	Smell	Yes	No			
20	**Indicate what method was used to diagnose deep infection if present at assessment:**					

20.1	**STONEEES**	Yes	No			
20.2	Size Bigger	Yes	No			
20.3	Increased Temperature	Yes	No			
20.4	Probe to bone (Os)	Yes	No			
20.5	New breakdown	Yes	No			
20.6	Exudate, erythema, oedema	Yes	No			
20.7	Smell	Yes	No			
21	**Was any other method used to diagnose infection?**					
21.3	Clinical judgement only	Yes	No			
21.4	Wound swab	Yes	No			
21.5	Other: Specify					
	Treatment options:					
22	**If during the wound assessment slough was present, what debridement method was indicated?**					
22.1	Sharp	Yes	No			
22.2	Autolytic	Yes	No			
22.3	Enzymatic	Yes	No			
22.4	Biological	Yes	No			
22.5	Other: Specify					
22.6	Has the patient consented for the debridement?	Yes	No			
23	**If infected: indicate what method of treatment was chosen?**					
23.1	Topical antimicrobial	Yes	No			
23.2	Systemic antibiotics	Yes	No			
23.3	Antiseptic cleansing	Yes	No			
23.4	Other: Specify					
24	**Indicate what cleansing solution was used**					
24.1	Normal saline	Yes	No			
24.2	Topical antiseptics	Yes	No			
24.3	Antimicrobials	Yes	No			
24.4	Tap water					
24.5	Other: Specify					
25	Was compression applied?	Yes	No			
26	Indicate what type of compression was applied					
26.1	Short stretch	Yes	No			
26.2	Long stretch 3-layer	Yes	No			
26.3	Long stretch 4-layer	Yes	No			
26.4	Zinc paste	Yes	No			
27	**Indicate if education was given regarding compression therapy**					
27.1	Reason for therapy	Yes	No			
27.2	Signs of increased pressure or complications	Yes	No			
27.3	Mobility	Yes	No			

28	**Indicate if education was given regarding holistic treatment (patient centred concerns)**					
28.1	Leg elevation	Yes	No			
28.2	Exercise	Yes	No			
28.3	Diet	Yes	No			
29	**Indicate if adjunctive therapy is being used**					
29.1	Topical Negative pressure	Yes	No			
29.2	Intermittent Pneumatic Compression	Yes	No			
29.3	Protease Modulator	Yes	No			
29.4	Skin replacement therapy	Yes	No			
29.5	None	Yes	No			
29.6	Other: Specify					
30.	**Indicate what pain management strategies are in place**					
30.1	Analgesic Rx as according to pain assessment	Yes	No			
30.2	Referral to GP for pain management	Yes	No			
30.3	None	Yes	No			
30.4	Other: Specify					
31.	Was a primary dressing applied?	Yes	No			
32.	**Indicate type of dressing used on first consultation**					
32.1	Foam	Yes	No			
32.2	Primary contact layer	Yes	No			
32.3	Absorbent dressing	Yes	No			
32.4	Hydrocolloid	Yes	No			
32.5	Antimicrobial	Yes	No			
32.6	Hydrogel	Yes	No			
33.	**Indicate what is used to treat the patient's skin at assessment**					
33.1	Moisturizer	Yes	No			
33.2	Emollient	Yes	No			
33.3	Zinc paste	Yes	No			
33.4	Zinc ointment	Yes	No			
33.5	Other: Specify					
34.	Was the patient followed up 24h after initial visit?	Yes	No			
	FOLLOW UP CARE: Outcomes					

35.	**Indicate if the following is noted on follow up visits at week 3 after initial consult**					
35.1	Reduction in Oedema	Yes	No			
35.2	Reduction in pain	Yes	No			
35.3	Reduction in wound size	Yes	No			
35.4	Advancing in wound edges					
35.5	Reduction in odour	Yes	No			
35.6	Reduction in exudate level	Yes	No			
35.7	Increase in activities of daily living	Yes	No			
35.8	Indicate if an improvement in the skin condition is noted	Yes	No			
36	Indicate if there was any incident of infection during the 3week treatment:	Yes	No			
37	If yes was answered in question 36 please indicate how the infection was assessed (either 38 or 39)					
38.0	**Indicate what method was used to diagnose superficial infection during first 3 weeks of treatment:**					
38.1	NERDS:	Yes	No			
38.2	Non-healing	Yes	No			
38.3	Erythema	Yes	No			
38.4	Red/Friable granulation	Yes	No			
38.5	Debris on the wound	Yes	No			
38.6	Smell	Yes	No			
39.0	**Indicate what method was used to diagnose deep infection during the first 3 weeks of treatment:**					
39.1	STONEEES	Yes	No			
39.2	Size Bigger	Yes	No			
39.3	Increased Temperature	Yes	No			
39.4	Probe to bone (Os)	Yes	No			
39.5	New breakdown	Yes	No			
39.6	Exudate, erythema, oedema	Yes	No			
39.7	Smell	Yes	No			
40.	**Indicate how superficial infection was treated**					
35.1	Topical antimicrobial					
35.2	Antiseptic solution irrigation					
35.3	Systemic antibiotics					
36.	**Indicate how deep infection was treated:**					
36.1	Topical antimicrobial					
36.2	Antiseptic solution irrigation					
36.3	Systemic antibiotics					
36.4	Other: Specify					

37.	**How soon after the infection incident was the patient followed up?**					
37.1	Within 24hours					
37.2	2-3 days					
37.3	3-5 days					
37.4	5-7 days					
38.	**What was the outcome of the incident**					
38.1	Infection resolved					
38.2	Wound deteriorated					
38.3	Wound progressed					
38.4	Other: Specify					
39.	**Indicate at what intervals the wound is re-assessed**					
39.1	With every consultation	Yes	No			
39.2	Weekly	Yes	No			
39.3	Every second week	Yes	No			
39.4	Every three weeks	Yes	No			
40	**Indicate the time it took for the wound to heal**					
40.1	10-12 Weeks	Yes	No			
40.2	12-24 Weeks	Yes	No			
40.3	More than 6 months	Yes	No			
40.4	Wound did not heal	Yes	No			
41.	**On completion of treatment was the patient measured for stockings?**	Yes	No			
42.	**If stockings could not be supplied was patient referred for stockings**?	Yes	No			

Appendix F: Final checklist

File audit- Process and Outcome

Official use

		Initial assessment		3 Week follow-up		Completion	
1	Indicate the type of assessment tool being used with initial assessment of the patient						
1.1	WHASA	Yes	No				
1.2	Own	Yes	No				
1.3	None	Yes	No				
1.4	Other, specify						
2	Has the patient signed consent for treatment?	Yes	No				
3	Does the file indicate where the patient was referred from?	Yes	No				
3.1	If referred specify discipline of referring person. (see coding)						
3.2	Was the patient referred during the first 3 weeks of treatment?	Yes	No				
3.3	If referred, please specify where? (To whom) (Discipline)						
3.4	Was the patient referred on completion of wound treatment					Yes	No
3.5	If referred on completion, please specify where? (To whom) (Discipline)						
4	Indicate if the assessment form contains the following information						
4.1	Family history of venous disease	Yes	No				
4.2	Gender (see coding)	Male	Female				

4.3	Body mass Index	Value		Value		Value	
4.3.1	Length in cm	cm		cm		cm	
4.3.2	Mass in kg	kg		kg		kg	
4.4	Number of pregnancies (female patients only)						
4.5	Vein stripping (History of)	Yes	No				

4	Indicate if the assessment form contains the following information CONTINUED…						
4.6	Sclerotherapy (History of)	Yes	No				
4.7	Type of gait	Normal	Abnormal				
4.8	Calf muscle functioning	Normal	Abnormal				
4.9	Previous DVT	Yes	No				
4.10	Varicose veins	Yes	No				
4.11	Is a pain assessment done with the first consultation?	Yes	No				
4.11.1	Name the tool used (see coding)	Name of tool:					
4.11.2	Indicate the pain score assessed						

5	**Indicate if the assessment form contains the following information**						
5.1	Age (In years)						

5.2	Smoking	Yes	No				
5.2.1	Cigarettes per day						
5.2.1.1	Type of Smoking (list) see coding list						
5.2.1.2	How many years have the patient been smoking?						
5.2.2	Has patient reduced smoking at week 3			Yes	No		
5.2.3	Has patient ceased smoking	Yes	No	Yes	No	Yes	No
5.3	Surgical history						
5.4	Medication						
5.4.1	Non-Steroid Anti Inflammatory (NSAID)	Yes	No	Yes	No	Yes	No
5.4.2	Cortico-steroids	Yes	No	Yes	No	Yes	No
5.4.3	Anti-Coagulant	Yes	No	Yes	No	Yes	No
5.4.4	Chemo therapeutic drugs	Yes	No	Yes	No	Yes	No
5.4.5	Exposure to radiation	Yes	No	Yes	No	Yes	No
5.5	Daily food intake noted	Yes	No	Yes	No	Yes	No
5.6	Has dietary issues been addressed by week 3			Yes	No	Yes	No

5	**Indicate if the assessment form contains the following information CONTINUED…**						
5.7	Indicate if the assessment form list Co-morbidities						
5.7.1	Diabetes	Yes	No				

5.7.2	Cardio Vascular disease	Yes	No				
5.7.3	Pulmonary diseases	Yes	No				
5.7.4	Anaemia	Yes	No				
5.7.4.1	Was HB done?	Yes	No				
5.7.4.2	What was the value	Value:--		Value:--		Value:--	
5.8	Age of the wound:						
5.8.1	Please indicate period patient has had wound in months						
5.8.2	Is it a recurrent wound?	Yes	No				
5.8.3	Indicate previous treatment (most recent)						
5.8.4	Duration of previous treatment (In weeks)						
5.8.5	Initial size of wound in Length & Width						
5.8.5.1	Length of wound:						
5.8.5.2	Width of wound:						
5.8.5.3	Depth of wound:						
5.8.6	Location of the wound						
5.9	Indicate if ABPI was performed	Yes	No	Yes	No	Yes	No
5.9.1	Indicate what the value of the ABPI was						
5.9.2	Indicate value measured in the Left leg						
5.9.3	Indicate value measured in the Right leg						
5.10	Does the file indicate if both legs were assessed?	Yes	No				
5.11	If the ABPI was <0.6 was the patient referred to a vascular surgeon?	Yes	No				

5.12	**Indicate if the wound was assessed according to:**						
5.12.1	Tissue viability	Yes	No	Yes	No	Yes	No
5.12.2	Infection	Yes	No	Yes	No	Yes	No
5.12.3	Inflammation	Yes	No	Yes	No	Yes	No
5.12.4	Moisture	Yes	No	Yes	No	Yes	No
5.12.5	Edge of the wound	Yes	No	Yes	No	Yes	No
5.12.6	Surrounding skin	Yes	No	Yes	No	Yes	No

6	**Physical Assessment: Process**						
6.1	**Has patient centred concerns with regards to treatment been assessed?**	**Initial assessment**		**3 Week follow-up**		**Completion**	
6.1.1	Pain	Yes	No	Yes	No	Yes	No
6.1.2	Malodour	Yes	No	Yes	No	Yes	No

6.1.3	Exudate level	Yes	No	Yes	No	Yes	No
6.1.4	Social functioning	Yes	No	Yes	No	Yes	No
6.1.5	General hygiene	Yes	No	Yes	No	Yes	No
6.1.6	Cultural beliefs	Yes	No	Yes	No	Yes	No
6.1.7	Religion	Yes	No	Yes	No	Yes	No
6.1.8	Any fear	Yes	No	Yes	No	Yes	No
6.1.8.1	If "Yes" specify type of fear						
6.1.9	Any anxiety regarding treatment	Yes	No	Yes	No	Yes	No
6.1.9.1	If "Yes" specify type of anxiety						
6.1.10	Financial issues	Yes	No	Yes	No	Yes	No

7	**Indicate what tool was used to assess chronic venous insufficiency**						
7.1	CEAP*Classification	Yes	No	Yes	No	Yes	No
7.2	Other: Specify						

8	If the CEAP classification was used as mentioned in question 7 was the following indicated?	Initial assessment		3 Week follow-up		Completion	
	Clinical classification						
8.1	C0 No Signs of venous disease	Yes	No				
8.2	C1a Telangiectasia	Yes	No				
8.2.1	C1b Reticular veins	Yes	No				
8.3	C2 Varicose veins	Yes	No				
8.4	C3 Presence of Oedema	Yes	No				
8.5	C4a Eczema	Yes	No				
8.5.1	C4b Pigmentation	Yes	No				
8.5.2	C4c Lipodermatosclerosis	Yes	No				
8.5.3	C4d Atrophie blanche	Yes	No				
8.6	C5 Evidence of a healed VLU	Yes	No				
8.7	C6 Active VLU	Yes	No				

9	Indicate how oedema was assessed	Initial assessment		3 Week follow-up		Completion	
9.1	Leg circumference measured	Yes	No	Yes	No	Yes	No
9.2	Stemmer sign indicated	Yes	No	Yes	No	Yes	No

	Wound Assessment						
10	**Indicate what tool was used to do wound assessment**						
10.1	WHASA	Yes	No				
10.2	Time	Yes	No				
10.3	Colour assessment	Yes	No				
10.4	Other: Specify						

11	**Indicate what tool was used to measure the size of the wound**	**Initial assessment**		**3 Week follow-up**		**Completion**	
11.1	Photo (Digital)	Yes	Yes	Yes	No	Yes	No
11.2	Ruler	Yes	Yes	Yes	No	Yes	No
11.3	Tracing	Yes	No	Yes	No	Yes	No
11.4	Other: Specify						

12	Indicate what method was used to diagnose superficial infection if present at assessment:						
	NERDS:	**Initial assessment**		**3 Week follow-up**		**Completion**	
12.1	Non-healing	Yes	No				
12.2	Exudate	Yes	No				
12.3	Red Friable granulation tissue	Yes	No				
12.4	Debris	Yes	No				
12.5	Smell (malodour)	Yes	No				

13	Indicate what method was used to diagnose deep infection if present at assessment:						
	STONEEES	**Initial assessment**		**3 Week follow-up**		**Completion**	
13.1	Size Bigger	Yes	No				
13.2	Increased Temperature: Peri-wound	Yes	No				
13.3	Probe to bone (Os)	Yes	No				
13.4	New breakdown	Yes	No				
13.5	Exudate	Yes	No				
13.6	Erythema, oedema(cellulitis)	Yes	No				
13.7	Smell(malodour)	Yes	No				

14	**Was any other method used to diagnose infection at Assessment?**	**Initial assessment**		**3 Week follow-up**		**Completion**	
14.1	Clinical judgement only	Yes	No				
14.2	Wound swab	Yes	No				
14.3	Other: Specify						

	Treatment Options:						
15	If during the wound assessment slough was present, what debridement method was indicated?	**Initial assessment**		**3 Week follow-up**		**Completion**	
15.1	Sharp	Yes	No				
15.2	Autolytic	Yes	No				
15.3	Enzymatic	Yes	No				
15.4	Biological	Yes	No				
15.5	Other: Specify						
15.6	Has the patient consented for the debridement?	Yes	No				

16	If the wound was infected: Indicated what method of treatment was chosen:	Initial assessment		3 Week follow-up		Completion	
16.1	Topical antimicrobial	Yes	No				
16.2	Topical antibiotic	Yes	No				
16.3	Systematic antibiotics	Yes	No				
16.4	Antiseptic cleansing	Yes	No				
16.5	Other: Specify						
16.6	Was compression discontinued when infection was diagnosed?	Yes	No	Yes	No		

17	Indicate what type of cleansing was used.	Initial assessment		3 Week follow-up		Completion	
17.1	Running water (shower head)	Yes	No	Yes	No		
17.2	Spray bottle	Yes	No	Yes	No		
17.3	Jet-ox	Yes	No	Yes	No		
17.4	Antimicrobial Wipes	Yes	No	Yes	No		
17.5	Indicate Type of cleansing solution used: Specify						

18	Was compression applied at assessment?	Initial assessment		3 Week follow-up		Completion	
		Yes	No	Yes	No	Yes	No

19	Indicate what type of compression was applied						
19.1	Short stretch	Yes	No	Yes	No	Yes	No
19.2	2 layers	Yes	No	Yes	No	Yes	No
19.3	3 layers	Yes	No	Yes	No	Yes	No

19.4	Multilayer (4 layers)	Yes	No	Yes	No	Yes	No
19.5	Zinc paste	Yes	No	Yes	No	Yes	No
19.6	African Bandage	Yes	No	Yes	No	Yes	No
19.7	Graduated Compression stockings	Yes	No	Yes	No	Yes	No

20	**Indicate if education was given regarding compression therapy**	**Initial assessment**		**3 Week follow-up**		**Completion**	
20.1	Reason for therapy	Yes	No	Yes	No	Yes	No
20.2	Signs of increased pressure	Yes	No	Yes	No	Yes	No
20.3	Complications	Yes	No	Yes	No	Yes	No
20.4	Mobility	Yes	No	Yes	No	Yes	No

21	**Indicate if education was given regarding holistic treatment (Patient centred concerns)**	**Initial assessment**		**3 Week follow-up**		**Completion**	
21.1	Leg elevation	Yes	No	Yes	No	Yes	No
21.2	Exercise	Yes	No	Yes	No	Yes	No
21.3	Diet	Yes	No	Yes	No	Yes	No
21.4	Risk factors	Yes	No	Yes	No	Yes	No

22	**Indicate if adjunctive therapy is being used**	**Initial assessment**		**3 Week follow-up**		**Completion**	
22.1	Topical Negative pressure	Yes	No	Yes	No	Yes	No
22.2	Intermittent Pneumatic Compression	Yes	No	Yes	No	Yes	No
22.3	Protease Modulator	Yes	No	Yes	No	Yes	No

22.4	Skin replacement therapy	Yes	No	Yes	No	Yes	No
22.5	None	Yes	No	Yes	No	Yes	No
22.6	Other: Specify						

23	**Indicate what pain management strategies are in place**	**Initial assessment**		**3 Week follow-up**		**Completion**	
23.1	Analgesic Rx as according to pain assessment	Yes	No	Yes	No	Yes	No
23.2	Referral to GP for pain management	Yes	No	Yes	No	Yes	No
23.3	None	Yes	No	Yes	No	Yes	No
23.4	Other: Specify						

24	Was a primary dressing applied at assessment?	Yes	No	Yes	No	Yes	No
25	**Indicate type of dressing used on first consultation**	**Initial assessment**		**3 Week follow-up**		**Completion**	
25.1	Foam: Specify	Yes	No				
25.1.1	Type of foam:						
25.2	Primary contact layer: Specify	Yes	No				
25.2.1	Type of contact layer						
25.3	Alginate	Yes	No				
25.4	Hydrofibre	Yes	No				
25.5	Hydrocolloid	Yes	No				
25.6	Antimicrobial	Yes	No				
25.7	Hydrogel	Yes	No				
25.8	Impregnated dressing	Yes	No				
25.9	No dressing	Yes	No				
25.10	Superabsorber	Yes	No				
25.11	Other: Specify						

26	**Indicate what is used to treat the patient's skin of the lower leg**	**Initial assessment**		**3 Week follow-up**		**Completion**	
26.1	Moisturizer	Yes	No	Yes	No	Yes	No
26.2	Emollient	Yes	No	Yes	No	Yes	No
26.3	Zinc ointment	Yes	No	Yes	No	Yes	No
26.4	50/50: liquid paraffin and soft paraffin	Yes	No	Yes	No	Yes	No
26.5	Other: Specify						

27	Was the patient followed up 24h after initial visit?			Yes	No		

Follow up Care: Outcomes

28	**Indicate if the following is noted on follow up visit if applicable.**	**Initial assessment**		**3 Week follow-up**		**Completion**	
28.1	Reduction in devitalized tissue			Yes	No	Yes	No
28.2	Reduction in Oedema			Yes	No	Yes	No
28.3	Reduction in pain			Yes	No	Yes	No
28.4	Reduction in wound size			Yes	No	Yes	No
28.5	Improvement in wound edges			Yes	No	Yes	No
28.6	Reduction in odour			Yes	No	Yes	No
28.7	Reduction in exudate level			Yes	No	Yes	No
28.8	Increase in activities of daily living			Yes	No	Yes	No
28.9	Indicate if an improvement in the skin condition is noted			Yes	No	Yes	No

29	Indicate if there was any incident of infection during the first 3 weeks of treatment			Yes	No		

30	**If yes was answered in question 29, please indicate how the infection was assessed (either question 31 or 32)**	

31	**Indicate what method was used to diagnose superficial infection during first 3 weeks of treatment. [NERDS]**	**Initial assessment**		**3 Week follow-up**		**Completion**		
31.1	Non-healing			Yes	No			
31.2	Exudate			Yes	No			
31.3	Red Friable Granulation Tissue			Yes	No			
31.4	Debris on the wound			Yes	No			
31.5	Smell (Malodour)			Yes	No			

32	**Indicate what method was used to diagnose deep infection during the first 3 weeks of treatment. [STONEEES]**	**Initial assessment**		**3 Week follow-up**		**Completion**		
32.1	Size bigger			Yes	No			
32.2	Increased Temperature of Peri wound			Yes	No			
32.3	Probe to bone (Os)			Yes	No			
32.4	New breakdown			Yes	No			
32.5	Exudate increase			Yes	No			
32.6	Erythema, oedema (Cellulitis)			Yes	No			
32.7	Smell (Malodour)			Yes	No			

33	**Indicate how superficial infection was treated**	**Initial assessment**	**3 Week follow-up**	**Completion**

33.1	Topical antimicrobial			Yes	No		
33.2	Antiseptic solution irrigation			Yes	No		
33.3	Systemic antibiotics			Yes	No		
33.4	Other: Specify						

34	**Indicate how deep infection was treated:**	**Initial assessment**		**3 Week follow-up**		**Completion**	
34.1	Topical antimicrobial			Yes	No		
34.2	Antiseptic solution irrigation			Yes	No		
34.3	Systemic antibiotics			Yes	No		
34.4	Other: Specify						

35	**How soon after the infection incident was the patient followed up?**	**Initial assessment**		**3 Week follow-up**		**Completion**	
35.1	Indicated time in days						

36	**What was the outcome of the incident**	**Initial assessment**		**3 Week follow-up**		**Completion**	
36.1	Infection resolved			Yes	No		
36.2	Wound deteriorated			Yes	No		
36.3	Wound progressed			Yes	No		
36.4	Other: Specify						

37	**Indicate at what intervals the wound is re-assessed**	**Initial assessment**		**3 Week follow-up**		**Completion**	
37.1	With every Consultation			Yes	No		
37.2	weekly			Yes	No		
37.3	Every second week			Yes	No		
37.4	Every three weeks			Yes	No		
38	Indicate the time it took for the wound to heal (in weeks)						
38.1	Wound did heal					Yes	No
38.2	If wound did not heal what action was taken?						

39	Was compression applied for two weeks after wound epithelization?					Yes	No

40	On completion of treatment was the patient measured for stockings?					Yes	No

41	If stockings could not be supplied was patient referred for stockings?					Yes	No

Appendix G: WHASA assessment form

WHASA PATIENT ASSESSMENT FORM

PATIENT DATA

Surname: | Title:
Full Names: | Initials:
Date of Birth: | ID Nr.: | Sex: Male Female
Address: Residential | Postal | Same as Residential
Tel. Nr. (H): | Tel. Nr. (W): | Cell Phone Nr.:
E-mail: | Patient type:
Medical Aid: | Option: | Membership Nr.:
Main Member: | ID Nr.:
Referal Doctor: | Tel. Nr.: | Practice Nr:

MEDICAL & SURGICAL HISTORY

Diabetes: | Circulation Problems: | Spinal Problems:

Stroke	Asthma	Smoking	Swollen Glands
Varicose Veins	COPD	Alcoholism	Deep Vein Thrombosis
Gangrene	Bronchitis	Porphyria	Alternative Treatments
Artherosclerosis	Parkinsons	Allergy	Previous Amputations
Hypertension	Altzheimers	Anaemia	Bowel Problems
Heart Failure	Quadriplegia	Cancer	Renal Problems
Pace Maker	Paraplegia	Chemotherapy	Immune Deficiency
Emphysema	Hep B	Radiotherapy	_____

PHYSICAL ASSESSMENT

Vital Data: Temperature: °C | Respiratory: /min | Length: cm
Blood Pressure: / mmHg | Blood glucose: | Mass: kg
Pulse Rate: /min | Cholesterol: | BMI:

Status:

Nutritional Status	Mental Status	Functional Status
Obesity	Orientated	
Malnutrition	Depressed	
Dehydration	Anxious	
Weight Loss >5kg	Comatose/Unconscious	
Weight Gain >5kg	Stressed	
Loss of Appetite	_____	
Supplements		
_____		

MEDICATION

- [ ] Anti-inflammatory
- [ ] Cortisone
- [ ] Antibiotic
- [ ] Anti-coagulant
- [ ] Other

LOWER EXTREMITIES

ABPI:	(L)		(R)	
Oedema Circumference:	(L)		(R)	
Foot Temperature:	(L)		(R)	
Capillary refill:	(L)		(R)	

Palpable Pulses:
- [ ] Dorsalis Pedis
- [ ] Posterior Tibial
- [ ] Popliteal

Pulse quality:

PAIN ASSESSMENT

- ○ 0 NO HURT
- ○ 1 HURTS A LITTLE BIT
- ○ 2 HURTS A LITTLE MORE
- ○ 3 HURTS EVEN MORE
- ○ 4 HURTS A WHOLE LOT
- ○ 5 HURTS WORST

LABORATORY TESTS

Albumin:		O_2 Saturation:		HCT:	
Hb:		CRP:		WBL:	
Wound Swab:					

DIAGNOSIS

Prior Wound Treatment:

Type of Wound:
- (•) Chronic Ulcer
- ( ) Mechanical Injury
- ( ) Burn Wound

Wound Bed:
Exudate:
Odour:
Wound Edges:
Exudate Colour:

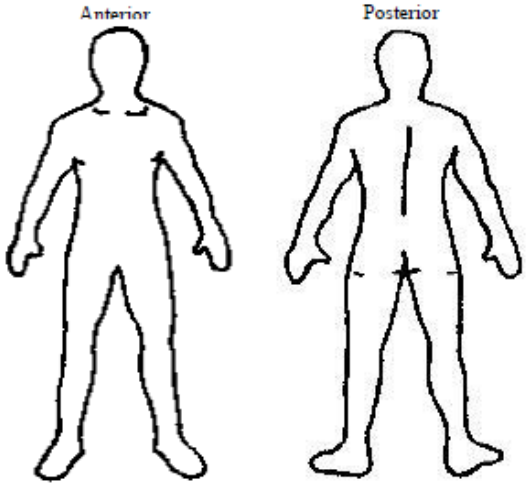
Wound Size: Length: mm Width: mm Depth: mm

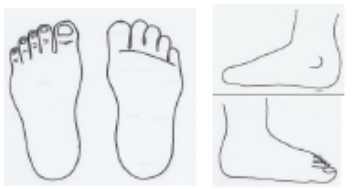
Wound appeared on:
Wound present for:

Wound Infection:
- [ ] Pus
- [ ] Cellulites
- [ ] Increased pain
- [ ] Change in exudate
- [ ] Surrounding skin feels hot
- [ ] Surrounding skin is red
- [ ] Unhealthy tissue
- [ ] Delayed wound healing
- [ ] Spontaneous Bleeding
- [ ] Increased Exudate Levels
- [ ] New Satellite Wounds
- [ ] Delicate granulation tissue

ICD10 Code:

Wound Location:




Left

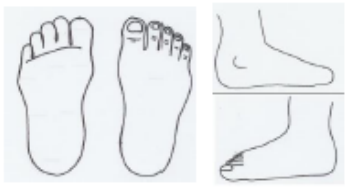

Right

Photo Report:

TREATMENT PLAN

Debridement: Autolytic

Moisture Control:

Infection: ☐ Antimicrobial ☐ Antibiotics

MEDICAL TEAM INVOLVED

☐ Wound Care Nurse	☐ Podiatrist	☐ Psychiatrist	☐ _____
☐ Vascular Surgeon	☐ Orthotist	☐ Dermatologist	☐ _____
☐ Dietician	☐ Specialist Surgeon	☐ Radiologist	☐ _____

Appendix H: WHASA wound assessment

REPORT NR:		DATE OF REPORT:	
ATTENTION:		CONTACT DETAILS:	

PATIENT DETAILS		
NAME:	ID: AGE:	REFERING DR.: PRACTICE NO*.:*
ICD10 CODE:	MEDICAL DIAGNOSIS:	MEDICAL AID: MEDICAL AID NR:

WOUND ASSESSMENT DETAILS				
T ***(Tissue viability)***	***I*** ***(inflammation or infection)***	***M*** ***(Moisture balance)***	***E*** ***(Edge/ surrounding skin)***	***MEASUREMENT*** ***(Length, width, depth)***

HISTORY

FACTORS INFLUENCING WOUND HEALING

PAIN MEASUREMENT									
1	2	3	4	5	6	7	8	9	10
No pain = 0 Excruciating pain = 10									

TREATMENT PLAN	
DEBRIDEMENT:	
INFECTION OR INFLAMMATION CONTROL:	
MOISTURE BALANCE/EXUDATE MANAGEMENT:	
EDGE/SURROUNDING SKIN:	
ADJUNCTIVE THERAPY:	
DRESSING CHANGE FREQUENCE:	

Appendix I: Annexure received from Department of Health

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Annexure 1
Declaration of intent from the clinic manager or hospital CEO

I give preliminary permission (name of researcher) to do his or her

research on _____
(research topic) in

_____ (name of clinic) or

_____ (name of CHC) or

_____ (name of hospital).

I know that the final approval will be from the Tshwane/Metsweding Regional Research Ethics Committee and that this is only to indicate that the clinic/hospital is willing to assist.

Other comments or conditions prescribed by the clinic or CHC manager or hospital CEO:

_____
Signature
Clinic Manager/CHC Manager/CEO

_____
Date

Appendix J: Informed consent

MAIN ICF. Version 3. July 2016

PARTICIPANT INFORMATION AND INFORMED CONSENT FORM
F.A. BRUWER

Name of Principal Investigator: Sr. F.A. Bruwer
Name of Organization: Nianwi Health Care
Name of Sponsor: No Sponsor
Protocol Nr. HSREC 146/2016
Protocol Title: A Survey of venous ulcer care in wound care practices in Gauteng.

Dear Colleague

This is an invitation to take part in a research study. Before you decide whether to take part, it is imperative that you understand why the research study is being performed and what it might involve. Please read the following information carefully. Please ask if anything is unclear or if you would like more information. Please take time to decide whether you wish to take part. Thank you for reading this or having it read to you.

1. **WHAT IS THE AIM OF THE STUDY?**
   The aim is to explore and describe the quality of lower leg venous ulcer care according to the Donabedian model within Wound Care practices in Gauteng.
2. **DURATION OF THE STUDY?**
   Data collection will take approximately 60 (sixty) minutes by the Field Worker who will be performing a structured interview while completing a checklist as well as patient file audits using a checklist.
3. **WHY HAVE YOU BEEN CHOSEN?**
   You and your facility have been randomly chosen to take part in this study as you and your facility fit the inclusion criteria identified for the study. A maximum of 41 centres will take part in the study.
4. **DO YOU HAVE TO TAKE PART AND YOUR RIGHTS AS PARTICIPANT?**
   The choice to take part or not is entirely up to you and your facility. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without having to give a reason.
5. **WHAT DO I HAVE TO DO?**
   After you have given your Informed Consent, you need to allow the assigned Field Worker to conduct a structured interview, completing a questionnaire as well as to allow him/her access to randomly selected patient files of patients

that presented or presents with lower leg ulcers of venous origin and that fall into the inclusion criteria, the files will need to be depersonalized.

6. **WILL YOUR TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**
   If you consent to take part in the study, the appointed fieldworker may inspect any of your patient's that presents with venous lower leg ulcers, medical records for purposes of analysing the results. Those patient's medical records may also be viewed by regulatory authorities or auditors to check that the study is being carried out correctly. Those patient's names however, will NOT be disclosed outside the study site nor will the facility name be made known. The patients will only be identified by a number and initials on paper records that are taken from the study site and entered onto a computer. All data will be handled in the strictest confidence. Only the study personnel that have signed non-disclosure agreements might have access to the information and all information will be password protected.
7. **WHAT HAPPENS TO RESULTS OF THE RESEARCH STUDY?**
   The data from this study will be analysed by Sr. F.A. Bruwer or a data analysis company duly authorised thereto and appointed by Sr. F.A. Bruwer. A report will be produced, and the results may be published in medical journals or presented at conferences or meetings.
8. **IF YOU HAVE MORE QUESTIONS OR DO NOT UNDERSTAND SOME POINTS?**
   The Field Worker will note this in her records of the visit to your site and report back to Sr. F.A. Bruwer who will attempt to answer your questions about the study and explain issues that you might not understand. Sr Bruwer can be contacted on the number indicated under point no. 12 of this document.
9. **WHAT HAPPENS IF YOU DECIDE TO TAKE PART?**
   You will be asked to sign the Consent Form. You will be given a copy of this Participant Information Sheet and Informed Consent Form to keep. Once you have consented to participate, a fieldworker will set up an appointment at a convenient time for you. You will also be asked to sign a consent form giving consent to the fieldworker to access patient files as according to the protocol. The interview will last approximately 60min and will be scheduled at a time convenient for you. Once the interview is completed, the fieldworker will then ask you to randomly choose patient files of patients that present with venous lower leg ulcers, for a file audit. The file audit will then be completed by the fieldworker. As soon as data has been collected, you will be required to sign a "completion form" which the fieldworker must return to Sr. F.A. Bruwer.
10. **WHAT HAPPENS IF YOU CHANGE YOUR MIND DURING THE RESEARCH?**
    You may withdraw from the study at any time without giving a reason and without fear of prejudice. No information collected will be used in the study once you have withdrawn. The researcher will also not have access to any identifying information regarding which clinics or facilities have withdrawn as facilities are only identified by numbers.

11. WHO HAS REVIEWED THE STUDY?

The study will be forwarded to the Health Sciences Ethics Committee (UFS).

12. WHO CAN YOU CONTACT FOR FURTHER INFORMATION?

Should you have questions about this trial, you may discuss them with Sr. F.A. Bruwer on telephone number 083-368-8568 or 011-822-8508.

CONSENT STATEMENT

By signing below, I herewith agree that:

PARTICIPANT IDENTIFICATION NUMBER FOR THIS TRIAL:

NR.	***DESCRIPTION***	✓
1.	I confirm that I have been informed by the Field Worker about the nature, conduct, benefits, and risks of this clinical trial and that I have read and understood the above information about the study and have had the opportunity to ask questions.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.	
3.	I understand that sections of any of patient's medical notes may be viewed by the researcher, Sr. F.A. Bruwer or responsible individuals appointed by her, local Ethics committees as well as auditors from Independent Regulatory Bodies where it is relevant to my taking part in research.	
4.	I give permission for the depersonalised use of my patient's data by Sr. F.A. Bruwer for the purposes of the study and for this data to be used outside of South Africa.	
5.	I agree to take part and comply with the requirements of the above study.	

_____	_____	_____
PARTICIPANT/FACILITY	***DATE***	***SIGNATURE***
_____	_____	_____
RESEARCHER	***DATE***	***SIGNATURE***
_____	_____	_____
PERSON TAKING IC IF NOT RESEARCHER	***DATE***	***SIGNATURE***

Appendix K(a): Instructions on how to utilize questionnaire

METHODS – Questionnaire

1. After having obtained a signed Access to facility and after having completed the Informed Consent with the participant, proceed to complete the Questionnaire.
2. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, the type of facility being used.
3. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, how accessible the facility is.
4. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what equipment is available at the facility.
5. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what the rank as indicated, is of the person in charge of the facility.
6. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what the level of education, as indicated, is of the person attending to patients at the facility.
7. On the Questionnaire, indicate in numbers how many years of clinical wound care experience the person attending to patients at the facility has.
8. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what the level of education, as indicated, is of the person attending to patients at the facility has.
9. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if the practice makes use of a best practice guideline with regards to treatment of lower leg ulcers.
    a. If the participant answered YES, please specify which guidelines are followed.
    b. If the participant answered NO, please indicate a possible reason and record same in appropriate space provided.
10. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what specialty, as indicated, the facility refers their patients to.
11. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if, as indicated, the practice has standard operating procedures in place, with regards to lower leg ulcer treatment at the facility.
12. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if, as indicated, the practice has standard operating procedures in place, with regards to lower leg ulcer treatment at the facility and where the S.O.P.’s are kept.
13. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if, as indicated, what products the practice has available at the facility.

14. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if the person performing sharp debridement, as indicated, has been trained.
15. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if, as indicated, what products the practice has available at the facility.
16. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, what type of advanced modalities, as indicated, are available at the facility.
17. Conclude the Questionnaire portion of the interview and move on to the File Audit as arranged.

Appendix K(b): Instructions on how to utilize File Audit check list

METHODS – File audit check list

1. On the Questionnaire, indicate the type of assessment tool being used with initial assessment of the patient:
   1.1 Specify the appropriate tool with a YES or NO as indicated.

2. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if the patient has signed consent for treatment?

3. On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative, if the file indicates where the patient was referred from?
   3.1 Specify the discipline of the referring person by using the Codes as per the coding list provided.
   3.2 On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative if the patient was referred during the first 3 weeks of treatment?
   3.3 Specify the discipline of the person referred to by using the Codes as per the coding list provided.
   3.4 On the Questionnaire, indicate with a tick in the appropriate column YES for positive or NO for negative if the patient was referred on completion of treatment?
   3.5 Specify the discipline of the person referred to by using the Codes as per the coding list provided.

4. On the Questionnaire indicate if the Assessment form contains the following information by ticking YES for positive or NO for negative:
   4.1 Family history of venous disease
   4.2 On the Questionnaire indicate the patient's gender by ticking the appropriate tick box indicating male or female.
   4.3 On the Questionnaire, indicate the patient's BMI by inserting the recorded number in the space provided
      4.3.1 On the Questionnaire, indicate the patient's length in centimetres by inserting the recorded number in the space provided
      4.3.2 On the Questionnaire, indicate the patient's weight in centimetres by inserting the recorded number in the space provided
   4.4 On the Questionnaire, indicate the number of pregnancies for female patients by inserting the recorded number in the space provided
   4.5 On the Questionnaire, indicate if the patient has a history of vein stripping by a tick in the appropriate column YES for positive or NO for negative
   4.6 On the Questionnaire, indicate if the patient has a history of sclerotherapy by a tick in the appropriate column YES for positive or NO for negative.
   4.7 On the Questionnaire, indicate the patient' type of gait by ticking the appropriate space indicating NORMAL or ABNORMAL in the space provided
   4.8 On the Questionnaire, indicate the patient's calf muscle functioning by ticking the appropriate space indicating NORMAL or ABNORMAL in the space provided
   4.9 On the Questionnaire, indicate if the patient has a history of previous DVT by a tick in the appropriate column YES for positive or NO for negative.
   4.10 On the Questionnaire, indicate if the patient has a history of varicose veins by a tick in the appropriate column YES for positive or NO for negative.
   4.11 On the Questionnaire, indicate if a pain assessment Is done with the first consultation by a tick in the appropriate column YES for positive or NO for negative.

4.11.1 Specify the name of the tool used to assess pain.

4.11.2 Indicate the pain score assessed by entering a value in the space provided.

5. On the Questionnaire indicate if the Assessment form contains the following information by ticking YES for positive or NO for negative or entering a value in the appropriate space.

5.1 Indicate the patient's age in years entering a value in the space provided.

5.2 On the Questionnaire, indicate if the patient has a history of smoking with a tick in the appropriate column YES for positive or NO for negative.

5.2.1 Indicate the quantity of cigarettes smoked by entering a value in the space provided

5.2.1.1 Indicate the type of smoking i.e. cigarettes

5.2.1.2 Indicate the amount of years patient has been smoking

5.2.2 to 5.2.3 On the Questionnaire, answer the questions by making a tick in the appropriate column YES for positive or NO for negative

5.3 to 5.6 On the Questionnaire, answer the questions by making a tick in the appropriate column YES for positive or NO for negative

5.7.1 to 5.7.4.1 On the Questionnaire, answer the questions by making a tick in the appropriate column YES for positive or NO for negative

5.7.4.2 Indicate the value of the HB by entering a value in the space provided.

5.8.1 On the questionnaire, indicate the age of the wound in months by entering a value in the space provided

5.8.2 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative

5.8.3 On the Questionnaire, indicate previous treatment, listing most recent by describing treatment in the space provided

5.8.4 On the Questionnaire, indicate previous treatment duration in weeks by entering a value in the space provided

5.8.51 – 5.8.5.3 On the Questionnaire, indicate initial size of wound in length, width, depth by entering a value in the space provided

5.8.6 On the Questionnaire, indicate the location of the wound by entering a comment in the space provided

5.9 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative

5.9.1 On the Questionnaire, indicate the value of the ABPI by entering a comment in the space provided

5.9.2 – 5.9.3 On the Questionnaire, indicate the ABPI values measured in both legs by entering a value in the space provided

5.10 to 5.11 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

5.12.1 -6.1.7 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

6.1.8 On the Questionnaire, indicate the type of fear by entering a comment in the space provided

6.1.9 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

6.1.9.1 On the Questionnaire, indicate the type of anxiety by entering a comment in the space provided

6.1.10 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

6.1.10.1 On the Questionnaire, indicate the type of financial issue by entering a comment as per the listed codes in the space provided

7. On the Questionnaire, indicate the what tool was used to assess chronic venous insufficiency by making a tick in the appropriate column YES for positive or NO for negative.

7.1 On the Questionnaire, indicate if the CEAP classification was used to assess chronic venous insufficiency by making a tick in the appropriate column YES for positive or NO for negative.

7.2 On the Questionnaire, indicate if other classifications were used to assess chronic venous insufficiency by recording a comment in the appropriate space.

8.1 to 9.2 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

10.1 to 10.3 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

10.4 On the Questionnaire, indicate if other tools were used to do wound assessment by recording a comment in the appropriate space.

11.1 to 11.3 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

11.4 On the Questionnaire, indicate if other tools were used to measure the size of the wound by recording a comment in the appropriate space

12.1 to 12.5 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

13.1 to 13.7 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

14.1 to 14.2 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative

14.3 On the Questionnaire, indicate if any other method were used to diagnose infection at Assessment. by recording a comment in the appropriate space.

15.1 to15.4 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

15.5 On the Questionnaire, indicate if during the wound assessment slough was present, what other debridement method was used by recording a comment in the appropriate space.

15. 6 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

16.1 to16.4 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

16.5 On the Questionnaire, indicate that, if the wound was infected, what other method of treatment was chosen by recording a comment in the appropriate space.

16.6 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

17.1 to 17.4 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

17.5 On the Questionnaire, indicate what other cleansing solution was used by recording the comment according to the coding list in the appropriate space.

18. to 22.5 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

22.6 On the Questionnaire, indicate what other adjunctive therapy was being used by recording the comment in the appropriate space.

23.1 to 23.3 On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

23.4	On the Questionnaire, indicate what other pain management strategies are in place by recording the comment in the appropriate space.
24.	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
25.1	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
25.1.1	On the Questionnaire, indicate what type of foam dressing was used by recording the comment in the appropriate space.
25.2	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
25.2.1	On the Questionnaire, indicate what other primary contact layer was used by recording the comment in the appropriate space.
25.3 to 25.11	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
26.1 to 26.5	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
27.	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
28.1 to 28.9	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
29.	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
30.	On the Questionnaire, indicate how the infection was assessed by recording the comment in the appropriate space.
31.1 to 31.5	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
32.1 to 32.7	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
33.1 to 33.3	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
33.4	On the Questionnaire, indicate how the superficial infection was assessed by recording the comment in the appropriate space
34.1 to 34.3	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
34.4	On the Questionnaire, indicate how the deep infection was assessed by recording the comment in the appropriate space
35.1	On the Questionnaire, indicate how soon after the infection incident was the patient followed up by recording the comment in the appropriate space
36.1 to 36.3	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
36.4	On the Questionnaire, indicate what the other outcome of the incidents were by recording the comment in the appropriate space
37.1 to 37.4	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.
38.	On the Questionnaire, indicate the time it took for the wound to heal in weeks by recording the comment in the appropriate space
38.1	On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

38.2 On the Questionnaire, indicate if wound did not heal, what action was taken by recording the comment in the appropriate space

39. On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

40. On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

41. On the Questionnaire, answer the question by making a tick in the appropriate column YES for positive or NO for negative.

Appendix L: Access to Facility form

CONSENT TO GAIN ACCESS TO FACILITY
F.A. BRUWER

Name of Principal Investigator: Sr. F.A. Bruwer
Name of Organization: Nianwi Health Care
Name of Sponsor: No Sponsor
Protocol Nr. HSREC 146/2016
Protocol Title: A survey of venous ulcer care in wound care practices in Gauteng.

Dear Colleague
I am herewith requesting permission to enter the following facility

_____

For the purpose of data collecting for the abovementioned study

1. **WHAT IS THE AIM OF THE STUDY?**
   The aim is to explore and describe the quality of lower leg venous ulcer care according to the Donabedian model within Wound Care practices in Gauteng.
2. **DURATION OF THE STUDY**

   Data collection will take approximately 60 (sixty) minutes by the Field Worker who will be conducting a structured interview using a questionnaire and checklists to perform file audits. The file audit will be done after the interview. The interview will be conducted with the person in charge of the facility and during a time that is convenient for both the person in charge and the facility, i.e. during lunch. A light lunch will be provided to the participants.

3. **WHY HAVE YOU BEEN CHOSEN**
   The abovementioned facility has been asked to take part in this study as it fits the inclusion criteria identified for the study. A maximum of 48 facilities will take part in the study.

4. **WILL YOUR TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**
   If you consent to the assigned fieldworkers' access to the facility, the facilities details however, will not be disclosed outside the study site. Your patients as well as the facility, will only be identified by a number and initials on paper records that are taken from the study site and entered onto a computer. All data will be handled in the strictest confidence.

5. **WHAT HAPPENS TO RESULTS OF THE RESEARCH STUDY**
   The data from this study will be analysed by a biostatistician of the University of the Free State or a data analysis company duly authorised thereto and

appointed by Sr. F.A. Bruwer. A report will be produced, and the results may be published in medical journals or presented at conferences or meetings.

6. **IF YOU HAVE MORE QUESTIONS OR DO NOT UNDERSTAND SOME POINTS?**
   Please contact Sr. F.A. Bruwer on 0118228508, who will attempt to answer your questions about the study and explain issues that you might not understand.

7. **WHO HAS REVIEWED THE STUDY**
   The study will be forwarded to the Health Sciences Ethics Committee (UFS).

CONSENT STATEMENT

By signing below, I herewith agree that:

Facility IDENTIFICATION NUMBER FOR THIS TRIAL:		
NR.	***DESCRIPTION***	✓
1.	I, in my capacity as manager or person in charge of the abovementioned facility, give consent that the assigned fieldworker may gain access to the aforementioned facility for the purpose of data gathering for the abovementioned study.	

_____ _____ _____

Manager/Person in charge ***DATE*** ***SIGNATURE***

_____ _____ _____

FIELDWORKER ***DATE*** ***SIGNATURE***