

**The Management and Experience of Pain  
Associated  
With Chronic Painful Leg Ulceration**

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The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

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## **Acknowledgements**

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## **Abstract**

**Aim:** To explore the experience and management of pain associated with chronic leg ulceration in older people. Two studies were designed, to address patient and professional perspectives.

### **Study 1**

**Method:** A qualitative study using grounded theory methodology, which explored the experience of pain from leg ulcers.

**Results:** Eleven patients aged 65 years and over described their pain as chronic, producing negative consequences such as depression and insomnia, in part due to inadequate pain management. A three phase theory was developed to illustrate patients' leg ulcer journey. In phase 1, leg ulcer pain has predominantly acute nociceptive properties. If this is not managed effectively, or ulcers do not heal, or they recur, the patient may develop chronic pain with both nociceptive and neuropathic properties (phase 2). If this pain is not managed effectively, patients may develop refractory chronic neuropathic pain (phase 3).

### **Study 2**

**Method:** A feasibility study which surveyed the knowledge and views of a sample of community nurses in the North of England. Data were collected using a postal questionnaire.

**Results:** 115 (32%) completed questionnaires were returned. The majority of respondents were female (n=102, 91.8%). Over one-third of the nurses had received no pain management training. Approximately half reported not assessing pain appropriately. A significant majority indicated they were using preconceived ideas rather than patient pain report as a basis for pain management decisions.

**Overall conclusion:** The results suggested that older patients had painful leg ulceration which produced negative consequences and they were not receiving appropriate pain management. Nurses had limited understanding of the nature, assessment and management of leg ulcer pain, particularly its neuropathic elements. The emphasis on healing appeared to impede effective pain management. Only when healthcare professionals understand and acknowledge the nature of the pain in this patient group, can the pain be managed effectively.

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## Abbreviations

ABPI.....	Ankle/Brachial Pressure Index
ADR.....	Adverse Reactions
BPI.....	Brief Pain Inventory
CA.....	College of Anaesthetists
CAM.....	Complimentary and Alternative Medicine
CAS.....	Coloured Analogue Scale
CNS.....	Central Nervous System
DoH.....	Department of Health
EMLA.....	Eutectic Mixture of Local Anaesthetic
HADS.....	Hospital Anxiety and Depression Scale
GP.....	General Practitioner
GPM.....	Geriatric Pain Measure
GRPD.....	General Practice Research Database
LANSS.....	Leeds Assessment for Neuropathic Symptoms and Signs
LTP.....	Long Term Potentiation
MPI.....	Multidimensional Pain Inventory
MPI-PS.....	Pain Severity Subscale of the Multidimensional Pain Inventory
MPQ.....	McGill Pain Questionnaire
NHS.....	National Health Service
NICE.....	National Institute of Health and Clinical Excellence
NMC.....	Nursing and Midwifery Council
NSAIDs.....	Non Steroidal Anti-inflammatory Drugs
PABA.....	Para-aminobenzoic Acid
PAQ.....	Pain Attitudes Questionnaire
PCT.....	Primary Care Trust
PDI.....	Pain Disability Index
PHN.....	Post Hepatic Neuralgia
PMI.....	Pain Management Index
RCN.....	Royal College of Nursing
RCS.....	Royal College of Surgeons
RCTs.....	Randomised Controlled Trials
SF-MPQ.....	Short Form McGill Pain Questionnaire
S-LANSS.....	Self Report Leeds Assessment for Neuropathic Symptoms and Signs
TENS.....	Transcutaneous Electrical Nervous Stimulation
UK.....	United Kingdom
US.....	United States
VAS.....	Visual Analogue Score
VRS.....	Verbal Rating Scale
WHO.....	World Health Organization
X <sup>2</sup> .....	Chi-Square

## **Chapter 1**

### **1.1 Introduction to the Project, Setting the Scene.**

This chapter explains the context and approach I applied to the research undertaken. This is relevant to the project because as researchers we cannot separate ourselves from what we know. Nor can we separate ourselves from who we are and how we understand the world in which we find ourselves (Cohen & Crabtree, 2008). My previous experiences and how I interpret the world and understand phenomena were a determinant in how the research was undertaken and what conclusions were developed as a consequence of the research. The impact of my possible bias has been explored and how this may have directed the studies and the conclusions made.

Previous to undertaking this PhD I undertook a master's degree course with the faculty of medicine and biological sciences at Leicester University. It was during this course I developed an interest in older people and pain. This was an excellent course which focused on pain management and allowed me to gain a master's degree in pain management. The focus of the research within this master's course was entirely quantitative; therefore my initial research experience was quantitative. I was taught using a medical model where quantitative research was a priority. My topic of research for the dissertation was on the pain attitudes and knowledge of nurses working with older people. My findings from this work suggested that the nurses had attitudes that may be counter-productive for effective pain management practices. It also highlighted to me the varied and complex problems associated with managing pain for older people. This encouraged me to develop an interest in older peoples' pain and in promoting effective and appropriate pain management for this patient group. I was keen to develop further research in this area. Therefore, I applied for and was successful in obtaining a full PhD scholarship at Leeds University to undertake research in patients with pain associated with chronic leg ulceration. I was aware that leg ulceration affected predominantly older people and as a pain specialist I was aware of the gap in pain management expertise within the community. Within the UK the focus of pain management initially had been developed within the acute trusts and had focused particularly on post operative pain management. This had been as a consequence to a report entitled "Pain after Surgery", published by the

Royal college of Surgeons and College of Anaesthetists (1990). So for several reasons the possibility of being able to undertake a PhD investigating patients with leg ulceration was appealing. It allowed me to further investigate pain experience in older people and also allowed me to move into the community field. The scholarship once offered required me to undertake research investigating pain associated with chronic leg ulceration. This was following on from Dr Briggs work which also concerned investigating pain associated with leg ulceration. Whilst the general topic of study was predetermined, I had freedom in deciding which aspect relating to pain and chronic leg ulceration I was going to research. Following the literature review I was keen to undertake a qualitative study, as there was limited research specifically investigating the pain experience of chronic leg ulceration in the older age group. This was a particular challenge for me as I was very much a quantitative researcher. I also found it particularly difficult because the contrast between qualitative methods, thoughts and processes are great when compared with quantitative methods, thoughts and processes. It was very difficult to remove myself from the quantitative "mind set". However, during the process of undertaking the study I developed a great respect and understanding of qualitative methods.

Whilst undertaking the qualitative study I was aware that I may influence the findings because of my pain management background. Perhaps because I was a pain specialist I may start to make assumptions and see things that were not actually there. However, I constantly questioned my findings and using the grounded theory method I was able to check and re-check my findings in a cyclical manner using the constant comparative method. Furthermore, whilst I had a lot of experience in managing pain in older people I had no experience in managing pain of leg ulceration. This is probably because most leg ulcer management is undertaken within the community and not within the acute care trusts. I had spent the majority of my career as an acute pain management specialist, working within the acute hospital sector. The focus of this role was on the management of acute post-operative pain.

Acute pain may be defined as an expected consequence of tissue injury; it is usually self limiting and is relatively easy to treat. Acute pain is defined by the British Pain Society (BPS) as a short-term pain of less than twelve weeks duration (BPS, 2008). Acute pain is sharp, immediate pain usually from an injury to the tissue although it can also be caused by physiological malfunction or illness. Acute pain has an obvious cause and its purpose is to warn of injury and/or damage (Nagy & Rice, 2003). Post-surgical pain is predominantly associated with acute wound pain; it has

an obvious cause and normally decreases with healing. Therefore, it has a defined trajectory. I had some experience of managing wound pain and its associated pain mechanisms which are described within the literature review (refer to Chapter 2). However, I had not viewed the pain associated with leg ulceration as a chronic problem whilst working as a pain nurse specialist. I thought that leg ulcers could be painful, but this could be managed using simple analgesics. I did not connect leg ulcer pain with chronic pain physiology and outcomes.

Chronic pain is continuous, long term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery (BPS, 2008). Chronic pain is defined by the International Association of the Study of Pain (IASP, 2007) and the American Geriatric Society (AGS, 2002) as a pain that has a multidimensional phenomenon characterized by unpleasant sensory and emotional experiences. Chronic pain is a state in which pain persists beyond the usual course of an injury or acute disease, and is associated with actual or potential tissue damage that continues for a prolonged period and that may or may not be associated with a recognizable disease process (AGS, 2002; Gordon *et al.* 2005; IASP, 2007). Sometimes associated with chronic pain is neuropathic pain. Neuropathic pain is initiated or caused by a primary lesion or dysfunction in the peripheral or central nervous system. An example of neuropathic pain would be pain caused by shingles, or an amputation or spinal cord trauma. Neuropathic pain can be associated with acute nociceptive pain. However, neuropathic pain is also likely to last longer than acute nociceptive pain because it is more difficult to treat and is associated with conditions that have a longer time scale and/or that are chronic (Attal *et al.* 2006; Dworkin, Backonja & Rowbotham, 2003; Finnerup, Otto & McQuay, 2005). Examples of these conditions include shingles, diabetes, and central pain associated with stroke and multiple sclerosis'. Therefore, neuropathic pain is most likely to be associated with chronic conditions and chronic pain (McDermott *et al.* 2006).

At the beginning of this research I was not aware of the severity and the impact of pain associated with chronic leg ulceration. Certainly during my initial nurse training and clinical work experience I had not been made aware of the disabling impact of painful leg ulceration. The sense of leg ulceration as an extremely painful condition was not apparent, either during initial nurse training or any time whilst working as a pain specialist. Interestingly not once whilst working as a pain specialist for over 6 years in London and the North of England, had I been called upon to either manage

someone with a painful leg ulcer, or assist with developing in house protocol to manage pain associated with leg ulceration.

When considering my perspective and my previous experiences regarding pain, particularly in relation to working as a pain specialist, it was inevitable that I would have biases. We all have bias related to our previous experiences which we may not be able to remove, but we can be aware of. Although I was a pain specialist and a healthcare worker, I was not a specialist in the field of wound care in the community. Thus, it can be stated that I entered the field of research as a hybrid researcher. The hybrid researcher undertakes research in the practice area of other practitioners and is familiar with that research area (Reed & Proctor, 1995). Jootun and McGhee (2009) described a hybrid researcher as a researcher in familiar territory who may have inherent biases and assumptions. However, they also state that the researcher's previous experiences may provide insight about the patients experiences which may not always be evident to the outsider. An outsider is a researcher with no professional experience and is essentially a visitor to the area of study (Reed & Proctor, 1995). This is pertinent to the study because it may be that my bias or my knowledge regarding pain allowed me to understand the pain experience being described to me by the patients. It can be suggested that if I had been a wound specialist, for example, I may not have acknowledged the pain description as a chronic pain condition. Thus, to assume bias as a negative component of research is not always accurate, particularly in relation to qualitative research.

However, whilst my experiences may have provided some insights, these could also threaten the validity of the findings. This is because I may have assumed premature conclusions which may have led to misinterpretation. However, I was aware of this and ensured a process of memoing and reflexivity which allowed opportunity for me to question any assumptions that I may have made. Reflexivity is largely associated with qualitative research and refers to the extent of influence that the researcher exerts, either intentionally or unintentionally, on the findings (Fontana, 2004). Hertz (1997) suggested that reflexivity creates a shift in our understanding of data; it can be achieved through detachment, internal dialogue and constant scrutiny of "what I know" and "how I know it". This can be achieved through collecting and transcribing interviews which is said to help raise awareness of the subtle ways in which the data can be affected. It also may help reveal area of data that require more exploration in subsequent data collection, particularly if the finding fell out of initial assumptions.

The qualitative method used for the first study was the grounded theory method. The process of grounded theory requires the use of methods that enhance validity and truthfulness. These are memoing and the constant comparative method (going back and forth between the data and the field of research to further verify suppositions and referring to relevant literature to further enhance the validity of the findings) (Strauss & Corbin, 1998). These methods are discussed further in the methods section of study one (refer to Chapter 3, section 3.4).

The process of undertaking the PhD and this particular research topic has given me a whole new perspective on wound pain, particularly pain associated with chronic wounds. On commencement of the project I viewed the pain associated with leg ulceration as an acute pain problem. However, it became apparent following the process of the research that this was not the case. The extent of the pain and the suffering that the patients with pain associated with leg ulceration experience was a new phenomenon to me. I found this intriguing because it had not been expected. It also gave me new understanding and an interest in chronic pain and the negative impact it can have on an individual. This has further developed my interest and desire to research pain, particularly concerning chronic disease and its management within the community.

## Chapter 2

### Literature Review: Pain Experience and Management Associated with Chronic Leg Ulceration in People 65 Years and Over.

#### **2.1 Background**

Leg ulceration represents a significant healthcare problem for patients and healthcare services and is more likely to occur in people 65 years and over (Nelzen, Bergqvist & Lindhagen, 1996). The majority of patients with leg ulceration are cared for in the community, by community nursing teams (Dowsett, 2005). It has been suggested that community nurses spend up to half their time caring for patients with leg ulceration (Lees & Lambert, 1992; Moffatt *et al.* 1992; Simon *et al.* 1996; Ruckley, 1997). The cost to the NHS of this care were estimated at being £250-400m a year, with much of this being spent on nursing time (Bosanquet, 1992; Simon, Francis & McCollum, 2004). The cost per patient to the NHS were estimated at being between 814-1994 Euros, in a study that compared costs in Sweden and the UK (Tennvall & Hjelmgren, 2005). To date, the emphasis of work undertaken on the topic of leg ulceration has mainly concentrated on healing rather than symptom control. The topic of pain as a symptom associated with chronic leg ulcers has been identified as a problem being reported by participants as part of qualitative studies investigating living with leg ulceration (Douglas, 2001; Husband, 2001a, 2001b; Ebbeskog & Ekman, 2001; Wissing & Unosson, 2002; Edwards, 2003; Hopkins, 2004; Nemeth *et al.* 2004). Additionally chronic pain is a problem that many elderly persons suffer. It is often poorly managed and the effect on the individual can be profound (Ferrell & Ferrell, 1992; Gagliese & Melzack, 1997; Gagliese & Melzack, 2003).

The elderly often receive inadequate pain relief for several reasons. These include ignorance of recommended guidelines for pain control or concern among healthcare professionals about prescribing appropriate analgesics (Gloth, 1996; Bernabei, Gambassi & Lapane, 1998).

It is known that in the Western world the elderly population is growing. Although the UK population grew by 8% in the last 30 years, from 55.9 million in 1971 to 60.2 million in mid-2005, this change has not occurred evenly across all age groups. Over the period of mid-1971 to mid-2005 the population of persons 65 years and over increased from 13% to 16%. Within the group aged 65 years and over, the percentage of people aged

85 years and over increased from 7% in mid-1971 to 12% in mid-2005. The number of people aged 85 years and over grew by 64,000 (6%) in the year 2005 to reach a record 1.2 million. Population ageing is projected to continue during the first half of this century, since the proportion of the population aged 65 years and over will increase (Office for National Statistics, 2006). Leg ulceration predominantly affects people 65 years and over and the population of this age group is growing.

There are factors that affect the pain experience of the elderly person with leg ulcers. Therefore, the literature review has included physiology and psychology of pain and pharmacology and pharmacokinetics of analgesics in older people. Understanding of pain and its management in older people, has informed further understanding of pain and its management associated with leg ulceration in older people. Evidence of neuropathic and nociceptive pain in leg ulceration has been reviewed, as well as evidence of its management.

### **2.1.1 Literature review strategy**

A computerized literature search was carried out using Full text Journal@Ovid, Medline (1950-2010), Embase (1980-2010), CINAHL (1982-2010), British Nursing Index (1985-2010), Amed (1985-2010), PsycINFO (1985-2010), EBM Reviews (1985-2010). These data bases were selected on the basis that they would contain the majority of the published research that had been peer reviewed. Comprehensive searches were undertaken to ensure that all relevant literature was accessed. Search terms were used alone and in combination. The searches were run initially in Medline and then further searches were carried out within the other databases. Search terms were adjusted and adapted as necessary using key terms identified from relevant papers. Publications from any country that had been written in English were eligible for inclusion. Selected clinical practice guidelines such as the RCN guidelines (RCN, 1998; RCN, 2006) for the management of patients with venous leg ulcers were also accessed. Reference chaining was used by searching for cited references, where appropriate, for their relevance to the literature review section. Selected text books and web sites were included in the search for current reviews and evidence pertaining to the literature review section. A table of each Medline search strategy has been provided at the beginning of each section.

### **2.2 Aetiology of leg ulceration**

A leg ulcer has been defined as a defect or break in the skin as a result of the presence of an underlying medical or physiological disorder (Roe *et al.* 1993). Most

lower limb ulcers are due to venous disease and arterial insufficiency alone or in combination (Phillips, 1999b).

**Medline search strategy for aetiology of leg ulceration**

#1 MeSH descriptor Leg ulcer explode et [Etiology]	3115
#2 (varicose ulcer* or venous ulcer* or leg ulcer* or arterial ulcer*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	10606
#3 MeSH descriptor Aged explode all trees/ or Aged "80 and over" explode all trees	1930672
#4 (#1 AND #3)	1073
#5 (#2 AND #3)	3690
#6 MeSH descriptor Wound healing explode/ co, dt, ge, pd, ph [Complications, Drug Therapy, Genetics, Pharmacology, Physiology]	17868
#7 (#1 AND #6)	76
#8 (#1 AND #3 AND #6)	34
#9 MeSH descriptor Integumentary system explode all trees	183996
#10 (#3 AND #9)	18816
#11 (#6 AND #10)	744
#12 (#1 AND #11)	82

The most commonly occurring type of leg ulcer in the older population is of venous origin. Approximately 65%–80% of ulcers in the older person will be of venous origin (Nelzen, Bergqvist & Lindhagen, 1994; Nelzen *et al.* 1996; O'Brien *et al.* 2000; Oien *et al.* 2000; Graham *et al.* 2003).

Chronic venous disease occurs whenever there is a malfunction of one of the components of the venous system. As a result of this malfunction, venous obstruction, valvular incompetence and calf muscle pump malfunction can occur (Fahey, 2003). Calf muscle failure can occur alone or alongside valvular incompetence and obstruction. Venous pooling and hypertension occurs if the pump is not working effectively due to its inability to create enough force to eject blood from the leg. In older people muscle wasting or disuse is another risk factor as this can also prevent blood from being effectively pumped back towards the heart (Rudolph, 2001). Venous hypertension is ultimately responsible for the symptoms of chronic venous insufficiency and venous ulceration. Venous ulceration is clearly associated with increasing age (Simon, Francis & McCollum, 2004) due to immobility and other chronic disease states. Sustained venous hypertension results in oedema in the affected limb. This in turn increases the distance that metabolites must diffuse from the microcirculation to tissue cells, causing the tissues around the ankle to become ischemic (Herrick *et al.* 1992). These changes result in chronic venous insufficiency that manifest as aching, heavy legs, itching, lipodermatosclerosis<sup>1</sup>, pigmentation, swelling, eczema and ultimately ulceration. Venous leg ulcers occur typically between the malleolus and the lower third

<sup>1</sup> Lipodermatosclerosis refers to a collective of symptoms; initially the oedema is pitting, but later becomes non-pitting. The skin surface becomes thinned or atrophic, with a loss of follicles and sweat glands Rudolph, D. 2001. Standards of care for venous leg ulcers: Compression therapy and moist wound healing. *Journal of Vascular Nursing* 19:20-7.

of the calf (Phillips, 1999b; Reichenberg & Davis, 2005). This location has been termed the "gaiter area", referring to a region on the boots of British Soldiers (Reichenberg & Davis, 2005).

Arterial disease accounts for another 5-10% of chronic leg ulceration. Arterial ulcers occur because of poor blood supply to the legs where there is a block in a leg artery or narrowing of the arteries by atherosclerosis (Nelson & Bradley, 2007). The most common cause is atherosclerotic disease of the medium and large sized arteries. Other causes include diabetes, thromboangitis, vasculitis, pyoderma gangrenosum, thalassaemia and sickle cell disease. Reductions in arterial blood supply result in tissue hypoxia and tissue damage.

Thrombotic and atheroembolic episodes may contribute to tissue damage and ulcer formation (Grey, Harding & Enoch, 2006). Arterial ulcers occur typically over the toes, heels and bony prominences of the foot (Phillips, 1999b; Grey, Harding & Enoch, 2006).

Although ulcers are often defined as venous or arterial there is some disagreement with this. It is believed by some that the reality is more complex since additional causes exist and that about one third of ulcers have a mixed or multifactorial background (Nelzen, Bergqvist & Lindhagen, 1991; Baker *et al.* 1992; Mekkes *et al.* 2003). Cornwall, Dore and Lewis (1986) suggested that mixed arterial and venous insufficiency are common in ulcerated legs and in a study undertaken by Nelzen *et al.* (1991), it was found that 26% of legs with venous ulcers had a detectable arterial impairment (Cornwall, 1986; Nelzen *et al.* 1991).

### 2.3 Chronicity of leg ulceration in older people.

Leg ulcers become chronic because they do not heal. Furthermore, poor healing rates and recurrence are more likely in the older adult. Prevalence rates have been shown to be greater amongst older adults and this prevalence increases with increasing age. To determine the likelihood of leg ulceration becoming a chronic condition in older adults, this section of the thesis addresses the literature regarding ageing skin, prevalence, poor healing rates and recurrence of leg ulcers in older people.

#### Medline search strategy for chronicity of leg ulceration

#1 MeSH descriptor Leg ulcer explode all trees	14667
#2 MeSH descriptor Prevalence explode all trees	139687
#3 (varicose ulcer*) or (venous ulcer*) or (leg ulcer*) or (arterial ulcer*). ab, kw, ti.	6067
#4 (#1 AND #2 AND #3)	91
#5 MeSH descriptor Integumentary System Physiology Phenomena explode all trees/ or Integumentary System explode all trees	215935

#6 MeSH descriptor wound healing explode/ an, ch, co, de, ge, um, ph [analysis, complications, drug effects, genetics, immunology, physiology]	26910
#7 (#1 AND #5 AND #6)	85
#8 MeSH descriptor Aged explode all trees/ Aged 80 and over explode all trees	1930672
#9 (#1 AND #2 AND #3 AND #8)	268
#12 MeSH descriptor Chronic Disease explode/ cl, di, ep, et, ph [Classification, Complications, Diagnosis, Epidemiology, Etiology, Physiology]	3464
#13 (#1 AND #12)	1
#14 (#3 AND #12)	2

### 2.3.1 Changes in the skin with ageing

As a person ages changes occur in the skin that impact the individual's ability to heal. Most of the changes occur in the dermis which thins by approximately 20%, leading to altered sensation, thermoregulation, rigidity and moisture retention (Uitto, Fazio & Olsen, 1989; Kaminer & Gilchrest, 1994; Miller, 2009). Factors such as an altered early inflammatory response and reduced levels of tissue inhibitors, during acute tissue repair, predispose older people to poor healing outcomes and development of chronic wounds (Phillips, 1999a). The observed changes in skin that occur with aging are complicated by the effects of sun exposure. Since the effects of sun exposure are cumulative, older persons show more changes in skin structure (Porth & Somer, 2010). Furthermore, immune responsiveness is compromised in elderly skin which can contribute to a higher incidence of infections (Lavker, 1979). In summary changes in ageing skin increase the risk of recurrence of leg ulceration and poor healing rates associated with leg ulceration.

### 2.3.2 Prevalence of leg ulceration in older adults

A higher prevalence of leg ulceration in older people compared with younger people has been reported in the literature. Graham *et al.* (2003) and Briggs and Closs (2003) undertook prevalence reviews and reported increasing prevalence rates with increasing age. Graham *et al.* (2003) undertook a review of prevalence studies in which they identified 22 reports of prevalence studies. Eight of these studies were clinically validated and reported prevalence rates of open ulcers ranging from 0.12% to 1.1% of the population. Their review also included studies without clinical validation and of these seven population based studies, rates of open ulcers ranged from 0.12%-0.32%. The authors commented that prevalence rates identified within some of the studies might not have been valid and that few of the studies used rigorous ascertainment methods. Clear definitions of leg ulceration were not given, and clinical assessment was not carried out. They concluded it was not possible to undertake a formal meta-analysis.

Briggs and Closs (2003) in their review came to similar conclusion to Graham *et al.* (2003), reporting the prevalence of patients with open leg ulcers receiving treatment from healthcare professionals at 0.11%-0.18%. Their review focused on the two definitions of prevalence and stratified the prevalence by these definitions. Point prevalence rates were shown as being between 0.11%-0.2%. Briggs and Closs (2003) commented that only 10-20% of patients who suffer leg ulceration will have an open ulcer at a single time point. Therefore, prevalence was shown as being higher (between 0.63%-1.9%) when estimating the prevalence of patients who suffer chronic leg ulceration, but do not necessarily have an open ulcer at the time of the data collection.

The two reviews resulted in similar conclusions: prevalence studies are useful and provide us with information with regard to the absolute burden of leg ulceration on individuals, healthcare organisations and society. However, completed studies have varied in their methodologies. Thus, it was difficult to ascertain precisely true prevalence rates.

To further support the premise that leg ulceration is more prevalent in older people, Nelzen *et al.* (1996) investigated people who were in the older age groups. Using a validated questionnaire they surveyed 12,000 randomly selected people, aged 50-89 years, in two defined regions of Sweden. Three hundred and six subjects reported open ulcers; the observed point prevalence rate of open leg ulcers was 0.63% of the total population. The overall prevalence of leg ulcer history (open plus healed) in the population was estimated to be around 2%. This study showed much higher prevalence rates than previously reported. This was probably due to differences in methodologies. This study included patients not being cared for by healthcare professionals and only included people between 50 years and 89 years.

In another study investigating leg ulcer epidemiology and aetiology in a regional health district in the UK with a population of 198900,357 age was shown to be the most important risk factor, with chronic venous hypertension being seven times more prevalent in persons aged 60 years and over compared with 20-year-old age group (Cornwall, Dore & Lewis, 1986). The study also showed that with each successive decade there was a progressive increase in patients with active leg ulcers both in absolute terms and relative to the population in that decade. Other studies have repeated this finding. Margolis *et al.* (2002) undertook a study that calculated prevalence rates amongst a cohort of people aged 65 years and over. They carried out

a retrospective cohort study in the UK. The population aged 65 to 95 years in the GPRD included more than 1 million persons. The data for the study were collected between 1988 and 1996, and constituted a 10% random sample of the full General Practice Research Database (GPRD) elderly population. They reported a prevalence rate of 1.69%, with occurrence being more frequent in women than in men. The prevalence rates reported in their study were lower than those of other studies, probably because they included only people with venous leg ulcers. This study also took retrospective data from a GPRD data base which may not have captured all patients with chronic leg ulceration. In a study undertaken by Moffatt, Franks and Doherty (2004) lower prevalence rates were reported: 45 per 100,000 population. However, they included only patients who were known to healthcare professionals and who had an open leg ulcer for 4 weeks or more ( $n=113$ ). However, this study did demonstrate prevalence rates which were highly age dependent, prevalence was shown to increase dramatically in the age group 85 years and over, with a prevalence rate of 8.29 per 1,000 in men and 8.06 per 1,000 in women.

The differences in prevalence rates reported by various research groups were due to differences in methodologies used. However, it was clear from the prevalence studies that leg ulceration was and is likely to continue to be a significant problem amongst older people in the community. . .

### **2.3.3 Healing rates and incidence of recurrence of leg ulceration in older adults.**

Despite the treatment available healing rates as low as 22% at 12 weeks and recurrence rates of up to 69% at 12 months have been reported (Monk & Sarkany, 1982; Wright *et al.* 1991; Moffatt *et al.* 1992). Nelzen, Bergqvist and Lindhagen (1994) have estimated that over 40% of patients will continue to have an open ulcer for over a year. In a study carried out by Callam *et al.* (1987) 600 patients with venous ulcers were investigated, as part of a population-based study. Roughly one half of the patients had a history of leg ulcers going back at least 10 years. Twenty percent ( $n=120$ ) of the ulcers were still open after 2 years despite extensive treatment and 8% ( $n=48$ ) of patients had the ulcers after 5 years. The typical patient was found to have had three episodes of ulceration over 9 years, with the most recent ulcer lasting for at least 9 months. Others have repeated this finding suggesting that leg ulcers have an average duration of at least 10 months. However, with many patients it was not unusual for them to last for years, even decades (Laible, Mayer & Evers, 2002). An Australian study reported that the recurrence rate in a sub group of patients with

venous ulcers was 76% (Baker *et al.* 1991). Callam (1992) and Cornwall, Dore and Lewis (1986) found that ulcer duration was similar in England and Scotland, showing that one half of the ulcers were present for over a year. Nelzen, Bergqvist and Lindhagen (1997) carried out a study to investigate the long-term prognosis for patients with chronic leg ulcers of varying aetiology. Long-term follow up was made at 54 months on a cohort of 382 patients with open leg ulceration. Patients with venous ulcers had the worst long term prognosis with only 44% remaining healed after nearly 5 years. Higher healing rates and non-recurrence rates were reported in the arterial group with 59% being healed with no recurrence and 69% from the other aetiology group (Nelzen, Bergqvist & Lindhagen, 1997). However, these results may be misleading as patients with arterial aetiology underwent active intervention with vascular reconstruction being performed in over one third of the patients who were assessed in follow up. Further, patients with venous aetiology had lower mortality rates. Only one third of patients with arterial aetiology survived up to the 54-month follow up point. The authors stated that patients with mixed aetiology and arterial aetiology had worse healing rates.

Good healing rates have been shown in other studies investigating healing in venous ulceration. However, these studies did not collect long-term data on recurrence rates. Thus, it may be that venous leg ulcers are more likely to heal because of the treatment techniques available, but the likelihood of them returning is great. In a study undertaken by Barwell *et al.* (2001), 587 patients with medically diagnosed venous leg ulcers were included. The aim of the study was to identify independent risk factors for delayed healing and increased recurrence of chronic venous leg ulcers. All patients were treated with four layer bandaging. The cumulative healing rate for these ulcers was 68% at 24 weeks. The cumulative recurrence rate was 65% ( $n=385$ ) at 3 years. The authors reported that elderly patients in their study were at greater risk of delayed healing and recurrence.

It can be concluded from the available evidence that leg ulceration is likely to be a chronic condition for older persons. As a result of skin changes associated with ageing, older people are at greater risk of leg ulceration, recurrence and poor healing outcomes. Leg ulcers with arterial or mixed aetiology are difficult to heal, leg ulcers of venous aetiology have better healing outcomes but recurrence rates are high.

## 2.4 Report of pain associated with leg ulceration.

Until recently, it would appear that researchers and clinicians have underestimated the pain associated with leg ulceration. Indeed, it has been portrayed as merely an uncomfortable problem hardly worthy of comment or attention (Porter, 1979; Bennett *et al.* 1985; Cornwall, Dore & Lewis, 1986; Buxton, 1987; Vallencia, Falabella & Kirsner, 2001). In a paper published in the Journal of Academic Dermatology in 2001, chronic venous insufficiency and venous leg ulceration management it was said that venous ulcers are: "viewed by many as a minor inconvenience on the basis they are usually not painful and infrequently lead to amputation" (Vallencia, Falabella & Kirsner, 2001, p.216). This is in stark contrast to the reports of pain given by patients living with leg ulceration in various qualitative studies. Briggs and Flemming (2007) in their qualitative research synthesis of living with leg ulceration found that pain was a regularly described symptom.

### Medline search strategy for report of pain associated with leg ulceration

#1 MeSH descriptor Leg Ulcer explode all trees	14667
#2 MeSH descriptor Pain explode all trees/ cl, di, et, mo, nu, pa, pc, rh, su, th [Classification, Diagnosis, Drug Therapy, Epidemiology, Etiology, Mortality, Nursing, Pathology, Prevention & Control, Rehabilitation, Surgery, Therapy]	217282
#3 (#1 AND #2)	282
#4 (varicose ulcer* or venous ulcer* or leg ulcer* or arterial ulcer*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	10606
#5 (#2 AND #4)	289
#6 MeSH descriptor Nervous System explode all trees/ or Neurons explode all trees	3567842
#7 (#4 AND #6)	2993
#8 (#2 AND #7)	83
#9 MeSH descriptor Pain Measurement explode/ is, mt, nu, px, st, sn, td [Instrumentation, Methods, Nursing, Psychology, Standards, Statistics & Numerical Data, Trends]	8963
#10 (#1 AND #4 AND #9)	7
#11 MeSH descriptor Wound Healing explode/ an, co, de, dt, ph [Analysis, Complications, Drug Effects, Drug Therapy, Physiology]	26157
#12 (#9 AND #11)	12
#13 MeSH descriptor Integumentary system explode all trees	183973
#14 (#2 AND #11 AND #13)	8
#15 MeSH descriptor Inflammation explode/ et, pa, ph, th [Etiology, Pathology, Physiology, Therapy]	54438
#16 (#11 AND #15)	280
#17 (#2 AND #16)	5
#18 (#1 AND #15)	103
#19 (dressing* or compression or gauze or hydrocolloid* or adherent or non-adherent or hydrogel* or alginate*).ab,kw,ti.	103129
#20 (#9 AND #19)	101
#21 (#1 AND #4)	14928
#22 (#20 AND #21)	3
#23 MeSH descriptor Women explode all trees/ or Nursing methodology research explode all trees/ or Adaptation, Psychological explode all trees/ or Questionnaires explode all trees	322254
#24 (#1 AND #23)	212
#25 lived experience.mp.	975
#26 (#25 AND #24)	6
#27 (#1 AND #4 AND #23)	3480
#28 (#9 AND 27)	173

#### **2.4.1 Evidence of pain associated with chronic leg ulceration.**

Pain as a symptom associated with chronic leg ulcers has been identified as a problem being reported by participants of qualitative and quantitative studies investigating living with a leg ulcer. Briggs and Flemming (2007), in their qualitative research synthesis, demonstrated that pain was found to be a regularly described symptom. In studies investigating the prevalence of pain in this patient population, at least three quarters of participants reported moderate to severe pain (Phillips *et al.* 1994; Chase *et al.* 2000; Wissing & Unosson, 2002; Nemeth *et al.* 2004; Hareendran *et al.* 2005; Heinen *et al.* 2007; Briggs *et al.* 2007; Park, Ferreira & Santos, 2008; Price *et al.* 2008). It is of no surprise that patients report pain associated with their leg ulceration. As a consequence to tissue damage noxious stimuli can be expected (see Appendix 1, Pain terms and physiology). Furthermore, wounds become chronic because they do not follow the normal wound healing trajectory associated with acute wounds. Chronic wounds remain in the inflammatory phase for too long (Snyder, 2005). The inflammation stage is the second stage of wound healing which presents with erythema, swelling, warmth and often pain.

An international study that investigated dressing related pain in patients with chronic wounds, found that pain was a symptom associated with chronic wounds (Price *et al.* 2008). Price *et al.* (2008) collected data from 15 different countries from 2,018 patients who were 69 years of age, on average. Participants with venous or arterial ulcers described greater pain intensity. Furthermore, patients with venous ulcers were more likely to describe pain in the surrounding skin as well as from the wound itself. This may suggest hyperalgesia associated with inflammation (see Appendix 1, Pain terms and physiology). Hyperalgesia is a likely occurrence associated with chronic leg ulceration because of the inflammatory response associated with the leg ulceration physiology. Tissue injury is generally followed by an inflammatory response; hyperalgesia is a component of that response. There is a biological role associated with this, in that it encourages the individual to immobilize and protect the injured tissue from further trauma (Nagy & Rice, 2003).

Briggs *et al.* (2007) undertook a prospective, longitudinal cohort study investigating pain in patients with leg ulceration. They monitored and recorded pain scores in 96 participants with leg ulceration over a 6-month period. Their findings demonstrated that neither patient characteristics nor leg ulcer characteristics such as ulcer type, size nor duration, could be used to determine pain intensity. This finding was supported by Hareendran *et al.* (2005), Heinen *et al.* (2007) and Park, Ferreira and Santos, (2008). Hareendran *et al.* (2005) using qualitative and quantitative methods, investigated the impact of venous leg ulcers on quality of life. They reported that

ulcer duration and size did not correlate with pain, although they did not use a validated pain intensity scoring tool. Rather, they took the pain report from the interviews; therefore, their report was ambiguous. Heinen *et al.* (2007) undertook a cross sectional study of 141 patients with leg ulcers and asked them about ulcer related problems. It was reported that 85% of them had pain and there was no difference in the pain reports of patients with arterial ulcers and with patients with venous leg ulcers. Park, Ferreira and Santos (2008) investigated the understanding of pain and quality of life of 40 patients with chronic venous ulcers attending an outpatient's clinic in Brazil. They measured pain using an 11-point numerical rating scale and also measured the quality of the pain using the McGill Pain Questionnaire-Short Form (SF-MPQ). The mean age of the patients was 67 years and 65% were women. Through analysis of variance (ANOVA) it was determined that age, and the number, duration and frequency of wounds were not associated with pain intensity. If we consider the experience of pain that these patients may have had within the context of the neuromatrix theory of pain, it would be expected that size, ulcer type and patient characteristics would not necessarily determine pain intensity. The neuromatrix theory of pain recognizes the simultaneous convergence of a myriad of influences such as past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems as well as immediate sensory input (Melzack, 1989; Melzack *et al.* 1997) (see Appendix 1, Pain terms and physiology).

Wissing and Unosson (2002) undertook a study to investigate the life situation and functioning of elderly people with and without leg ulcers ( $n=144$ ). Although their study did not measure pain intensity, it does inform us that ulcer pain was reported. These researchers asked participants if they had ulcer related pain and if they responded affirmatively, they asked if the pain was continuous, at rest, at night, during mobilisation or related to dressing changes. Pain was reported as most common at night or whilst resting. Phillips *et al.* (1994) provided further evidence of pain associated with leg ulceration from a study investigating the impact of leg ulcers on quality of life. They reported that 65% ( $n=61$ ) of their participants reported severe pain. However, this finding needs to be read with some caution as the participants were only given two options to choose from regarding pain intensity: "mild to moderate pain" or "severe to very severe pain". Chase *et al.* (2000) investigated pain amongst patients with venous leg ulcers and found that, 19% ( $n=4$ ) reported severe to moderate pain. However, this study only took data from 21 participants and did not discuss the types of pain intensity tool used. The authors did acknowledge the small sample size and stated that the findings should be used as preliminary information. Hareendran *et al.* (2005) undertook a study using qualitative and quantitative methodology investigating the impact of

venous leg ulcers on quality of life. They interviewed 38 patients with venous leg ulcers using semi-structured interviews. Participants also completed a health related quality of life (HRQoL) questionnaire. The findings suggested that pain was a problem as 80.5% ( $n=31$ ) of the participants reported having pain. Unfortunately they did not use validated measurements of pain; rather, the report of pain was taken from semi structured interviews. Quantitative data were extrapolated, 69.4% ( $n=26$ ) reported itching, 44.4% ( $n=17$ ) "felt low" or depressed, and self-confidence decreased in 30.6% ( $n=11$ ). Harrendran *et al.* (2005) discussed pain and depression amongst patients with chronic leg ulceration but did not discuss the link between depression and chronic pain. Depression has been documented as a frequent concomitant of chronic pain (Roy, Thomas & Matas, 1984). The pain was not described as chronic but was described as a symptom the patient had as well as depression.

Another study that measured pain and depression in patients with venous ulceration was carried out by Jones *et al.* (2006). They assessed 190 patients with chronic venous ulceration using the hospital anxiety and depression scale (HADS). A total of 27.4% ( $n=52$ ) of patients scored as depressed. They also explored the associations between anxiety and depression and odour and pain. They reported that the association between depression and pain as well as odour were significant. However they measured pain using two pain scoring methods with questionable validity. Firstly they used a categorical scale with only 4 descriptors. These descriptors were none, mild, moderate and severe. Evidence has demonstrated that using a 4-point descriptor scale may not be as accurate as using a numerical scale. Gagliese, Weizblit and Ellis, (2005) compared different pain intensity scales with younger and older surgical patients. They found that the scale with most acceptability and validity was the numerical rating scale using 11 points. It was reported as having the lowest error rate, and higher convergent, divergent and criterion validity than the other scales, which were the visual analogue scale and the categorical rating scale. Jones *et al.* (2006) also measured pain using, what they termed a numerical rating scale, the scale they used only went from 0=no pain to 4=worst pain. However, this was not a recognized, validated numerical pain intensity scale. Preston and Coleman (2000) tested the reliability and validity of scales with varying points rating from 2 to 101 points ( $n=149$ ). They determined that in terms of reliability, validity and discriminating power, the two-points, three-point and four-point scales performed poorly. Test re-test reliability was lowest for 2, 3 and 4 point scales and was significantly higher for scales with more response categories. Therefore, the methods used by Jones *et al.* (2006) to measure pain were not entirely trustworthy and may have given a false

finding. However, we can determine from this study that patients with pain associated with leg ulceration may be at risk of chronic pain sequelae such as depression. Briggs *et al.* (2007), Heinen *et al.* (2007), Park, Ferreira and Santos (2008) and Price *et al.* (2008), undertook studies that used validated methods to determine pain prevalence and pain intensity in people who were suffering from chronic leg ulceration. Therefore, we can determine from these studies that pain is likely amongst patients with chronic leg ulceration. Although the other studies discussed did not use validated methods to measure the prevalence and intensity of pain, (Phillips *et al.* 1994; Chase *et al.* 2000; Hareendran *et al.* 2005, Jones *et al.* 2006), their findings tentatively suggested that pain was a problem for patients with leg ulceration. Further, qualitative studies investigating patients with chronic leg ulceration often reported pain as a problem for this group of patients (Walshe, 1995; Chase, Melloni & Savage, 1997; Douglas, 2001; Husband, 2001a, 2001b; Hopkins, 2004; Ebbeskog & Emami, 2005; Flaherty, 2005). One of the first qualitative studies to report about pain associated with leg ulceration was undertaken by Walshe (1995). This was a phenomenological study involving 13 participants. Pain was an overwhelming description given by the participants and for many the pain was described as continuous. Krasner (1998) also undertook a phenomenological study investigating themes and stories about living with painful venous leg ulceration ( $n=14$ ). Krasner's study was the only study that investigated pain. The themes associated with pain were described as expecting pain, swelling equals pain, and starting the pain all over again. These studies used phenomenological methods therefore they described the lived experience but did not develop theory as to why these patients described their experiences the way they did. Husband (2001a) undertook a grounded theory study to investigate patients with venous ulcers. It was reported in this study that the patients wanted help in managing their pain but the nurses focused on the treatment to heal. Husband (2001a) suggested that patients with leg ulcers had pain and did not get that pain managed. Interestingly Husband also undertook interviews with the nurses and the doctors looking after these patients. The theory developed described a conflict of focus between the patient, the nurse and the general practitioner. The nurses were described as focused on the healing and the patients were focused on the pain. Doctors were described as handing the care over to the nurses, because they perceived wound management to require nursing expertise. This study had some interesting elements but it did not provide in-depth information about the pain experienced. It also did not discuss the impact or subsequent outcomes of the pain, it simply identified that patients had pain that was not managed. Husband (2001a) summarised that a focus on healing allowed for a trajectory of care of the ulcer and not of the person. She stated that a focus on the

wound led to approaches that viewed pain as a diagnostic marker rather than as a symptom that merited equal consideration for management. There was no discussion of the findings within the context of the pain literature. Furthermore, whilst this study was stated as being a grounded theory it did not include a description of the methods undertaken associated with grounded theory, such as the constant comparative method and coding processes. Therefore, it was difficult to determine the credibility of the theory developed. Douglas, (2001) also undertook a grounded theory study and the coding of data was described. A major category identified by Douglas was the physical experience of ulcers, and pain was a category within that category. Dressing related pain was described by the participants from this study and analgesia to manage the pain was reported as being ineffective. Douglas's discussion focused on the impact of pain on patients' compliance with treatment. Thus, the focus of the work remained on the healing aspect and it was suggested that by managing pain, patients' compliance would increase. This study also did not discuss the pain experience and its impact on the individual. Flaherty (2005) reported that long term pain was a problem for patients with healed venous leg ulcers. One participant's description was suggestive of neuropathic pain: *"I sit sometimes, and it is like a shock, something digging into me, but that is something you have got to live with"*. (Flaherty, 2005, p.82). Unfortunately, whilst this paper had some interesting findings the qualitative methodology used was not described. Nor was there any discussion of how the themes were derived. Therefore, it was not possible to ascertain the credibility of the findings reported.

#### **2.4.2 Evidence of neuropathic pain report**

Neuropathic pain is initiated or caused by a primary lesion or dysfunction in the peripheral or central nervous system. Neuropathic pain can be associated with acute nociceptive pain. However, neuropathic pain is also likely to last longer than acute nociceptive pain because it is more difficult to treat and is associated with conditions that have a longer time scale and that are chronic (Attal *et al.* 2006; Dworkin, Backonja & Rowbotham, 2003; Finnerup, Otto & McQuay, 2005). A study investigating the incidence of neuropathic pain in patients with leg ulceration showed that 45.3% ( $n=43$ ) of them had signs of neuropathic pain (Briggs *et al.* 2007). Although Reinhart, Wetzel and Vetten (2000) demonstrated a disturbance in the nerve fibres of patients with venous insufficiency, Briggs *et al.* (2007) completed the only study that investigated the incidence of neuropathic pain in this patient group. Park, Ferreira and Santos (2008) in their cross-sectional study of 40 patients with venous leg ulcers, did not measure patients for neuropathic pain but they did assess the pain characteristics using the

McGill Pain Questionnaire Short Form (SF-MPQ). With regard to the words chosen by the patients using the SF-MPQ short form, patients without pain chose a lower percentage of words than patients with mild, moderate or severe pain. Sensory words selected to describe the pain associated with venous leg ulceration were throbbing (70%,  $n=28$ ), pricking (75%,  $n=30$ ), sharp (75%,  $n=30$ ) and burning (65%,  $n=26$ ). Therefore, whilst this study did not investigate the incidence of neuropathic pain the sensory word descriptors suggested that the patients may have had neuropathic pain.

The fact that patients with chronic leg ulceration are at risk of developing neuropathic pain is not unexpected because of the association between central sensitisation and the development of neuropathic pain (see Appendix 1, Pain terms and physiology). If inflammation becomes chronic, neurogenic changes can cause the hyperalgesia to become neuropathic with associated central mechanisms (Treede *et al.* 2004).

An interesting observation whilst looking at the qualitative studies collectively, suggested a neuropathic component. These studies did not discuss or describe neuropathic pain but the language that was used by the participants from these studies, suggested neuropathic pain. Word descriptors that patients choose when describing their pain from several of the qualitative studies provided evidence that they may have had neuropathic as well as nociceptive pain (see Table 1) (Walshe, 1995; Krasner, 1998; Hyde *et al.* 1999; Douglas, 2001; Ebbeskog & Ekman, 2001; Husband, 2001b; Nemeth *et al.* 2004; Flaherty, 2005; Harrendran *et al.* 2005). Boureau, Doubrere and Luu (1990) found that when patients with neuropathic pain completed the MPQ, the six sensory descriptors electric shock, burning, cold, pricking, tingling, and itching were used most frequently. The pain associated with neuropathic mechanisms is often described as a continuous burning pain, or spontaneous lancinating or electrical pain (Gracely & Kwilosz, 1988; Rasmussen *et al.* 2004; Bennett, 2006).

Krasner's (1998) was the only study that specifically investigated the pain experience. However, theory regarding the pain described was not developed by Krasner because phenomenological methods were used. Phenomenology, rather than developing theory development, focuses on the lived experience of the individuals being studied (Thorne, 2000). The other qualitative studies investigated living with chronic leg ulceration and pain was a theme derived from the data. Flaherty's (2005) study is of particular interest because patients with healed venous leg ulcers were interviewed ( $n=11$ ). There was some description that may suggest

that these patients continued to suffer with pain despite their ulcers having healing. Furthermore, this pain was described in such a way that was suggestive of a neuropathic element. However, Flaherty did not discuss neuropathic pain but simply described the pain as something that patients with healed venous ulcers reported. Therefore, whilst these papers discussed pain, the nature of the pain, its outcomes and management were not fully explored. These researchers did not explore the pain these patients were describing with regard to patient outcomes. They did not explore in-depth that the patients were describing pain that appeared to be chronic with associated outcomes such as insomnia and depression. The majority of the researchers did not discuss their findings within the context of the pain literature. The only study to do this was Jones *et al.* (2006) which did provide some discussion within the context of the pain literature regarding the connection between pain and depression, but the focus was not pain which limited the ability to provide information about the nature of the pain experience for the group of people.

**Table 1: A summary of sensory word descriptors used by participants describing their pain (from qualitative studies investigating pain in patients with leg ulceration).**

Study authors	Methodology	Demographic data	Description of data collection	Themes derived from the data	Sensory words used by participants when describing their pain
Flaherty (2005) England.	Semi-structured interviews.  <i>n</i> =10	5 men & 5 women ages ranging from 52-92 years. No mean age reported.	Data was collected from single, semi-structured interviews.	Pain was one of the 3 themes derived from the data.	Shock Digging Ache
Hareendran <i>et al.</i> (2005) UK	Qualitative Transcribed interviews  <i>n</i> =38	Mean age 72 Female=26 Male=12	Open ended questions to explore the impact of venous leg ulcers on the quality of life.	Pain was a common theme, with feelings of depression.	Nagging Sharp Burning Dull Niggly Gnawing Stabbing Itching
Ebbeskog & Ekman (2001) Sweden	Phenomenological-hermeneutical approach interviews Recruited in consultation with district nurses <i>n</i> =15	Mean age 79.4 Female=80% Male=20% All participants had venous ulcers	Participants were encouraged to describe their experiences of living with a leg ulcer.	At the centre of the experience was pain, The painful ulcers occupied their minds.	Cramp Scraping
Husband (2001b) UK	Qualitative grounded theory Selected doctors and nurses recruited appropriate patients from caseloads <i>n</i> =39	Mean age=69 Female=90% Male=10% All participants had venous ulcers	Participants were given open questions and theories were obtained from analysing the interviews.	The main factor for participants to approach their GP was pain. Pain from ulcers was described as disrupting their lives.	Gnawing Horrible
Douglas (2001) UK	Qualitative grounded theory Patients interviewed Patients put forward by GP's, district nurses and managers <i>n</i> =8	Age range: 65-94yrs Female=6 Male=2 Ulcer type not specified	Participants were given open questions and theories were obtained from analysing the interviews	Non-adherence to treatment was related to pain. Experience of pain was a feature for all participants.	Stinging Persistent

**Table 1: A summary of sensory word descriptors used by participants describing their pain (from qualitative studies investigating pain in patients with leg ulceration).**

Hyde <i>et al.</i> (1999) Australia	Qualitative grounded theory Patients interviewed. Participants invited from among the women who were being treated by the Sydney Home. Nursing Service  <i>n</i> =12	Age range: 70-93 years All participants were female. Ulcer type not specified.	Participants were given open questions and theories were obtained from analysing the interviews	All participants reported pain relating to the ulcer.  Pain was the most common concern reported by participants.	Nagging Stabbing Irritating Gnawing Ache
Krasner (1998) US	Qualitative Heideggerian hermeneutic phenomenology Patients interviewed Recruited from a leg ulcer clinic <i>n</i> =14	Age range=30-86 years Female=7 Male=7 All participants had venous leg ulcers	Participants were given open questions and theories were obtained from analysing the interviews.	All patients' expected pain with the ulcer. Swelling equals pain. Debridement started the pain all over again.	Aching Annoying Burning Dull Hot Hurting Nagging Nerve pain Sharp Shooting Stabbing Sticky Stinging Throbbing Tingling
Walshe (1995) UK	Qualitative phenomenological Study Patients recruited from district nurse's caseloads in one district. <i>n</i> =13	Age range=all were elderly, with half the sample aged over 85years. Female=92% Male=8% Ulcer type not specified	Participants were given open questions and theories were obtained from analysing the interviews.	The overwhelming feature of description of the experience of living with a leg ulcer was of it being painful.	Burning Shooting "Red-hot needles"

### 2.4.3 Summary

Leg ulceration has been shown to cause a significant amount of pain to individuals. This pain has been shown to have nociceptive and in some cases neuropathic pain mechanisms. Patients with leg ulceration are at risk of chronic pain; the two components associated with chronic pain are inflammation and peripheral nerve damage. The inflammatory response creates hyperalgesia that causes further pain. Reports of pain from people with leg ulcers have been demonstrated in both qualitative and quantitative studies. Furthermore, neuropathic pain is likely to occur in some patients. The case of neuropathic pain has been highlighted by Briggs *et al.* (2007) and by word descriptors used when describing the pain. Thus, it can be assumed that an individual with leg ulceration is likely to suffer with pain. The

evidence is unequivocal. Pain is associated with all types of leg ulcers, venous, arterial as well as ulcers with mixed aetiology (Ebbeskog, Lindholm & Ohman, 1996; Briggs & Flemming, 2007; Closs, Nelson & Briggs, 2008).

The literature review indicated that these patients may have chronic pain with chronic pain sequelae such as depression. Overall, the majority of the researchers did not make the link between the pain experience these patients described and the pain experience described by others with chronic pain. Jones *et al.* (2006) discussed their findings, briefly within the context of the pain literature but came to the conclusion that patients with leg ulceration were at risk of depression associated with pain and odour. They did not develop their analysis further to consider the chronic pain condition. The qualitative literature in particular reveals that patients have pain but the pain experience was not developed in greater depth. There was limited discussion of the pain experience within the context of the pain literature. It was apparent from the literature that patients with pain associated with leg ulceration are at risk of developing a chronic pain condition. The review of the literature demonstrated that there was a gap in the field with regard to the nature of the pain, which people with chronic leg ulceration suffer. The topic of pain associated with chronic leg ulceration needs to be explored with more emphasis on the nature of the pain, its management and related outcomes for the patient experiencing the pain.

### **2.5 Effects of leg ulcer treatment on pain**

There was evidence in the literature that suggested that the treatment of leg ulceration causes further pain (Franks, Moffatt & Connolly, 1994a; Ebbeskog & Emami, 2005; Briggs & Closs, 2006; Mudge *et al.* 2006). Patients, once under the care of the community nurses, will have their ulcers managed in a specific way depending on the ulcer aetiology. The reality of leg ulcers is more complex, however, since additional causes exist and it is known that about a third of ulcers have a mixed or multi-factorial background (Nelzen *et al.* 1991; Baker *et al.* 1992). Compression therapy is the mainstay of treatment and prevention of ulcers with venous aetiology (Cullum & Roe, 1995; Briggs *et al.* 2004; Mekkes *et al.* 2003; RCN, 2006; O'Meara, Cullum & Nelson, 2009). Arterial ulcers may require surgery to re-establish adequate vascular supply (SIGN, 1998; Mekkes *et al.* 2003; Phillips *et al.* 2004; Dowsett, 2005). Ulcers of mixed aetiology may benefit from reduced compression bandaging (Moffatt *et al.* 1992). Other forms of treatment include debridement (surgical/mechanical, autolytic, chemical, biosurgery/maggot), cleansing and dressing of the wound, antibiotics, skin grafting and life style changes (RCN, 1998; Phillips, 1999a; Phillips, 1999b; RCN, 2006).

Treatments for leg ulcers have been shown to predominantly cause more pain or in some cases relieve pain (Arnold *et al.* 1994; Noonan & Burge, 1998; Krasner, 1998; Naylor, 2001; Vanscheidt, 2001; Wissing & Unosson, 2002; Reddy *et al.* 2003; Heinen *et al.* 2004; Briggs & Closs, 2006).

The purpose of the following section was to discuss the treatments used and how they potentially impact on the pain experience. Effectiveness and head to head comparisons regarding techniques to heal leg ulceration are multiple. It was beyond the remit of this thesis to discuss the success of healing associated with various treatments. Therefore, the focus of this section will remain on the pain experience associated with these treatments.

#### **Medline search strategy for effects of leg ulcer treatment on pain**

#1 MeSH descriptor Leg Ulcer explode all trees	14667
#2 (varicose ulcer* or venous ulcer* or leg ulcer* or arterial ulcer*).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	10606
#3 MeSH descriptor Pain explode all trees	98836
#4 (#1 OR #2)	15624
#5 (#3 AND #4)	364
#6 (dressing* or compression or gauze or hydrocolloid* or adherent or non-adherent or hydrogel* or alginate*). ab, ti, kw.	118027
#7 (#3 AND #6)	1943
#8 MeSH descriptor Debridement explode all trees	9520
#9 (#3 AND #8)	199
#10 (#4 AND #9)	26
#11 MeSH descriptor Larva explode all trees	35719
#12 (#4 AND #11)	87
#13 (#3 AND #12)	5
#14 MeSH descriptor Stockings, Compression explode all trees	562
#15 (#3 AND #14)	23
#16 (#4 AND #15)	11
#17 MeSH descriptor Skin Care explode all trees/ or Dermatological Agents explode all trees	140695
#18 (#3 AND #17)	1467
#19 (#4 AND #18)	50
#20 MeSH descriptor Wound Infection explode all trees	32295
#21 (#4 AND #20)	408
#22 (#3 AND #21)	6
#23 Procedural.mp	13571
#24 (#3 AND #6 AND #23)	21

### **2.5.1 Wound cleansing**

The process of wound cleansing involves the application of a non-toxic fluid to remove debris, wound exudates and metabolic waste to create an optimal environment for wound healing (Murphy, 1995; Waspe, 1996; Rodeheaver, 1999). In a systematic review carried out by Fernandez, Giffiths and Ussia (2008) 11 trials were evaluated with the primary outcome being wound infection and secondary outcome being pain and discomfort. The authors concluded that there was no evidence demonstrating that tap water was less likely to cause pain on application

compared with antiseptics such as hypochlorite solution, iodine and acetic acid. However, this was determined from one study included in the review and the study did not investigate the use of tap water in chronic wounds. Rather, the study investigated procaine spirit with tap water for washing postoperative wounds (Tay, 1999). Therefore, it was not possible to determine if tap water was less painful compared with other solutions, for the cleansing of chronic wounds. A study that investigated nurses' views regarding wound pain and trauma was undertaken by Moffatt, Franks and Hollinworth (2002) who collected data from 11 different countries; a total of 14,657 questionnaires were distributed and 3,918 people responded (response rate 27%). Nurses agreed that wound cleansing was likely to cause pain for patients. However, they did not collect data about various solutions used to cleanse the wounds. Price *et al.* (2008) investigated patients' perceptions of dressing related pain across 15 countries. Patients were asked to rate the different stages of the dressing change procedure using a scale 1=no pain to 5=very painful. Cleansing of the wound was reported as the second most painful aspect associated with dressing changes (24%,  $n=1335$ ). This study did not investigate the solutions used to cleanse the wound; therefore no information was available about the pain experience associated with the solution used for cleansing. Briggs and Closs (2006) investigated the impact of treatments and products on patients' experiences of leg ulcer pain. They obtained data from 210 treatment episodes for 96 patients with leg ulceration. Cleansing of the wounds caused pain in 22% ( $n=11$ ) of episodes and relieved pain in 27% ( $n=13$ ) of the episodes. It was shown that the only agent not to cause pain was tap water. Moreover, tap water was shown to relieve pain more frequently than did other agents.

In summary it is to be expected that cleansing an already inflamed wound with possible neuropathic symptoms is likely to be painful. Evidence from Briggs and Closs (2006) study suggests that water was the only agent not to cause pain. However, further work is required because Briggs and Closs (2006) study investigated several components associated with leg ulceration and did not focus entirely on cleansing solutions and pain.

### **2.5.2 Debridement**

Debridement is the removal of necrotic tissue, to allow formation of good granulation tissue and adequate epithelialisation. It is thought to be one of the most important steps in wound management. However, the scientific evidence for this has been questioned (Steed *et al.* 1996; Bradley, Cullum & Sheldon, 1999). Removal of necrotic

tissue can be achieved using different forms of debridement these including mechanical/surgical, autolytic, chemical and biosurgical. Chronic ulcers of multi-factorial origin often harbour necrosis or at least fibrin slough, thus the main principles of treatment are relief of any pressure on the wound site.

### **2.5.2.1 Autolytic debridement and dressings.**

Autolytic debridement is the use of a synthetic dressing over an ulcer that allows self-digestion through the action of enzymes normally present in wound fluid. An occlusive dressing is recommended to create a moist environment and to prevent the dressing from sticking to the wound. Some have stated that it is important to maintain a moist environment for the wound, as this has been found to reduce the time for wound healing by as much as 50% compared with a dry environment (Geronemus & Robins, 1982). The principles of moist wound healing are based on the research by Winter (1962). There is agreement that by using a moist environment the removal of dressings can be less painful and can prevent damage being caused by stripping away newly formed epithelium on removal (Geronemus & Robins, 1982; Phillips, 1999a; Norman & Bock, 2003). Support in the positive benefit of pain reduction being created by the use of moist dressings shows that by maintaining a moist environment and using a protective covering for the wound prevents the nerve endings from being exposed, thus reducing the nociceptive stimuli (Field & Kerstein, 1994). Emflorgo (1999) goes as far as to suggest that traditional dressings such as gauze or paraffin tulle be discontinued because they dry out and adhere to the wound or become incorporated into tissues within the wound. Therefore, causing pain and damage on removal (Hollinworth & Collier, 2000). Further to this soaking these dressings to aid removal is rarely effective (Hollinworth, 1995). Eaglstein and Falanga (1997) suggested that an occluded wound encourages autolytic debridement; it yields painless debridement, provides formation of granulation tissue, and minimizes constant pain and tenderness. Occlusive barriers such as hydrocolloid dressings act as barriers from micro-organisms in the environment and also maintain a slightly acidic pH, which is most optimal to wound healing, and are somewhat hostile to bacteria (Agren & Wijesinghe, 1994; Eaglstein & Falanga, 1997). An added benefit of using such techniques is that less frequent dressing changes may be required, thus, reducing pain stimuli caused by dressing changes and reducing costs of nursing care. Rudolph (2001) reported that when a protocol of hydrocolloid dressings was used; the required frequency of change was every 5 to 7 days. In protocols of care that used conventional gauze dressings, the required frequency of change was every day or even more often, depending on the

amount of exudate (Hutchinson & McGuckin, 1990; Rodeheaver, 1997; Gilchrist, 1999).

A study that investigated nurses' views regarding wound pain and trauma was undertaken by Moffatt, Franks and Hollinworth (2002). They collected data from 11 different countries, a total of 14,657 questionnaires were distributed and 3,918 people responded (response rate 27%). They asked questions relating to the pain and trauma experienced at the time of dressing change. Preventing trauma was the most important factor considered with regard to dressing changes. Responders indicated that dried out dressings and products that adhered to the wound were considered the most likely cause of pain. Gauze was not identified as the most likely to cause pain on removal, rather adhesive dressings and cleansing was considered the most likely to cause pain. This was surprising to the authors because gauze is believed to adhere to the wound and thus cause pain. Furthermore, the most common pain avoidance strategy used was to soak the old dressings before removal. This is an unfortunate practice because soaking before dressing removal has been shown to be ineffective in reducing pain and trauma and is not recommended (Dykes, Heggie & Hill, 2001).

Hydrogels, hydrofibres, alginates and soft silicones were reported to be the least likely to cause pain on removal. Price *et al.* (2008) undertook a large international study of patients' perceptions of their wound pain. A total of 2,018 patients, from 15 different countries, participated. The return rate varied between countries, and ranged from 1.3% ( $n=26$ ) in Belgium and 19.5% ( $n=392$ ) in Italy. The authors acknowledged the poor response rates and because of the size of their data set, focused on the results of all countries combined stratified by wound type. Antimicrobial dressings were most frequently reported as causing pain, whereas the most common dressings that were reported as reducing or minimizing pain were soft silicone polyurethane foam, a hydrofibre and foam with topical ibuprofen. Briggs and Closs (2006) investigated the pain experience related to dressing changes ( $n=210$ ), they reported that of the most commonly used dressing types, low adherent dressings were the least likely to cause pain.

### **2.5.2.2 Biosurgical/maggot/larval debridement**

Over the past 10 years sterile maggot therapy has become an accepted wound care resource. The larvae of the common green bottle fly (*Lucilia sericata*) are the only species used for maggot debridement therapy in the UK (Thomas *et al.* 2001). The

maggots secrete powerful proteolytic enzymes that break down necrotic tissue into semi-liquid form, which is subsequently ingested by the maggots (Thomas *et al.* 2001).

When examining maggot therapy and its impact on the pain experience Dumville *et al.* (2009) demonstrated that patients had, higher pain scores when receiving larvae therapy compared with hydrogel therapy ( $n=267$ ). They conducted a three armed randomised control trial to compare the clinical effectiveness of larval therapy (loose larvae and bagged larvae) with a standard debridement technique (hydrogel). Their primary outcome measure was healing rates but they also measured pain using a visual analogue scale, from 0mm for no pain to 150 mm for the worst pain imaginable. The mean pain scores were higher in both larvae groups compared with hydrogel group (mean differences in pain score were reported as: loose larvae vs. hydrogel 46.74,  $p<0.001$ ; bagged larvae vs. hydrogel 38.58,  $p<0.001$ ). In another study carried out by Woolf and Hansson (2003) which also measured pain, one-quarter of the study participants experienced less pain with maggot therapy during treatment, 41% reported no difference in the pain experience and 34% reported an increase in pain. Most of the patients that reported an increase in pain nonetheless wanted to continue with the therapy because of the apparent improvement in wound debridement.

A qualitative study that investigated patients' perceptions and experiences of larval therapy was undertaken by Kitching (2004). Four of the participants experienced less pain ( $n=6$ ), an example of the patient's comments follows:

*"I felt a tickling sensation while they were on"* (Kitching 2004, p.29).

*"It saved me a lot of pain"* (Kitching 2004, p.28).

*"I didn't have pain but twinges made me jump"* (Kitching 2004, p.29).

The third comment may be suggestive of neuropathic pain mechanisms.

In another qualitative study exploring patients' perceptions of larval therapy, an exacerbation of pain was described (Spilsbury *et al.* 2008).

One patient said:

*"I was gasping for breath and I have a high pain threshold. I was told the maggots would be painful but it was very bad"* (Spilsbury *et al.* 2008, p.153).

Another patient described having such bad pain and itchiness that she had to stop the maggot therapy.

It could be postulated that patients, who have neuropathic pain with associated allodynia and hyperalgesia, can be expected to experience more pain with maggot therapy because of the pain stimulated by movement across the wound surface. The researchers who have discussed the pain associated with maggot therapy did not assess their patients for neuropathic pain and did not discuss it (Woolf & Hansson, 2003; Kitching, 2004; Spilsbury *et al.* 2008, Dumville *et al.* 2009). Maggots have been shown to cause pain for some patients; however some patients want to persevere with the treatment because of visual improvements. Further research is required to determine whether patients with neuropathic pain are more likely to experience an exacerbation of pain with maggot therapy.

### **2.5.2.3 Sharp/mechanical debridement**

Mechanical debridement physically removes debris from the wound in an expeditious manner; methods of mechanical debridement include dextranomers, hydrotherapy, irrigation, and wet to dry dressings. Surgical or sharp debridement is the fastest method of mechanical debridement; it involves the actual removal of necrotic areas with surgical instruments (Norman & Bock, 2003). The RCN (1998) guideline suggests that surgical debridement is relatively swift and inexpensive, and recommends that the procedure is undertaken by someone with specific training in the skill. However, the guideline does not mention pain management strategies to accompany the procedure. Davies *et al.* (2005) discussed sharp debridement in their paper exploring debridement options. They suggested that there is a risk of damaging the underlying blood vessels but did not suggest that patients are at risk of pain associated with sharp debridement. Krasner (1998) undertook a descriptive qualitative study investigating themes and stories of patients living with venous leg ulcers. Most of the participants found that their pain experience was most intense when they underwent mechanical debridement. The participants reported that the pain caused by debridement was associated with "starting the pain all over again". Two descriptions of the experience of pain with debridement were given by patients that were particularly compelling;

*"How bad can this be, it's just a little hole here, just be calm, he's going to be finished in a couple of minutes. But it ruins your whole day. Because you're in twice as much pain as you were when you walked in there and you gotta go back to work.... Dr (X) would debride it a little, then it would aggravate it more, and the pain would start all over again. Then it seemed when just, just when it was like*

*manageable, it would be time to come in again, and he would do it again. Start all over again. Just this vicious cycle” (Krasner 1998, p.164).*

*“Why do they cut on me and they don’t give me no needles or nothing? I’m really ..... where they cut on you and scrape it off, and get it over with and get me out of here” (Krasner 1998, p.164).*

This particular participant went onto say:

*“I’m getting a little tired. I really am tired of this... Sit me in the middle of the road and let some truck hit me (Krasner 1998, p.164).*

Phillips (1999a) suggested that sharp debridement should only be undertaken using local anaesthetic or general anaesthetic, as with any other surgical technique. The use of topical lidocaine-prilocaine cream being applied to the ulcer before sharp debridement has been shown to significantly reduce the pain associated with this technique (Holm, Andren & Grafford, 1990; Hansson, Holm & Lillieborg, 1993). Other topical preparations such as lidocaine, benzocaine or prilocaine may also be helpful (Fowler & Van Rijswijk, 1995). Further discussion regarding the use of local anaesthetic to reduce the pain associated with debridement is provided in Chapter 2, section 2.7.3.1 within this literature review.

Wet to dry saline dressings have been used for many years in the US for wound debridement. This is a method of mechanical debridement, which involves applying dampened gauze on a wound and then allowing it to dry. The dried dressing, in which necrotic debris becomes embedded, is then removed (Phillips, 1999a). Removal of the dressing can be agonizing (Norman & Bock, 2003) and can strip away newly formed epithelium when used on clean wounds (Hulten, 1994). It has been recommended that wet to dry dressings should not be used and that this form of debridement should be discontinued because of the associated pain and damage caused to the healthy tissue (Phillips, 1999a; NICE, 2001; Edwards & Stapley, 2002).

In summary sharp debridement has been shown to cause a significant amount of pain for some patients. This is to be expected if patients do not receive adequate analgesia or anaesthesia for what essentially is, a surgical procedure. Fortunately, this has been acknowledged and there are clinical trials to determine the effectiveness of using local anaesthetic to reduce sharp/mechanical debridement pain.

### 2.5.3 Compression therapy

Compression therapy is the mainstay of treatment and prevention of ulcers with venous aetiology (Cullum & Roe, 1995; Mekkes *et al.* 2003; RCN, 2006; O'Meara, Cullum & Nelson, 2009). Compression therapy is considered the gold standard in the treatment of venous leg ulcerations (Meyer *et al.* 2002; Moffatt, McCullagh & O'Connor, 2003; O'Brian *et al.* 2003). Compression therapy involves the application of external or counter pressure to the lower extremity to facilitate venous return from the peripheral veins to the heart. The therapeutic effects include alleviation of hypertension, increased venous return, decreased venous pooling, stimulation of fibrinolysis, reduction of oedema, increased oxygenation, and provision of an environment conducive to wound healing (Harris, Brown-Etris & Troyer, 1996; O'Meara, Cullum & Nelson, 2009). Short-stretch bandages compress the lower extremities by resisting changes in force during muscle activity (Rudolph, 1998), they are more popular in continental Europe apart from the UK, where clinicians have a preference for the four-layer technique possibly because it was developed in the UK. Compression is promoted as it has been shown to aid healing of leg ulcers. However, there was some evidence in the literature that compression may exacerbate the patients' pain. Mallett (1999) observed that in one particular clinic, many patients, because of the unacceptable levels of pain they experienced, could not use compression therapy. However, once these patients had their pain addressed they were able to tolerate the compression therapy. Although this was an interesting observation the findings were not from a controlled trial and it was not clear how the data were collected and measured. Many patients have pain associated with swelling (Krasner, 1998), so if the compression reduces that swelling it may be possible that the pain will also be reduced. Brereton *et al.* (1997) compared patients' tolerance of compression bandaging with their tolerance of usual leg ulcer care. The nurses completed weekly forms about their patients' tolerance of their treatments. They achieved an 80% return rate from 233 participants and found that more patients experienced pain in the compression group than in the other group. However, we must be cautious in interpreting this report because the data collected were from the nurses who cared for the patients and not directly from the patients. No actual pain measurements or scores were recorded; subjective assessments were made by the nurses. Briggs and Closs (2006) study provided quantitative evidence regarding pain scores and the use of compression therapy. They undertook a longitudinal cohort study using prospective data collection. Of a total of 210 treatment episodes, 98 episodes were compression therapy. In only 55% ( $n=53$ ) of these episodes was full compression tolerated; in 47% ( $n=26$ ) of these episodes, the patients reported their

bandages were painful. In 27% ( $n=26$ ) episodes the patients persevered with full compression despite their pain, but in 22% ( $n=23$ ) episodes they were unable to tolerate the pain and the compression was reduced. In another quantitative study, undertaken by Heinen *et al.* (2007) the problems encountered by patients with leg ulcers were described. The researchers used a descriptive, cross sectional design with patients recruited from 7 outpatient clinics for dermatology ( $n=141$ ). Compression therapy was reported by 36% ( $n=50$ ) of the participants as a problem because it was painful and too tight. Further evidence of exacerbation of pain being caused by compression was available from qualitative studies. In a phenomenological study investigating older patients' experiences of dressing changes on venous leg ulcers (Ebbeskog & Emami, 2005) it was reported that one patient believed that the bandages on her legs should not be wrapped as tightly as they were, although the nursing staff said that the wound would not heal without such compression. She tried to prepare herself for this painful procedure but it was extremely difficult. She felt nauseated and the bandages left marks on her legs. The participants in this study complained that they did not receive enough pain medication or other assistance during the changing of their bandages.

*"Many of these bandages although they're supposed to be good, hurt and chafe the skin"* (Ebbeskog & Emami, 2005, p.1228).

When she complained of pain the nurses told the patient that the therapy had to hurt.

*"They just kept wrapping that bandage and I felt sick, I said; I don't want that"* (Ebbeskog & Emami 2005, p.1228).

In another qualitative study investigating living with leg ulceration (Mudge *et al.* 2006) issues concerning adherence suggested that patients tolerate compression to promote healing. The participants made it clear that they felt pain was an inevitable part of their condition and something that had to be tolerated.

*"Whatever happens, pain is always an issue, if it's uncomfortable you wear it anyway"* (Mudge *et al.* 2006, p.1169).

*"I kept it (the bandage) on for a week and never slept for the whole week, it was terrible"* (Mudge *et al.* 2006, p.1169).

Van Hecke *et al.* (2008) undertook a survey of community nurses in Belgium regarding leg ulcer treatment. Nurses employed by the community healthcare organizations and independent nurses in private practices ( $n=789$ ) were recruited. They had a 10% ( $n=50$ ) response rate from the independent nurses and 50%

( $n=692$ ) response rate from the community nurses. Within their study they collected data regarding pain and compression but did not investigate the impact compression had on the pain. Furthermore, the pain reports were taken from the nurses not directly from the patients. It was reported that only 58.7% of the patients were treated with compression, which the authors believed was because of issues associated with health insurance (compression bandaging was not covered). A study that did address compliance with compression and the pain impact was undertaken by Annells, O'Neil and Flowers, (2008). They undertook a qualitative study to explore the reasons for use or non-use of compression bandaging by district nurses. Nurses were either interviewed independently ( $n=12$ ) or were included in a focus group ( $n=10$ ). The nurses reported that patients had a lack of willingness for differing reasons. The preliminary reasons that the nurses described were patients having negative experiences in the past, disbelief in efficacy and mixed messages received. Pain and discomfort were reported by the nurses as a reason for non-compliance. However, the focus remained on the healing as they explained that pain was caused by tightness and swelling. Furthermore, the nurses reported frustration with patients who removed their bandaging or refused compression because of the pain.

*"Often people are quiet resistant to using it, or they find its very painful, and sometimes you have difficulty getting them to keep it on"* (Annells, O'Neil & Flowers, 2008, p.355).

The focus of the discussion remained on the healing; pain was discussed as a problem because it prevented the nurses from carrying out the treatment to promote healing.

In summary, it can be determined that for some patients compression is likely to be painful; reasons for the compression being painful appear to focus on incorrect application or the application being too tight. There was no discussion regarding the potential of neuropathic pain and its relationship with compression. Furthermore, the management of associated pain focuses on managing the pain so the patient will tolerate the compression, not managing the pain to improve the patient's quality of life.

#### **2.5.4 The use of antibiotics to manage report of pain**

Prescribing antibiotics for the report of pain associated with chronic leg ulcerations may not always be an appropriate management strategy. This section discusses the

evidence within the literature regarding pain report and the use of antibiotics associated with leg ulceration.

Moist chronic skin ulcers are an ideal medium for bacterial growth and a variety of microorganisms can be cultured from these lesions. Research findings suggest that 80-100% of chronic leg ulcers may be colonised with bacteria (Halbert *et al.* 1992; Brook & Frazier, 1998; Harker, 2001). The commonest isolates are staphylococcus aureus and haemolytic streptococci (Harker, 2001). The recognised clinical signs of infection include inflammation, increased pain, purulent exudates, rapid deterioration of the wound and pyrexia. Literature also states that early indicators of infection include increases in exudates with associated inflammation (Cutting & White, 2005). Cutting and White (2005) carried out an extensive literature review to identify criteria for the diagnosis of wound infection. With venous leg ulcers they suggested that the presence of pain was a common characteristic of these ulcers even without infection. Therefore, the permutation of signs and symptoms must be interpreted in the context of patient familiarity and notable changes in presentation. Gardner, Frantz and Doebbeling (2001) carried out a study to assess the validity of various clinical signs and symptoms used to identify localized chronic wound infection. Increasing pain was expressed by less than one half of patients with infected wounds. The authors commented that increasing pain was not a clear indicator of infection given that one third (31%,  $n=11$ ) of the sample either could not perceive pain or could not report pain information. However, they also reported that 100% of the wounds with increasing pain were infected. Caution is required with interpretation of these results, however, because the questions regarding the experience of pain did not establish if the increase in pain was actually caused by infection. Rather, the patients were asked to indicate which of the following related to their experience: 1) I am not able to detect pain in ulcer area. 2) I am having less ulcer pain now than I have had in the past. 3) The intensity of the ulcer pain has remained the same since the ulcer developed, or 4) I have more ulcer pain now than I have had in the past. The questions did not determine the duration of increase in their pain. Thus, the patients who reported experiencing an increase in their leg ulcer pain were saying they have more pain now than they have had in the past. The patients were not stating they had more pain since infection. The questions were not able to measure a true increase in pain since infection. To measure accurately the pain resulting from infection a more robust methodology using a validated pain intensity tool would be required, which would be sensitive enough to distinguish changes in the patient's pain intensity before and after the onset of infection. The authors concluded that signs specific to secondary wounds appeared to be more valid indicators of chronic wound infection

including serous drainage, inflammation, delayed healing, discoloration, friable granulation, foul odour and wound breakdown. There were some reports of infection causing further pain in the leg ulcer literature. However, this evidence was from a few qualitative studies investigating patients with chronic leg ulceration. Only one study suggested that an increase in pain may have been caused by infection (Hyde *et al.* 1999). Hyde *et al.* (1999) in her qualitative study investigating older women living with leg ulceration suggested that a commonly held belief among the women was that pain was a warning sign that they had an infection. One other qualitative study highlighted infection as a problem but did not correlate infection with pain (Edwards, 2003).

In the three available reviews investigating living with chronic leg ulceration, infection was not linked to an increase in pain. In the first of these reviews carried out by Persoon *et al.* (2004) qualitative and quantitative research studies were included. Infection was not mentioned as a separate theme but rather as a cause of the unpleasant smells. Herber, Schnepf and Rieger (2007) carried out a review of qualitative and quantitative studies investigating living with leg ulceration ( $n=24$ ). Herber, Schnepf and Rieger (2007) did not conclude that infection was a problem for this patient group. Herber, Schnepf and Rieger (2007) did not identify infection as a problematic symptom nor was infection mentioned as a cause of increased pain. Briggs and Flemming (2007) in their systematic review of qualitative papers investigating living with chronic leg ulceration did conclude that infection was a problem. However, only one paper that they reviewed suggested that infection was a problem and this was not linked with the pain experience.

In summary it was not possible to determine whether the presence of pain can be used as an indicator for infection. This is because a large number of patients will have associated pain with or without infection. Furthermore, if patients are prescribed antibiotics when they report pain they are not likely to get effective pain management and may also be taking antibiotics inappropriately.

### **2.5.5 Summary**

It appears from the literature that aspects of the treatments used to promote healing of the leg ulcers either exacerbate or relieve pain. For wound cleansing it can be assumed that tap water was the most cost effective. Further, tap water has been shown to cause the least amount of discomfort and may provide pain relief (Briggs & Cross, 2006). The principles of moist wound dressings allow for less pain during

dressings removal (Phillips, 1999a; Norman & Bock, 2003). The evidence for the use of one dressing type over another was limited and the recommendation was that they should be simple, low adherent, low cost and acceptable to the patient (RCN, 2006).

It appears from the literature that the most acceptable form of debridement with regard to pain was autolytic therapy (Geronemus & Robins, 1982; Field & Kerstein, 1994; Phillips, 1999a; Norman & Bock, 2003). Manual and surgical debridement appeared to be the most aggressive forms and the most likely to cause pain (Krasner, 1998). The pain experienced whilst undergoing surgical/sharp debridement has been reported as being extreme, not only was the pain severe whilst the procedure was being carried out but the on-going pain can continue for hours following debridement (Vanscheidt, 2001). Of course the fact that surgical/mechanical debridement causes pain was not a surprise, with an already painful and inflamed wound with associated hyperalgesia, stimuli of this form is likely to cause a substantial amount of pain. When it is considered that the site potentially has allodynia and hyperalgesia and may have a neuropathic pain element, pain associated with sharp/mechanical debridement should be an expected outcome.

The gold standard for treatment of venous leg ulcers is the use of compression therapy (Cullum & Roe, 1995; Meyer *et al.* 2002; Mekkes *et al.* 2003; Moffatt, McCullagh & O'Connor, 2003; O'Brian *et al.* 2003; Briggs *et al.* 2004; RCN, 2006; O'Meara, Cullum & Nelson, 2009). It is unfortunate that compression therapy may exacerbate the pain of leg ulceration. Various qualitative and quantitative studies have provided evidence that compression bandaging in some cases was so painful that the patients were not able to tolerate it (Ebbeskog & Emami, 2005; Briggs & Closs, 2006; Mudge *et al.* 2006; Heinen *et al.* 2007). The pain associated with compression therapy was perhaps to be expected when these patients were also reporting neuropathic pain. Allodynia is a likely characteristic of neuropathic pain (Wall, 1991). Thus, applying a tight heavily layered bandage can be expected to cause further pain.

The evidence suggested that pain may be used as an important indicator of infection; however, other signs of infection would need to be present to form a valid diagnosis. It can be concluded that the decision to prescribe antibiotics should be based on other criteria rather than simply patients' reports of an increase in pain (Gardner, Frantz & Doebbeling, 2001; Cutting & White, 2005). Antibiotics should not be prescribed to manage pain because an increase in pain does not necessarily indicate infection. Moreover, if the patient receives antibiotics and not analgesics when they

complain of pain, they are unlikely to gain adequate pain relief if the pain is not associated with infection.

In studies investigating patients' experiences with living with a leg ulcer it has been found that whilst patients' desire healing they focus on their pain and management of that pain (Krasner, 1998; Husband, 2001b). If we are to manage patients with leg ulcers effectively and improve their quality of life, more emphasis needs to be given to the management of symptoms rather than concentrating all efforts on healing alone. Adequate pain management of leg ulcers is a vital component if these individuals' quality of life is to be improved.

## **2.6 Experience of pain and its management in people 65 years and over.**

Leg ulceration predominantly affects people 65 years and over. Therefore, it was necessary to understand the pain experience and management of people 65 years and over and how their age may moderate the experience. It has been found that many subscribe to the myth that to grow old is to hurt and that older adults are less sensitive to pain than are their younger counterparts (Morris & Goli, 1994). Clinicians and many elderly people themselves assume that ageing is associated with both a reduction in the ability to perceive pain and an increase in non-specific pain related suffering and pain complaints (Harkins, Price & Martelli, 1986; Yong, 2006).

This section considers the physiological changes with regard to pain perception and pain management of the older adult. The aim was to outline the true significance of physiological changes to the pain experience for the elderly. Cognitive and behavioural factors are discussed, to ascertain if there are significant changes in either of these, and how this impacts on the pain experience of the older person. Furthermore, it was evident that prescribing for analgesics is inadequate for older people. Therefore, it was necessary to have an understanding of two factors that may impact on the pharmacological pain management relating to older people, these are pharmacokinetics and polypharmacy.

### **Medline search strategy for experience of pain and its management in people 65 years and over.**

#1 MeSH descriptor Pain explode all trees	253629
#2 MeSH descriptor "Aged, 80 and over" explode all trees/ Aged explode all trees	1930672
#3 MeSH descriptor Physiology explode all trees	116702
#4 (#1 AND #2 AND #3)	118
#5 MeSH descriptor Hyperalgesia explode all trees	5087
#6 (#2 AND #5)	164
#7 MeSH descriptor Cognition explode all trees	84111
#8 (#1 AND #2 AND #7)	302
#9 Analgesia MeSH descriptor Analgesia explode all trees	277723
#10 (#2 AND #9)	4623
#11 MeSH descriptor Analgesia explode ae. [Adverse Effects]	2518
#12 (#2 AND #11)	454

#13 MeSH descriptor Pharmacokinetics explode all trees	132268
#14 (#11 AND #13)	7
#15 (#2 AND #13)	10895
#16 (#9 AND #15)	15
#17 MeSH descriptor Polypharmacy explode all trees	1394
#18 (#2 AND #17)	851
#19 MeSH descriptor Neuralgia explode all trees/ or Pain explode all trees	253858
#20 (#2 AND #9 AND #19)	2435
#21 (#13 AND #20)	13
#22 MeSH descriptor Pain measurement explode all trees	44976
#23 (#2 AND #22)	12699
#24 (#7 AND #23)	113

### 2.6.1 Experimental and clinical studies

There is a defined physiological process to the pain experience (Appendix 1, Pain terms and physiology). Pain serves as an important biological function; it informs us of injury and assists in maintaining a homeostatic balance (Gibson & Farrell, 2004). The question with regard to physiology was; to what extent does age related changes affect nociception and how does this manifest in the older person?

Various changes in the physiology of pain have been reported in several studies. Functional, biochemical and structural changes have been reported in peripheral nerves of older subjects. The density of unmyelinated fibres has been found to decrease by the age of 60 years (Ochoa & Mair, 1969). Others have found that the sensory fibres (both myelinated and unmyelinated) decrease in numbers. Moreover, the authors reported there were signs of damage and degeneration with advancing age with a slowing of the peripheral nerve conduction (Kakigi, 1987; Alder & Nacimiento, 1988; Verdu *et al.* 2000). In biochemical studies there has been a marked reduction in substance P content in aged human skin (Helme & McKernan, 1984) and in thoracic and lumbar dorsal root ganglion cells. The latter finding however, was from studies of rats and whether this finding would translate to humans has yet to be established.

Studies using noxious stimuli to gain a pain response such as heat and pressure have been inconclusive. Chakour *et al.* (1996) investigated the possibility of differential age related changes in heat pain sensitivity sub-served by A-delta and C fibres. The noxious stimulus used to create a pain response was a carbon dioxide laser heat pulse. The investigators measured pain thresholds before, during and after a compression block, which selectively impaired A-delta fibre conduction whilst leaving C fibre conduction intact. They found that younger adults exhibited a significant increase in heat pain thresholds during the compression block that disturbed A-delta fibre transmission, compared with healthy older volunteers whose pain thresholds remained

stable. This may suggest a selective age related impairment of myelinated nociceptive function and potentially impairment to the early warning functions of A-delta fibres. Zheng *et al.* (2000) tested the effects of age on hyperalgesia (an increased response to painful stimulation) using capsaicin. The use of capsaicin is a useful model because of its ability to create a realistic experimental response to injury in a subject. The aim of the study was to examine possible age differences in the development and resolution of capsaicin induced hyperalgesia. They found that younger and older adults displayed a similar magnitude of pain, hyperalgesia and flare response. However, it was shown that older persons had an increased latency to the onset of pain. The study also confirmed that the area of post-capsaicin application, hyperalgesia took substantially longer to recover in the older person. Hyperalgesia allows damaged tissues extra protection whilst the occurrence of further noxious stimuli could have the greatest potential to exacerbate damage or prevent healing (Gibson & Farrell, 2004). Persistent increases in sensitivity would not be compatible with recovery and the reduction of inflammation and therefore pain should occur in synchronisation with the healing of the damaged tissue. The biological benefit obtained through the sensitisation of injured tissue becomes maladaptive if the hyperalgesia is not resolved in synchronisation with the healing (Gibson & Farrell, 2004). Thus the very slow resolution of hyperalgesia in older people is clinically significant. This finding was repeated in another study investigating thermal pain. The investigators found that the area of hyperalgesia took longer to resolve in the older adults (Edwards & Fillingim, 2001).

In studies investigating pain perception in clinical situations changes in pain perception and age have been demonstrated. In clinical situations where it would be expected that the individual would suffer severe pain (e.g. myocardial infarction and intra-abdominal emergencies) in some cases with the elderly person severe pain was not reported. The pain maybe reported later, less frequently or not at all (Ambepitya, lyngar & Roberts, 1993). Gibson and Helme (2001) suggested that sensations of visceral pain decline as a person ages, thus myocardial infarction may be quite silent for the oldest old (Gibson & Helme, 2001). In a study undertaken by Miller, Sheps and Bragdon (1990) increasing age was a risk factor in the perception of cardiac ischaemic pain, regardless of the severity of the disease. The actual clinical relevance of reduced pain report is still an on going debate. It cannot be assumed from these studies that older people feel less pain. Pain is a complicated subject and how it is experienced is dependent on many variables.

### 2.6.2 Cognitive factors

There is increasing evidence that suggests cognitive factors such as attitudes and beliefs about pain play an important role in influencing the individual's reports and the experience of pain. Several studies have shown that cognitive factors have been shown to influence compliance with treatments, pain coping mechanisms and resultant outcomes (Turk & Rudy, 1992; Crombez *et al.* 1999; Turner, Jensen & Romano, 2000; Jensen *et al.* 2002). Perceptions of pain and beliefs about pain have an impact on how the individual copes and deals with their pain. Gagliese and Melzack (2003) undertook a study that found age related differences in the qualities but not the intensity of chronic pain. The mean age in the young age group was 42.93 years ( $n=139$ ); and 70.1 in the older age group ( $n=139$ ). All the participants were chronic pain patients from a Canadian pain centre. They were matched on primary diagnosis or pain location, duration and sex. All completed the McGill Pain Questionnaire (MPQ), numeric ratings (0-10) of pain intensity, a pain map and the Hospital Anxiety and Depression Scale (HADS). The results showed that there were age differences in the measure of pain qualities were found. The elderly group had significantly lower MPQ total and sensory scores and chose fewer words to describe their pain than the younger group. Use of the MPQ has been validated for use with both young (Melzack, 1992) and older patients (Corran, Helme & Gibson, 1999; Gagliese & Katz, 2003). When using the numerical pain measuring scales there were no statistically significant differences between how each group scored their pain intensity. It was also found that there were no age differences on Pain Management Index (PMI) scores, which is a measure of the adequacy of analgesic therapy (Breitbart *et al.* 1996). Other authors have found age differences when using the MPQ, in samples from pain clinics, surgical wards and community dwelling adults (Gagliese & Melzack, 2003; Gagliese & Katz, 2003). Thus, ageing may be associated with a change in the quality but not the intensity of pain (Gagliese & Katz, 2003).

Beliefs about health and illness are thought to play an important mediating role between the occurrence of chronic pain and the consequent level of emotional and functional impact (Turk & Meichenbaum, 1989). Wallston, Wallston and DeVellis (1978) developed a scale that measured how cognitive factors affected people's health. It is the most commonly used measure of perceived control in the health area, known as the Multidimensional Health Locus of Control Scale (Wallston, Wallston & DeVellis, 1978). This questionnaire was adapted for work undertaken by Main and Waddell (1991) to allow for specific beliefs regarding control over pain to be investigated (Main & Waddell 1991; Toomey *et al.* 1991). Previous research has

shown that chronic pain patients with a predominantly internal locus of control reported a decrease in pain intensity (Toomey *et al.* 1991; Jordan, Lumley & Leisen, 1998). In contrast to this, persons who were thought to have a chance locus, so an external locus of control, were found to have greater self-reported pain (Toomey *et al.* 1991), higher levels of depression (Skevington, 1983) and were more likely to use maladaptive coping strategies, such as catastrophizing (Crisson & Keefe, 1988). It has been stated by some that elderly people may exhibit a more external locus of control when confronted with health related problems (Folkman & Lazarus, 1980; Melding, 1995). Other studies have replicated this finding that the older person is more likely to display an external locus of control and when dealing with health problems, the older person relies more heavily on factors such as chance and powerful others (Folkman & Lazarus, 1980; Blanchard-Fields & Robinson, 1987; Melding, 1995). A study undertaken by Gibson and Helme (2000) provided further support for this, they showed that adults older than 81 years had significantly higher scores on chance locus and a strong trend for higher scores on the powerful others with regard to their pain control. They suggested that this may simply be a reflection of maturity and hence a more pragmatic view, as they rightly believe that many events, especially with regard to health status are beyond their control. In a study investigating pain amongst the oldest old in community and institutional settings (Zyczkoska *et al.* 2007), it was concluded that the oldest, old may report less pain especially chronic pain because they have partly accepted their pain and have become accustomed to it. The authors' suggested that the oldest old may adapt to their pain by modifying their activities to reduce the likelihood of experiencing pain. This study was of particular interest as it investigated pain in large numbers of older people aged 65 years and over ( $n=193,158$ ) with 788 of them being 100 years and over. They reported that the report of pain declined in the oldest old groups. However, they assessed pain using a four point categorical rating scale. Assessors documenting the pain score were also instructed to use their clinical judgement to record the most appropriate response based on non-verbal signs, such as wincing, verbalizations and indications of discomfort. Therefore, data of the nurses' perceptions of the older persons' pain were recorded, not the individuals' pain report. Furthermore, chronic pain should be assessed using various assessment tools, a pain scoring system only measures the intensity of the pain. The study showed a decline in pain scores with age, which might reflect people's acceptance and ability to get used to their pain rather than a true decline in pain *per se*. The authors suggested that the differences in pain reports with increasing age might be due to increased stoicism rather than a decrease in actual pain.

In a study undertaken by Strong, Ashton, and Chant (1992) it was reported that there were no differences in attitudes and beliefs when comparing an older age group with a younger age group. This was in contrast to other studies that suggested there was a difference (Folkman & Lazarus, 1980; Blanchard-Fields & Robinson, 1987; Melding, 1995; Gibson & Helme, 1995; Riley *et al.* 2000; Gagliese & Melzack, 2003; Gagliese & Katz, 2003). However, on closer examination Strong, Ashton, and Chant (1992) investigated age differences using a median split of 43 years. The numbers of participants in the study were 96 and the mean age was 46.1. The authors did not report the number of participants who were in the older age groups and gave no indication of how many participants were 65 years and over. Thus the finding that the authors reported with regard to differences in attitudes and beliefs when comparing older age groups, was ambiguous.

In another study undertaken by Riley *et al.* (2000) differences amongst age groups were identified. The study tested age related differences in the magnitude and association of the four stages of pain processing using a model developed by Heyneman *et al.* (1990). This group developed a model that they used to study the differences in the processing of chronic pain across the adult life span (Heyneman *et al.* 1990; Wade *et al.* 1996). Riley *et al.* (2000) tested age related differences in the magnitude and association of the four stages of pain processing. Their study used data collected from 1,585 chronic pain patients that were divided into three age cohorts: younger adults 18-44 years ( $n=895$ ), middle aged adults 45-64 years ( $n=538$ ) and older adults 65-85 years ( $n=159$ ). No differences in the magnitude of the association were found for the two initial stages of pain processing. The results did however show a statistically significant age related effect on the third and fourth stages. In comparison with the younger and middle aged groups, older adults in this study were found to have less emotional distress related to their pain. The authors suggested that the differences found were likely to be a function of differences in life circumstances, attitudes and beliefs about pain and ageing (Riley *et al.* 2000).

Another factor affecting the pain behaviour of individuals is stoicism, it has been cited as a cause for the under-reporting of pain symptoms observed in older people (Portenoy & Farkash, 1988; Parmelee, 1994; Foley, 1994; Helme & Gibson, 2001). Yong (2006) investigated stoicism and age related variations in levels of self-reported pain, mood disturbance and functional interference in chronic pain patients. Psychometric measures were administered to 338 chronic pain patients. Attitudes towards their pain were assessed using a revised version of the Pain Attitudes

Questionnaire (PAQ) developed by Yong (2006) to assess pain related stoicism. Pain was assessed using the McGill Pain Questionnaire; pain severity was assessed using the pain severity subscale (MPI-PS) of the Multidimensional Pain Inventory (MPI). Levels of depression and anxiety were also measured using validated tools. The study reported that stoic-fortitude was clearly demonstrated as having an impact on measures of pain, mood disturbance and functional interference. The authors reported that stoicism, if present, could result in the underreporting of pain symptoms.

### **2.6.3 Pharmacological pain management for older people**

Older people suffering from pain are likely to receive inappropriate pharmacological treatment (Bernabei, Gambassi & Lapane, 1998; Landi, Onder & Cesari, 2001). Despite the widespread diffusion of the World Health Organizations (WHO) 3-level ladder (Stjernsward, 1988) and the demonstration that its correct use can alleviate pain in more than 90% of cases pain management continues to be inadequate (Zech, Grond & Lynch, 1995; Levy, 1996). Studies among nursing home residents with cancer and among subjects in home care programs found that more than one quarter of patients with daily pain did not receive any analgesics and that those older than 85 years were least likely to receive any treatment (Bernabei, Gambassi & Lapane, 1998; Landi, Onder & Cesari, 2001).

Changes in pharmacokinetics and problems with polypharmacy may account for inappropriate analgesic administration amongst older adults. There are certain physiological changes associated with ageing, these changes progress with age but the rate at which they progress is not well defined and may be very different between individuals (Macintyre, Upton & Ludbrook, 2003). Also the changes are not only due to ageing but can be associated with other diseases. Therefore although a decrease in cerebral volume appears to be inevitable in the elderly (Marchal, Rioux & Petit-Taboue, 1992), data suggest that a reduction in cardiac output or fluid volume reflects concomitant disease (Rodeheffer, Gerstenblith & Becker, 1984). The liver and kidneys decrease in size with ageing thus there is a potential for accumulation of opioid metabolites (Macintyre, Upton & Ludbrook, 2003). Ageing is also associated with an increase in body fat and a reduction in muscle mass, highly lipophilic drugs may contribute to a more rapid decline in blood concentrations due to their accumulation in fat (Gloth, 1996). Although there are physiological changes in elderly persons as they age, these should never be a reason to withhold useful and beneficial analgesics and adjuncts (Rochon & Gurwitz, 1995). It is recommended in the literature that by careful selection of drugs within a class, starting with low doses and increasing slowly if required, with careful monitoring of increments and by

considering any new symptoms and signs as possible drug side effects, both the risk of adverse reactions and the need for further therapy to counteract them can be reduced (Helme, 2001; Macintyre, Upton & Ludbrook, 2003).

It is well known that an increasing prevalence of diseases and symptoms comes with ageing, which frequently require pharmaceutical treatment (Gaddi, Cicero & Pedro, 2004). Multiple drug use in elderly persons is the most important risk factor for adverse reactions (ADRs) and increases the risk of drug interactions and compliance. ADR's are responsible for about 10% of all hospital admissions of elderly persons. The drugs most commonly involved are cardiovascular, psychotropics and anti-inflammatory agents (Gaddi, Cicero & Pedrom, 2004). It is difficult to predict the likelihood of side effects of certain drugs because many of the randomised controlled trials of non-steroidal anti-inflammatory agents included few older people and hardly any people over the age of 85 years (Helme, 2001).

#### **2.6.4 Summary**

To summarize, studies have shown that older persons do have some physiological changes with regard to pain. However, the impact of ageing was not conclusive. Studies investigating hyperalgesia responses have shown slower resolution of hyperalgesia in older people and this has clinical significance, particularly regarding wound pain. Ageing may be associated with a change in the quality but not the intensity of the pain experienced (Gagliese & Katz, 2003).

When looking at cognitive factors the evidence informs us that there are differences amongst age groups. Persons with an external locus of control are less likely to respond to non-pharmacological pain management techniques and are more likely to experience depression as a result of chronic pain (Folkman & Lazarus, 1980; Blanchard-Fields & Robinson, 1987; Melding, 1995; Gibson & Helme, 2000). Moreover, stoicism has been cited as a cause for the under-reporting of pain symptoms observed in older people (Portenoy & Farkash, 1988; Foley, 1994; Parmelee, 1994; Helme & Gibson, 2001). Thus, it can be assumed that the cognitive differences found amongst age groups suggests that older persons are more at risk of the negative impacts of chronic pain and may also under-report their pain. Furthermore, it is apparent that older people are less likely to have their pain managed, which is due partly to changes in pharmacokinetics and fears of side effects and polypharmacy.

It can be concluded from the available work related to elderly persons' pain experiences, that elderly persons may have some differences in how they perceive their pain. However, the pain intensity is just as great, and it could be that their ability to describe, or express their pain is different. People 65 years and over are most at risk of chronic leg ulceration and are also at risk of extended hyperalgesia and its associated outcomes. Older persons are more at risk of the negative impact of chronic pain and may also under-report their pain. When managing pain associated with chronic leg ulceration in older people changes in pain perception and pain expression need to be considered, especially with regard to procedural and treatment related pain. Understanding the changes in pharmacokinetics and the true risks of opioid use in older age groups is required, to ensure that older persons receive adequate pain management. The management of pain in the elderly person may be more complicated but this should not be an excuse for poor pain management.

## 2.7 Present pain management of chronic leg ulceration

The aim of this section was to explore the evidence relating to the current management of pain associated with chronic leg ulceration. Pain is a very real problem for patients with chronic leg ulcers; it is one of the most frequently reported symptoms. However, presently the pain associated with leg ulceration appears to be poorly managed. Whether this is because it is pain associated with leg ulceration or whether it is because patients with leg ulceration are most likely to be 65 years or older, is unclear.

### Medline search strategy for present pain management of chronic leg ulceration

#1 MeSH descriptor Pain explode all trees/ or Pain measurement explode all trees	269149
#2 MeSH descriptor Aged, "80 and over" explode all trees/ or Aged explode all trees	1930769
#3 MeSH descriptor Leg Ulcer explode all trees/ or Varicose Ulcer explode all trees	14667
#4 (#1 AND #3)	437
#5 (#2 AND #4)	227
#6 Assessment? MeSH descriptor Geriatric assessment explode all trees/ or Nursing assessment explode all trees	41273
#7 (#1 AND #3 AND #6)	47
#8 Primary care? MeSH descriptor Primary Health Care explode all trees	60829
#9 (#1 AND #3 AND #8)	6
#10 (#3 AND #8)	107
#11 Analgesic* MeSH descriptor Analgesics explode all trees/ or Non-narcotic explode all trees/ or Analgesics, Opioid explode all trees	378630
#12 (#3 AND #11)	136
#13 (public health or home care services or public health nursing or primary care or community care) ab. kw. ti	209717
#14 (#1 AND #13)	3102
#15 (#3 AND #14)	8
#16 non-pharmacological? ab. kw. ti	2287
#17 (#1 AND #3 AND #16)	1
#18 (#13 AND #16)	119

### 2.7.1 Evidence of pain assessment

To manage pain it is necessary to assess and measure it. To manage patients' pain effectively, clinicians must start by routinely asking patients about their pain and all information regarding the pain should be recorded (Donaldson, 2009). With regard to leg ulceration there was very little evidence of this activity in the literature. In a study of district nursing practice in relation to leg ulcer management, Roe *et al.* (1993) observed that 55% ( $n=80$ ) of nurses caring for patients with leg ulceration, did not assess pain as part of their care of these patients. However, the study results need to be read with caution as the questionnaires were disseminated to groups of nurses, the responses were group responses, not individual responses. Therefore, these responses may be a reflection on what the groups of nurses thought they should be doing, not what they were actually doing. Hollinworth (1995) found similar results, observing that nurses often failed to assess pain verbally or to use pain assessment tools. However, Hollinworth's (1995) focus of research was on nurses' views regarding pain and trauma at dressing changes. They distributed 1000 questionnaires to nurses with an interest in wound care and achieved a response rate of 37%. Much of the discussion concerned types of dressings used to prevent trauma and pain rather than pain assessment. In another study undertaken by Moffatt, Franks and Hollinworth (2002) they investigated nurses' views regarding pain and trauma at dressing changes across 11 different countries. A total of 14,657 questionnaires were distributed and 3,918 were returned (response rate 27%). The findings demonstrated that nurses placed little importance on pain assessment before and after dressing changes. There were differences regarding pain assessment practices between countries but the most important factor in identifying pain was talking to the patient. In the US, Finland and France body language was considered to be the most important factor in identifying pain. Lorimer, Harrison and Graham (2003) reported that out of 66 nursing records taken from patients receiving home care; only 15% ( $n=9$ ) contained any pain documentation. Over one half (55%,  $n=36$ ) of the community nurses did not undertake regular pain assessment. In another quantitative study (Kammerlander & Eberlein, 2002) investigating nurses' views about pain and trauma at dressing changes, 3,300 questionnaires were distributed to nurses from three European countries with a 15.1% ( $n=498$ ) response rate, they found only 16% ( $n=79$ ) of respondents used a standardized pain scale. In a large European study investigating the prevalence of chronic pain in the community, data investigating pain measurement were also collated. Of 46,394 respondents with chronic pain, 15% ( $n=6,959$ ) had received any form of pain measurement (Breivik *et al.* 2006). These studies suggested that pain assessment was not a routine activity

amongst community nurses, despite International wound pain assessment recommendations. The European Wound Management Association and the World Union of Wound Healing Societies have both produced position and consensus documents to address the importance of wound associated pain (EWMA, 2002; World Union of Wound Healing Society, 2004). There are further pain management recommendations published in the wound literature (Woo *et al.* 2008; Fogh *et al.* 2008); these articles discuss wound pain and emphasise the importance of pain assessment. Whilst these studies suggest pain assessment was lacking for patients being cared for in the community, they did not discuss the reasons.

The literature supports the recommendation that pain can only be assessed on an individual basis using self-report, careful pain histories and external indicators (McCaffery & Pasero, 1999; Brown, 2004). Moreover, the provision of appropriate pain relieving interventions depends on accurate assessment (Closs, 2005). The Royal College of Surgeons and College of Anaesthetists state that the ability to evaluate pain experience is an essential feature of high-quality nursing practice and research (Royal College of Surgeons, 1990).

Without a comprehensive pain assessment, the judgment of professionals dictates how, what and when analgesia is administered. Unfortunately, studies have indicated that professionals tend to underestimate pain needs, under-prescribe and under-medicate in general and in older people in particular (Blomqvist & Hallberg, 1999).

Pain assessment in older people presents with a specific set of problems, studies have identified a range of factors that impede accurate pain assessment in the older population. These include; less likelihood of report of pain because of a reluctance to bother staff (Closs *et al.* 2002), an expectation that they will experience pain (Closs, 1994), a feeling that their reports are not taken seriously (Brockopp *et al.* 1996), not being prepared to take an active part in their pain control (Brockopp *et al.* 1996), not equating pain with soreness (Herr & Garand, 2001) and not recognizing the sensations as pain (Kovack *et al.* 1999). It is common for older adults to deny pain but admit to other sensations such as aching, hurting, soreness or some other descriptor (Feldt, Ryden & Miles, 1998; Closs & Briggs, 2002). In summary older people demonstrate some differences in reporting pain. However, it can be assumed that older adults can provide self-reports of pain, several measures have been found to have adequate reliability and validity when used with older people with mild to moderate dementia including the 0-10 pain assessment scale (Weiner, Peterson & Keefe, 1999a; Closs *et*

*al.* 2004) the 21 point box scale (Chibnall & Tait, 2001) the verbal descriptor scale and the coloured analogue scale (CAS) (Scherder & Bouma, 2000).

If a patient is to be successfully treated for neuropathic pain, appropriate assessment and diagnoses are required. For clinicians to successfully diagnose neuropathic pain, Bennett developed a pain scale to assess for neuropathic signs and symptoms (Bennett, 2001), known as the Leeds assessment of neuropathic symptoms and signs (LANSS). The LANSS pain scale has been shown to distinguish patients with neuropathic pain from those with nociceptive pain (Bennett, 2001), allowing quick and effective screening. The scale has since been tested and validated in several settings (Potter *et al.* 2003; Yucel *et al.* 2004; Kaki, El-Yaski & Youseif, 2005).

The apparent lack of activity of pain assessment in people with chronic leg ulceration may be partly due to the fact that leg ulceration affects predominantly people 65 years and over. The literature suggests that pain assessment was poor in this age group thus further compounding inadequate pain management. Assessment of pain is crucial if pain is to be managed effectively. The literature has demonstrated that there are pain assessment tools that have been validated with this age group. Therefore, what is required is further research investigating why pain assessment is lacking in patients with chronic leg ulceration. In summary we can assume that older people with pain associated with chronic leg ulceration are at risk of poor pain assessment for three significant reasons which the literature has demonstrated. Firstly pain assessment of patients with leg ulceration was lacking, routine pain assessment was not undertaken within community areas and pain assessment in older people was often inadequate.

### **2.7.2 Evidence of current pain management**

There were various qualitative and quantitative studies investigating living with leg ulceration that described relevant pain management issues. Ten quantitative studies investigating living with leg ulceration reported on pain management (Nelzen, Bergqvist & Lindhagen, 1994; Ebbeskog, Lindholm & Ohman, 1996; Hofman *et al.* 1997; Noonan & Burge, 1998; Wissing & Unosson, 2002; Nemeth, Harrison & Graham, 2003; Nemeth *et al.* 2004; Heinen *et al.* 2007; Guarnera *et al.* 2007; Price *et al.* 2008). Ten studies using qualitative methods were identified, these studies investigated living with chronic leg ulceration amongst various cohorts. The majority of the studies did not investigate pain as a separate issue rather, pain was a theme derived from the data. (Hyland, Lay & Thomson, 1994; Walshe, 1995; Chase, Meloni & Savage, 1997; Hyde *et al.* 1999; Husband, 2001a, 2001b; Ebbeskog & Ekman, 2001; Douglas, 2001; Ebbeskog & Emami, 2005; Hareendran *et al.* 2005).

### 2.7.2.1 Report of analgesic use and effectiveness

Nelzen, Bergqvist, and Lindhagen (1994) was one of the first group of researchers to describe the analgesic use of patients with chronic leg ulceration, based on a cross sectional survey ( $n=827$ ). Four other studies also reported the percentage of patients who took analgesics but as with Nelzen, Bergqvist, and Lindhagen (1994) paper they did not report the type of analgesics used (Wissing & Unosson, 2002; Heinen *et al.* 2004; Nemeth *et al.* 2004; Price *et al.* 2008). This was probably because these studies were not investigating the pain aspect alone and rather the pain aspect formed a part of the study undertaken. Nelzen, Bergqvist, and Lindhagen (1996) undertook a large prevalence study ( $n=270,800$ ) and the analgesic report formed a small part of what was reported within the study. They reported that 51% of patients with non-venous leg ulcers and 38% of patients with venous ulcers were taking analgesics but did not provide further information regarding analgesic type and effectiveness. Wissing and Unosson's (2002) study was undertaken to determine the prevalence, aetiology, level of care and treatment options in patients with leg ulceration. However, they sent questionnaires to healthcare professionals. Whilst they reported that pain was experienced by 44% ( $n=63$ ) of patients and 24% ( $n=34$ ) received analgesia this was a report taken from healthcare professionals and not from patients. Therefore this may not be an accurate account of what patients were actually doing regarding their pain management.

Heinen *et al.* (2007), Nemeth *et al.* (2004) and Price *et al.* (2008) characterised the effectiveness of analgesics. Price *et al.* (2008) carried out a cross sectional international survey investigating dressing related pain in patients with chronic wounds. Fifty six percent of respondents indicated that they took analgesics ( $n=1141$ ). However, 21% ( $n=239$ ) of this group indicated that their analgesics were not effective. Within the study, the participants were only asked if they took analgesics and if they found them helpful. Therefore, there was no information regarding analgesic type and how frequently analgesics were taken. Heinen *et al.* (2007) carried out a study using a quantitative cross sectional design; they reported that 70% ( $n=98$ ) of patients using analgesics indicated that they experienced "acceptable" levels of pain after taking them. Further, 16% ( $n=23$ ) reported insufficient pain relief and 25% ( $n=35$ ) of the participants only used analgesics occasionally. Again this paper did not report the type of analgesic used or the method and frequency of administration. Nemeth, Harrison, and Graham (2003) reported similar effectiveness with 75% ( $n=99$ ) of their research participants reporting that they found their analgesics effective. However, 48% ( $n=122$ ) of the participants

reported that they did not use any analgesics. This study did not provide a description of type of analgesic, method of administration and frequency of administration. In Husbands (2001a; 2001b) qualitative study patients described taking analgesics and also reported that they were not effective. The effectiveness of analgesics was reported on in other qualitative studies (Walshe 1995; Douglas 2001), in both studies the participants found that their analgesics were ineffective. Further, there was a report that patients found that maintaining effective pain control was difficult (Douglas 2001). Harrendran *et al.* (2005) reported that ( $n=38$ ), some participants had no analgesics prescribed and did not take any. Hyland, Lay, and Thomson (1994) also reported that some patients did not take analgesics. Further, Harrendran *et al.* (2005) commented that patients who had taken analgesics found they had not helped much.

*"It can keep you awake day and night and even a painkiller doesn't help much".*

(Hareendran *et al.* 2005. p.57).

Several studies reported that some patients with pain did not take analgesics (Hofman *et al.* 1997; Nemeth, Harrison & Graham, 2003; Heinen *et al.* 2007). Heinen *et al.* (2007) and Hofman *et al.* (1997) reported that 25% of patients with pain did not take analgesics. However, these studies did not provide any explanation of why these patients were not taking analgesics. In a few of the qualitative studies, the participants reported that they would avoid taking analgesics (Hyde *et al.* 1999; Ebbeskog & Ekman, 2001), either because they were believed to be "bad for the body" or because they were uncomfortable taking them. Ebbeskog and Ekman (2001) investigated the experiences of elderly people living with a leg ulcer using a phenomenological-hermeneutic approach. Fifteen people aged 74-89 years were interviewed. Pain management was discussed; the participants reported that they took painkillers when the pain got too much to bear. If they could they would avoid painkillers, feeling they would be bad for their bodies. Some of the participants described their existence in terms of the number of painkillers taken.

*"I have during this period consumed several packages of painkillers"* (Ebbeskog & Ekman, 2001, p.239).

It was not possible to determine from these studies if it was the type of analgesia that was inadequate or the frequency and method of administration that were inadequate.

### 2.7.2.2 Report of type of analgesic taken.

Several studies described the type of analgesic used for the management of pain associated with leg ulceration. Nemeth *et al.* (2004) in a prospective pilot study reported that 67% ( $n=13$ ) of participants were prescribed opioids and only 66% ( $n=8$ ) of those given opioids took them. However, this study was a pilot study and had 19 participants. Ebbeskog, Lindholm and Ohman (1996) had larger numbers in their study ( $n=294$ ), they reported that the commonest analgesics used were a combination of dextropropoxyphene (mild opioid less effective than codeine) and paracetamol. Unfortunately they did not collect data to determine if these analgesics were beneficial. They also distributed their questionnaires to healthcare professionals and did not collect data directly from patients. Therefore, this study was a representation of what healthcare professionals perceived their patients were taking for pain. This may also explain why they did not collect data about pain management outcomes. A more recent study that described analgesic use in patients with leg ulceration was carried out by Guarnera *et al.* (2007), who undertook a multicentre cross sectional study ( $n=381$ ) in which they found 66% ( $n=251$ ) of participants had received some form of analgesia including paracetamol, diclofenac and codeine. They also collected pain scores but did not compare the pain scores with analgesic use. Rather, they compared the pain scores with quality of life. Three of the qualitative studies provided some information with regard to analgesics taken (Chase, Melloni & Savage, 1997; Hyde *et al.* 1999; Husband 2001b). Hyde *et al.* (1999) in a qualitative descriptive study stated that the most frequently prescribed analgesics were paracetamol and codeine. This finding was repeated by Husband (2001b) in her grounded theory study, most patients reported taking codeine and paracetamol analgesics.

*"Dr X said she would give me something for the pain... when they got so bad where I couldn't stand it, I would take paracetamol...."*

(Husband, 2001b, p.38).

*"All I take is Tylenol (paracetamol) I took three before I came (to clinic) and I'll take three more after".*

(Chase, Melloni & Savage, 1997, p.75).

These papers collectively suggested that pharmacological pain management may be inadequate for this patient group. The literature provides some information regarding analgesic use but evidence regarding the use of particular analgesics was limited. There was also limited information regarding the frequency of medication. Therefore,

it was difficult to determine if it was the actual drug that was inadequate to manage people's pain or the dosage and amount taken. To determine this, robust randomised controlled trials of patients taking analgesics for leg ulcer pain management are required. Furthermore, there was no evidence regarding the use of specific pharmacology to manage neuropathic pain associated with leg ulceration.

### **2.7.2.3 Report of non-pharmacological pain management.**

Only two of the quantitative studies described the use and effectiveness of non-pharmacological methods of pain management (Hofman *et al.* 1997; Noonan & Burge, 1998). Noonan and Burge (1998) carried out an interview based study- collecting data ( $n=51$ ) to assess pain severity using the VAS and the SF-MPQ. They also collected information about treatments being carried out for the leg ulcer related to healing and pain management strategies. Information about the strategies being used to relieve pain was limited, it was suggested that gentle ankle movements, in contrast to walking relieved pain. However, no statistics for this were provided and it was more of a suggestion rather than a finding. In contrast to this, Hofman *et al.* (1997) did provide statistics about non-pharmacological management, although, this was also very limited in that only one strategy was discussed. They established that 50% ( $n=70$ ) of the study population found that leg elevation reduced pain. There was very limited information with regard to non-pharmacological pain management within the qualitative studies. Only three studies mentioned non-pharmacological management strategies. Putting the leg in different positions and doing massage were reported as providing some relief from the pain (Ebbeskog & Ekman, 2001). Participants in Hyde's *et al.* (1999) study spoke of methods to manage their pain such as using a cradle over the leg to sleep to prevent contact with bedclothes.

*"I've got a cradle over it; I could not sleep without the cradle"* (Hyde *et al.* 1999, p.193.)

Another strategy that was mentioned included getting out of bed and walking around (Harrendran *et al.* 2005).

Evidence of the use of non-pharmacological pain management associated with leg ulceration was limited. Furthermore, the non-pharmacological management that was reported appeared to be patient initiated.

### 2.7.3 Studies investigating modalities for pain management of leg ulceration

The modality that appeared to have gained most attention was the use of local anaesthetic for procedural related pain (Holm, Andren & Grafford, 1990; Johnson & Repper, 1992; Hansson 1993; Lok 1999; Rosenthal *et al.* 2001; Agrifoglio *et al.* 2000). There were several studies that had investigated the use of topical ibuprofen (Flanagan, Vogensen & Hasse, 2006; Jorgensen, Friis & Gottrup, 2006; Romanelli *et al.* 2009). The use of topical morphine for leg ulcer pain was apparent but predominantly from case studies. However, there were two studies which investigated the use of topical morphine with leg ulcers (Vernassiere *et al.* 2005; Jansen *et al.* 2009) and some report of the use of topical morphine with other skin ulcers (Zeppetella, Paul & Ribeiro, 2003). No studies could be found of the use of oral analgesics, either for nociceptive pain or neuropathic pain associated with leg ulceration. There was one study investigating the use of transcutaneous electrical nervous stimulation TENS (Ravenscroft *et al.* 2000).

#### Medline search strategy for studies investigating modalities for pain management of leg ulceration

#1 MeSH descriptor Leg Ulcer explode all trees/ or Varicose Ulcer explode all trees	14667
#2 MeSH descriptor Pain explode all trees	253649
#3 MeSH descriptor Analgesics explode all trees/ or Non-Narcotic explode all trees/ or Analgesics explode all trees	378630
#4 (#1 AND #2 AND #3)	27
#5 Wound*.mp.	222057
#6 (#4 AND #5)	9
#7 MeSH descriptor Administration, Topical explode all trees/ or Dermatological agents explode all trees/ or Skin explode all trees	340679
#8 (#1 AND #2 AND #7)	42
#9 Neuro?pathic MeSH descriptor Neuralgia explode all trees/ or Nervous system diseases explode all trees	1733469
#10 (#3 AND #9)	56761
#11 (#1 AND #10)	34
#12 MeSH descriptor Complementary Therapies explode all trees	143645
#13 (#1 AND #2 AND #12)	9
#14 MeSH descriptor Transcutaneous Electric-Nerve Stimulation explode all trees	4516
#15 (#1 AND #14)	5
#16 Tricyclic analgesics* MeSH descriptor Amitriptylene explode all trees	5551
#17 (#1 AND #2 AND #16)	0
#18 MeSH descriptor Acetaminophen explode all trees	11743
#19 (#1 AND #18)	3
#20 NSAID* MeSH descriptor Anti-Inflammatory Agents explode all trees/ or Non-Steroidal explode all trees/or Aspirin explode all trees	351132
#21 (#1 AND #20)	297

#### 2.7.3.1 Topical local anaesthetics

During the last few years many attempts have been made to provide adequate local anaesthetic of the skin, especially in dermatology (Schmid & Korting, 1996). It appears from the literature that the most frequently investigated topical local anaesthetics were lidocaine and prilocaine. Lidocaine and prilocaine are amide type local anaesthetics

(Huang & Vidimos, 2000). The use of EMLA cream to manage pain associated with debridement of leg ulcers has been investigated. EMLA is an emulsion in which the oil phase is a eutectic mixture of 2.5% lidocaine and 2.5% prilocaine, it works by targeting the free nerve endings, preventing the initiation and transmission of nerve impulses. This is achieved by limiting sodium ion permeability (Huang & Vidimos, 2000). EMLA cream has been shown to be effective in relieving the pain associated with debridement of chronic leg ulcers. In a systematic review carried out by Briggs and Nelson (2010), it was reported that the use of EMLA 5% could be considered to reduce the pain of sharp debridement. Six randomised controlled trials of EMLA vs. "placebo" or "no anaesthesia" were included (Holm, Andren & Grafford, 1990; Johnson & Repper, 1992; Hansson 1993; Lok 1999; Rosenthal *et al.* 2001; Agrifoglio *et al.* 2000). Five of the trials reported a statistically significant pain reduction when EMLA was applied topically for 30 to 40 minutes prior to debridement. The meta analysis demonstrated statistically significant reductions in the mean pain scores. Therefore, it was concluded that a significant reduction in pain can be achieved using EMLA prior to debridement.

Although this is useful and the potential for managing pain associated with debridement is obvious, no studies were included in the systematic review or could be found in the literature describing the use of EMLA 5% for the management of chronic pain associated with leg ulceration. There was some evidence to show that the application of topical 5% lidocaine cream applied to burn wounds at concentrations of 1mg/cm<sup>2</sup> offers significant pain relief of long duration of up to 4-6 hours without associated side effects (Pal, Cortiella & Herndon, 1997). In a double blind, controlled study carried out by Rowbotham *et al.* (1996), patients with post hepatic neuralgia (PHN) were given patches to allow for topical absorption of lidocaine 5%. The study demonstrated that topical 5% lidocaine in patch form reduced the pain of PHN. Further, systemic absorption was minimal after 6 hours despite large surface areas being covered. The patches were tolerated for a period of 12 hours without systemic side effects or significant skin irritation. This study was especially useful as it showed that the LA was effective on neuropathic pain.

Reports of toxicity associated with the topical use of local anaesthetics have mainly been observed with its application to mucosal membranes leading to rapid absorption and the application of lidocaine gel to large burn wounds causing seizures in children (Pal, Cortiella & Herndon, 1997). Others stated that hypersensitivity reactions and systemic toxicity from EMLA were extremely rare (Huang & Vidimos, 2000). The

studies included in the Cochrane review (Briggs & Nelson, 2010) showed similar adverse reactions in the EMLA and placebo groups, these reactions were minor and included itching and burning.

The main concern with using topical LA for the management of pain associated with leg ulcers appears to be the unknown potential effect that LA may have on healing.

EMLA has a biphasic action on cutaneous blood vessels, with a vasoconstrictive effect that is maximal after 1 hour, followed by vasodilatation 2 to 3 hours after application. Whether or not this affects healing is unknown (Bjerring & Arendt-Nielsen, 1989). Studies that measure the effect of LA on healing are required, although healing may not be the main priority for all patients with leg ulcers. Thus, for these patients symptom management becomes the priority.

### **2.7.3.2 Topical ibuprofen**

None steroidal anti-inflammatory drugs (NSAIDs) have analgesic, anti-inflammatory and antipyretic properties. They should be used for mild to moderate pain associated with injury or inflammation, they can also be given in combination with opioid medications for the treatment of severe pain (Manning & Richer, 2003). However, elderly patients given NSAIDs are at greater risk of gastric and renal side effects than younger patients and the incidence of side effects is increased when longer half-life NSAIDs are used, therefore these should be avoided in the elderly (Macintyre, Upton & Ludbrook, 2003). Between 1964 and 1985, 600 deaths were reported in the UK to the committee on safety of medicines in association with the use of NSAIDs; 90% were people aged 60 years or more (CSM, 1986). NSAID use in the elderly is vast, Worldwide 30 million patients use prescription NSAIDs on a daily basis and half of these patients are over 60 years of age (Ruoff, 1998).

There was some suggestion that NSAIDs should not be used for pain management of wounds because of the associated negative impact on healing (Enoch, 2006; NHS, 2010). However, the debate regarding the impact of NSAIDs and impact on healing is on going. Much of the research associated with NSAIDs and the impact on healing has focused on bone healing (Bandolier, 2004), and ophthalmic surgery (Lindstrom *et al.* 2006). The Bandolier review concluded that there was no good clinical evidence that NSAIDs inhibit bone healing (Bandolier, 2004). Caldwell and Reilly (2007) investigated the impact of nepafenac (NSAID) on healing following ophthalmic surgery. This study was of particular interest because they administered nepafenac in one eye and saline in the other, therefore reducing patient bias. This was a randomized, double masked

study involving 66 participants (132 eyes). No differences with regard to epithelial healing time were apparent and all the participants eyes were healed by day 4 following surgery. There was further evidence with regard to NSAIDs effect on healing on surgical wounds. Busti *et al.* (2005) undertook a review to determine impact from NSAIDs on healing in surgical patients. They concluded that it was only possible to rely on either small animal studies or extrapolation of data from human studies that did not specifically look at wound healing. Therefore, no clear consensus existed with regard to withholding NSAIDs to promote healing. There were no studies investigating the use of oral NSAIDs for patients with chronic wounds and healing outcomes. However, there were studies investigating the use of topical NSAIDs for pain management of leg ulceration. These studies reported that topical NSAIDs did not deter healing (Gottrup *et al.* 2008; Jorgensen *et al.* 2008). In an editorial discussing the impact NSAIDs have on wound healing, the author concluded that it was not possible to state that NSAIDs impact negatively on wound healing and that further research was required (Salcido, 2005).

Ibuprofen should be the first choice of NSAID drug therapy (Griffin, 1998). No studies could be identified that investigated the use of oral ibuprofen in the management of leg ulcer pain. However, there were studies investigating the use of ibuprofen as a topical agent for the pain management of leg ulceration.

The Cochrane review carried out by Briggs and Nelson (2010) looking at topical agents or dressings for pain in venous leg ulcers included a review of the use of topical ibuprofen. They identified seven studies but only two of the studies met the inclusion criteria. Gottrup *et al.* (2008) was an RCT double blind study, comparing a non-adhesive foam dressing with ibuprofen (Biatain-Ibu) ( $n=62$ ) with a non-adhesive dressing without ibuprofen ( $n=60$ ). Patients in the ibuprofen group were statistically significantly more likely to have reduced pain. Moreover, the study required patients to swap treatments at day 43-47. Patients who had been receiving ibuprofen experienced an increase in pain once dressings without ibuprofen were administered. Healing rates were found to be similar. The other study included in the review was undertaken by Romanelli (2009). This study measured the effect of a foam dressing that released ibuprofen ( $n=98$ ) compared with local best practice ( $n=87$ ). Patients were randomised to either topical ibuprofen or local best practice (LBP). The study included 185 people with ulcers of different aetiology; wound pain was evaluated by the patient in the morning and evening on a five point verbal rating scale. The pain relief was statistically significantly better for the ibuprofen-dressing group, pain intensity reduced from

baseline 6.2 to 3.5 after 24 hours. The LBP group had a pain reduction from 5.1 to 4.1. This study also recorded changes in oral concomitant pain relieving medication and showed that 26% of the ibuprofen group decreased their dosage compared with just 5% in the LBP group. There was no information with regard to concomitant analgesic type and again this study did not compare with a group taking oral NSAIDs. Patients had their pain assessed daily using a 5 point verbal rating scale over 7 days of treatment. However, the results formed part of an International study where the sample size was calculated to be more than 800 patients. The authors stated that the results were not powered and the full report would be reported at a later stage.

Briggs and Nelson (2010) concluded in their review that if reductions in pain from both the Gottrup *et al.* (2008) and the Romanelli (2009) studies were statistically significant then this would be clinically relevant. They were unable to compare pain score reductions because there was no variance data from both studies.

The most comprehensive study with large numbers involved recruiting patients from 12 countries across Europe, Israel and Canada (Domenech *et al.* 2008). Eight hundred and fifty three people were recruited to this study. They received either Biatain Ibu or local best practice. The treatment group had a pain intensity reduction of 3.7 compared with 1.5 for local best practice. However, this study did not include a group receiving placebo and the patients were not blinded to their treatment. A study carried out by Jorgensen *et al.* (2008) investigating the use of Biatain-Ibu also collected data on the dressings ability to absorb exudates and minimise leakage, ibuprofen content, reduction in wound area and adverse effects. Twenty four patients with painful venous leg ulcers were recruited. Wound pain decreased from a mean and SD of  $6.3 \pm 2.2$  at baseline to  $3.0 \pm 1.7$  at 12 hours. Jorgensen, Friis, and Gottrup (2006) carried out a single blinded cross over trial using a pre-treatment period of two placebo dressings, a test treatment period of five active foam dressings containing ibuprofen and a wash out period with two placebo dressings. The patients were aged between 58 and 89 years (mean=82.9years), all had venous leg ulcers and most of them had leg ulcers before. The Biatain-Ibu treatment correlated with a decrease in pain intensity scores from 7 in the pre-treatment period to approximately 2.5 in the Biatain-Ibu phase. Patients were also assessed for blood plasma levels of ibuprofen, blood serum samples showed no ibuprofen. However, only 10 patients were included in the trial.

Another study investigating the use of topical ibuprofen used case series methodology and collected qualitative as well as quantitative data (Flanagan, Vogensen & Hasse,

2006). This study had small numbers ( $n=10$ ; 5 men and 5 women). Participants were treated with the foam dressing releasing ibuprofen for six dressing changes, followed by non-pain relieving foam dressing in the non-active treatment phase. Pain was found to be significantly greater at baseline compared with the active treatment phase. Pain was also significantly higher one week after the study compared to pain assessed at active treatment phase.

These studies suggest that ibuprofen maybe useful when applied topically for management of pain associated with leg ulceration. However, none of the studies investigating topical ibuprofen used a control group taking oral NSAIDs. It would be useful to measure the effect against a group taking oral ibuprofen. Studies investigating the use of topical NSAIDs in other chronic painful conditions, have demonstrated similar analgesic and gastric effects between oral NSAIDs and topical NSAIDs (Hosie & Rapier, 1993; Sandelin *et al.* 1997).

### **2.7.3.3 Topical opioids**

The mechanism of opioid therapy up until recently has been based on a systemic action with the opioid action exclusively relating to the central nervous system (CNS) (Stein, Machelska & Schafer, 2001). Patient case studies and controlled trials are showing evidence that opioids may have a positive effect when used topically. These analgesic effects have been shown to be particularly prominent in inflammatory conditions and have been demonstrated in humans and animals (Stein, Machelska & Schafer, 2001).

Vernassiere *et al.* (2005) assessed the efficacy of topically applied morphine on painful skin ulcers. They applied 10 milligrams of morphine with intrasite gel ( $n=11$ ) or intrasite gel with placebo ( $n=10$ ) daily for five days. Only 2 patients in the morphine group had complete pain relief compared with 1 in the placebo group. The authors suggested that morphine cannot be an alternative to morphine administered by other routes in painful skin ulcers. Jansen *et al.* (2009) undertook a pilot study to investigate the pain relieving properties of topically applied morphine on arterial leg ulcers. The study was double blind, placebo-controlled and had three-way crossover to determine the effectiveness of topically applied morphine compared with systemic morphine and placebo. This pilot study involved 9 patients who each received the three treatment arms, each treatment lasted 24 hours. The study determined that there was no difference in treatment outcomes in terms of pain relief provided. The authors suggested that topical morphine did not have a clinically relevant analgesic effect in patients with arterial leg ulcers. However, for both studies numbers were

small and perhaps studies with larger numbers would produce statistical differences. There were studies that had investigated the use of topical morphine and/or opioids for skin ulcers. In a study undertaken by Zeppetella, Paul and Ribeiro (2003) ( $n=5$ ) patients with painful sacral sores were treated for two days either with 10mg morphine sulfate or placebo (water) applied topically to the ulcer. The mean VAS score for all patients given placebo was 47mm and for patients given morphine the mean VAS score was 15mm, the two groups were compared and the differences were shown to be significant, despite small numbers.

A locally acting opioid analgesic would be advantageous in patients with pain associated with leg ulcers, as it would allow systemic medication to be reduced or avoided. This could result in fewer systemic adverse effects, which is particularly pertinent to the older adult. The use of topically applied opioids to manage pain associated with leg ulcers maybe of particular benefit, it is something that requires further research.

#### **2.7.3.4 Summary**

In summary this patient group has been poorly served regarding evidence of pharmacological pain management. There were no trials investigating any oral analgesics either to manage nociceptive pain or neuropathic pain. The focus of pain management appeared to be on managing procedural pain rather than managing the chronic pain that patients have described in various studies. There was an obvious lack of focus on the pain associated with leg ulceration in the pain literature. An example of this can be provided by looking at the number of publications discussing leg ulceration compared with other chronic diseases with associated pain, in an international pain journal. A search in the journal "Pain" (between 1978-2010) identified only 2 papers that discussed the pain associated with arterial ischemic disease and none discussed the pain associated with venous leg ulceration, compared with 839 discussing rheumatoid arthritis, 3,570 discussing back pain and 393 discussing post herpetic neuralgia. Due to the lack of empirical evidence investigating pharmacology to manage pain for this group of patients, we cannot determine the effectiveness of pharmacological strategies. Further research is required to investigate analgesic effectiveness in managing chronic pain associated with leg ulceration.

#### **2.7.3.5 Non-pharmacological Management**

The only study investigating non-pharmacological management was a trial undertaken by Ravenscroft *et al.* (2000). They performed a double blind, randomised, controlled pilot study to assess the effect of a single application of transcutaneous electrical

nervous stimulation (TENS) on leg ulcer pain. Eleven patients were recruited and randomised to receive a 30 minute application of either active TENS ( $n=6$ ) or placebo TENS with no current output ( $n=5$ ). Baseline pain level was recorded using a six point verbal rating scale. TENS reduced pain in 5/6 patients in contrast to placebo TENS in which 1/5 patients reported less pain and 2/5 reported increased pain. This pilot study suggested that TENS might be beneficial in alleviating pain associated with leg ulceration. However, far more research is required with much larger study numbers before any conclusions can be made. There does not appear to have been any follow up work to this, which was a pity as this form of pain management would be ideal for the older age group, due to the nature of TENS. It is non-pharmacological and has no side effects. It can also be applied by the patients and is relatively cheap and easy to use.

#### **2.7.4 Summary**

The evidence from qualitative and quantitative work seems to suggest that patients take analgesics such as paracetamol and codeine with poor effect and use self-management techniques such as massage, leg elevation and walking. There was no evidence available on the use of drugs for neuropathic pain associated with leg ulcers such as tricyclic analgesics and anticonvulsants. There was also an absence of report in any of the studies of patients having their pain measured and assessed. The reasons for poor pain management in this patient group were not reported on. When looking at the available evidence it seemed apparent that patients were not having adequate pain management for chronic pain. The evidence suggested that analgesics were taken that would be suitable to manage acute mild pain such as paracetamol and codeine. However, there was limited evidence to demonstrate how these drugs were taken and how frequently they were taken. Therefore, it was not possible to determine if it was the drug or the way the drug had been taken that created inadequate analgesia. Leg ulceration affects predominantly older people and it is apparent that older people are less likely to have their pain managed. This is due partly to changes in pharmacokinetics or rather fears of side effects and polypharmacy. Moreover, studies investigating pain assessment within the community suggested that assessment of pain was not routine. Thus, this group of patients appear to be at risk of poor pain management because of lack of pain assessment activity amongst community nurses, the lack of pain assessment and appropriate management in older adults, focus of care appears to be on the healing aspect and because the pain associated with leg ulceration is likely to be chronic and may also have a neuropathic component. The limited evidence regarding analgesic

use in this patient group suggested that pharmacology for acute pain management was being used and the neuropathic component did not appear to be addressed. Therefore, this may offer an explanation as to why there appears to be such a deficit in the prescribing habits for pain management in this patient group.

The focus of research investigating pharmacological pain management has been on the procedural pain. There was also a focus of pharmacological management using topical agents such as local anaesthetic, ibuprofen and topical morphine. From the available literature investigating methods of pain management, it can be assumed that LA application can be useful in managing pain associated with debridement and dressing changes of chronic leg ulcers. There may also be some potential for the use of LA with management of chronic pain associated with chronic leg ulcers especially as it appears to have an effect on neuropathic pain and nociceptive pain. Studies investigating the use of topical ibuprofen have shown promising results but it would be interesting to compare the use of topical ibuprofen with oral ibuprofen. The work investigating the use of topical morphine was interesting but further work is required before conclusions can be made.

Whilst there were studies investigating pharmacological modalities to manage pain associated with leg ulceration these were limited. It appeared that chronic pain associated with leg ulceration has been poorly served by drug trials. The lack of research investigating pharmacological management to manage chronic pain associated with leg ulceration was apparent.

## **2.8 Conclusion**

Leg ulceration in people 65 years and over is a frequent complaint. Prevalence amongst older people is higher than in the general population. Prevalence rates amongst people aged 65 years and over are reported as between 0.26 to 8.5/1000 (Baker *et al.* 1991; Nelzen, Bergqvist & Lindhagen, 1991; Nelzen, Bergqvist & Lindhagen, 1994; Nelzen, Bergqvist & Lindhagen, 1996; Marklund, Sulau & Lindholm, 2000; O'Brien *et al.* 2000; Margolis *et al.* 2002; Moffatt, Franks & Doherty, 2004). Thus, in the older population of people 65 years and over development of leg ulceration is a real risk and this risk increases as the individual ages. In the majority of patients it was associated with venous disease but in reality was almost invariably multifactorial; and there was a high rate of recurrence. Furthermore, recurrence and problems with healing are associated with older people.

Leg ulceration has been shown to cause a significant amount of pain to individuals. Pain can be an expected consequence to any wound and can be considered a normal physiological response. Hyperalgesia is an aspect of wound pain and is considered part of normal physiology. Therefore, it can be assumed that the majority of patients with leg ulceration will have pain regardless of leg ulcer type. However, because chronic wounds remain in the inflammatory healing phase, risk of neuropathic changes associated with hyperalgesia, are greater. The risk of extended hyperalgesia was also apparent in older adults. Report of pain from people with leg ulcers has been clearly demonstrated in qualitative and quantitative studies. Moreover, neuropathic pain is likely to occur in some patients. The case of neuropathic pain has been highlighted by Briggs *et al.* (2007) and by word descriptors used when describing pain, from various qualitative studies and from Park, Ferreira and Santos (2008) quantitative study. Thus, it can be assumed that an individual with leg ulceration is likely to suffer with pain. The evidence is unequivocal. Pain is associated with all types of leg ulcers, venous, arterial as well as ulcers with mixed aetiology (Ebbeskog, Lindholm & Ohman, 1996; Briggs & Flemming, 2007; Briggs *et al.* 2007). When looking at the management of leg ulceration and how this impacts on the pain experience, it appears that aspects of the treatments used to promote healing of the leg ulcer either exacerbate or relieve pain. Of course the fact that surgical/mechanical debridement caused pain was not a surprise, with an already painful and inflamed wound, stimuli of this form was going to cause a substantial amount of pain. When it is considered that the site potentially has allodynia and hyperalgesia and may have a neuropathic pain element, pain associated with sharp/mechanical debridement should be an expected outcome. The literature suggested that the one therapy that has been shown to have positive outcomes in healing also has negative outcomes in pain. The gold standard for treatment of venous leg ulcers is the use of compression therapy (Cullum & Roe, 1995; Meyer *et al.* 2002; Mekkes *et al.* 2003; Moffatt, McCullagh & O'Connor, 2003; O'Brian *et al.* 2003; Briggs *et al.* 2004; RCN 2006; O'Meara, Cullum & Nelson, 2009). It is unfortunate then that compression therapy may exacerbate the pain of leg ulceration. Various qualitative and quantitative studies have provided evidence that compression bandaging in some cases was so painful that the patients were not able to tolerate it (Ebbeskog & Emami, 2005; Briggs & Closs, 2006; Mudge *et al.* 2006; Heinen *et al.* 2007). The pain associated with compression therapy is perhaps to be expected when these patients are also reporting neuropathic pain. Allodynia is a likely characteristic of neuropathic pain (Wall, 1991). Thus, applying a tight heavily layered bandage can be expected to cause further pain. The literature review also

examined pain experience in people 65 years older because leg ulceration is more prevalent in this age group. If there are changes in physiology and experience this will impact on the pain experience, report and eventual management. With regard to physiological changes in pain for older people, studies have shown that there are some physiological changes. However, the true impact of this was not conclusive. It can be summarised from the available work in elderly person's pain experience, that an elderly person may have some differences in how they perceive their pain. However, their intensity is just as great and it could be that their ability to describe, or express their pain is different. Further, it was apparent that older people are less likely to have their pain managed and this is due partly to changes in pharmacokinetics or rather fears of side effects and polypharmacy.

Despite the fact that leg ulceration causes pain there was a smattering of evidence with regard to the management and assessment of this pain. The evidence suggested that pain assessment was not a routine activity amongst community nurses (Roe *et al.* 1993; Hollinworth 1995; Kammerlander & Eberlein, 2002; Lorimer, Harrison & Graham, 2003; Breivik *et al.* 2006). The reasons for poor pain management in this patient group were not reported on. However, further research is required to establish an accurate estimate of pain assessment amongst community nurses. The evidence suggested that analgesics may not be effective, however it was not clear if it was the type of analgesic or the way it had been taken (e.g. as required or regularly). There was no evidence available on the use of drugs for neuropathic pain associated with leg ulcers such as tricyclic analgesics or antiepileptic's (e.g. amitriptylene, gabapentin, pregabalin). When looking at the available evidence it seems apparent that patients are not having adequate pain management for this chronic pain. From the available literature investigating methods of pain management, it can be assumed that LA application can be useful in managing pain associated with debridement and dressing changes of chronic leg ulcers. There may also be some potential for the use of LA with management of chronic pain associated with chronic leg ulcers especially as it appears to have an effect on neuropathic pain and nociceptive pain. This comprehensive literature review has failed to identify any research that aimed to understand why patients with leg ulceration continue to have pain, despite evidence that this patient group have pain and despite the availability of pain management techniques. There was a lack of evidence discussing the pain experience and the impact that pain may have on the individual, particularly within the context of the pain literature.

Research was required to investigate what patients are doing to manage their pain. More information about analgesics used, how they are being taken and why they are not effective was needed, as well as investigation concerning the apparent lack of management of neuropathic pain.

Nurses predominantly care for this patient group therefore; investigation about nurses' attitudes and knowledge regarding pain management of patients with leg ulceration was required. This allowed for further understanding of what was happening with regard to pain management for this patient group.

In summary the literature review has shown

- i. Chronic leg ulcers are common in people 65 years and over.
- ii. The pain associated with leg ulcers can be described as chronic with nociceptive and neuropathic components.
- iii. Persons with leg ulcers frequently reported pain as a symptom, and reported that it was under managed, especially with regard to techniques being used to promote healing in the leg ulcer.
- iv. The literature suggested that older people's pain experience may show some differences in how they perceive their pain, however the intensity is just as great as younger persons and it could be that their ability to describe, or express their pain is different.
- v. The literature suggested that pain assessment of patients being cared for in the community, was not adequate.
- vi. The literature suggested that the current pharmacological management for pain associated with leg ulcers, did not address the apparent chronic, neuropathic element.

## **2.9 Aims of the research**

The literature reviewed suggested that in relation to pain associated with chronic leg ulceration the following questions remained unanswered.

- i. What is the nature of pain associated with chronic leg ulceration?
- ii. What are the outcomes for patients with pain associated with their chronic leg ulcers?
- iii. What are people with pain associated with leg ulcers doing to manage their pain?

- iv. What reasons are there for inappropriate pain management?
- v. What do nurses looking after these patients understand about the pain?
- vi. What strategies do nurses use to manage their patients' pain?
- vii. Do nurses have confidence in managing pain for this group of patients?

These questions have been incorporated into 2 overall aims of this PhD thesis, which were:

**Aim 1.** To understand the experience of having pain from leg ulcers and to develop theories about why the pain relief for people with leg ulcers is sub optimal. To address questions i-iv.

**Aim 2.** To investigate community nurses' views about the management of the painful leg ulceration, using findings from study one as a basis. To address questions iv-vii.

These aims are addressed by two studies (Study 1 and Study 2). Chapter 3 describes study 1. This was a grounded theory study, which attempted to answer the question posed in aims i-iv. Chapter 4 portrays a feasibility census survey of the population of community nurses employed by a primary care trust in the north of England, to address aims iv-vii.

## **Chapter 3**

### **Study 1: “Never Mind the Pain Heal the Ulcer”.**

#### **A Grounded Theory Study of Older People with Painful Leg Ulceration.**

##### **3.1 Introduction**

Pain associated with leg ulceration has been widely reported in the published literature. This pain has been shown to have nociceptive and in some cases neuropathic pain mechanisms. Reports of pain from people with leg ulcers have been demonstrated in both qualitative and quantitative studies.

Briggs *et al.* (2007); Heinen *et al.* (2007); Park, Ferreira, and Santos (2008) and Price *et al.* (2008) provided empirical evidence that patients with leg ulceration are very likely to have pain. These papers described the intensity of the pain experienced and provided some information about the nature of the pain. However, there was little if any evidence related to the outcomes of the pain for the patients. The report of pain within the qualitative research arena was also apparent (Walshe 1995; Chase *et al.* 2000; Douglas 2001; Husband 2001a; Husband 2001b; Hopkins 2004; Ebbeskog and Emami 2005; Flaherty 2005). Yet, the majority of these qualitative studies did not specifically investigate pain. Rather, they investigated what it was like for people to live with leg ulceration. Whilst they discussed the presence of pain, the nature of that pain and its management were not fully explored. Pain was identified as a theme which was then discussed within the results of the papers. Krasner's (1998) was the only qualitative study that specifically investigated the pain experience. Krasner used phenomenological methods and therefore described the lived experience, but did not develop theory as to what had caused the patients to experience what they described. Phenomenology, rather than developing theory development, focuses on the lived experience of the individuals being studied (Thorne, 2000). Husband (2001a; 2001b) and Douglas (2001) undertook grounded theory studies investigating patients with venous leg ulceration. Husband's (2001a, 2001b) study had some interesting elements but it did not provide in-depth information about the pain experienced. It also did not discuss the impact or subsequent outcomes of the pain, it simply identified that patients had pain that was not managed. A major category identified by Douglas (2001) was the physical experience of ulcers, and pain was a category within that category. However, Douglas's discussion focused on the impact of pain on patients'

compliance with treatment. Thus, the focus of the work remained on the healing aspect and it was suggested that by managing pain, patients' compliance would increase. (Flaherty's (2005) study was of particular interest because patients with healed venous leg ulcers were interviewed ( $n=11$ ). There was some description that may suggest that these patients continued to suffer with pain despite their ulcers having healed. Furthermore, this pain was described in such a way that was suggestive of a neuropathic element. However, Flaherty did not discuss neuropathic pain but simply described the pain as something that patients with healed venous ulcers reported.

Overall, the majority of the researchers did not make the link between the pain experience these patients described and the pain experience described by others with chronic pain. Jones *et al.* (2006) discussed their findings, briefly within the context of the pain literature but came to the conclusion that patients with leg ulceration were at risk of depression associated with pain and odour. They did not develop their analysis further to consider the chronic pain condition. The qualitative literature in particular revealed that patients have pain but the pain experience was not developed in greater depth. There was limited discussion of the pain experience within the context of the pain literature. It was apparent from the literature that patients with pain associated with leg ulceration were at risk of developing a chronic pain condition. The topic of pain associated with chronic leg ulceration needs to be explored with more emphasis on the nature of the pain, its management and related outcomes for the patient experiencing the pain.

The literature did not describe the outcomes for patients with pain associated with leg ulceration and it did not describe the nature of the pain from the patient perspective. The problem of pain associated with chronic leg ulceration has been studied; therefore, this research aimed to expand on the theory already developed. The researcher did not want to develop theory that was remote from what had already been described but wanted to focus on verification of theory and hypothesis testing (Strauss and Corbin, 1990), within the context of the available literature. Therefore, this grounded theory study aimed to understand the experience of having pain from leg ulcers and to develop theory which would explain the experience of pain and its outcomes, as reported by the individuals that have pain associated with chronic leg ulceration.

### **3.2 Aim**

This study aimed to provide new insights and theory regarding the experience of pain associated with leg ulceration and the impact the pain experience has on the

individual. Whilst there was evidence that patients with leg ulceration may have nociceptive as well as neuropathic pain and that this pain may not be well managed, there was no available evidence exploring the pain experience in depth, particularly in the context of the pain literature.

### **3.3 Research questions**

- i. What is the nature of pain associated with chronic leg ulceration?
- ii. What are the outcomes for patients with pain associated with their chronic leg ulcers
- iii. What are people with pain associated with leg ulcers doing to manage their pain?
- iv. What reasons are there for inappropriate pain management?

### **3.4 Study design and methodology**

There was limited evidence on the subject of how the patients experienced their pain within the context of their lives. The evidence informs that chronic leg ulceration is painful and that this group of patients suffers as a result. However, there was limited evidence with regard to how these patients manage that pain, the actual impact of the pain on the individual and the outcome of the pain. Thus it was deemed most appropriate to use qualitative methodology to allow for an open exploration of the issues and to generate thematic understanding of the challenges faced by patients. It was likely premature to apply quantitative methods because the salient factors were not known and thus there was insufficient knowledge to determine the variables that ought to be measured. The identification of appropriate variables or measures would have necessitated a certain amount of guessing, which would have been inappropriate and could have potentially given an inaccurate account of what was actually happening. The choice between research methods should depend upon what you are trying to find out (Silverman, 1993).

#### **3.4.1 Qualitative methodology**

Qualitative research has the ability to explore the social meanings of everyday behaviour, which can be derived from people's personal accounts of their experiences. Qualitative research is highly appropriate to address the multifactorial components that encompass a person's coping strategies with chronic pain (Lansbury, 2000). Researchers use qualitative approaches to explore the behaviour, perspectives and

experiences of the people they study (Holloway, 1997). The aim is to investigate the perspectives of the interactants: it is their definitions, meanings, and values given to a phenomenon that will be identified, described and analysed (Chenitz & Swanson, 1986).

Qualitative research has its origin in the interpretive perspective (Holloway, 1997). Interpretivism or the interpretive approach is a direction in social sciences, which focuses on how human beings interpret and make sense of their reality. The interpretivist concept can be correlated to Weber's *Verstehen* approach (*Verstehen* is German for understanding). Weber believed that numerically measured probability is quantitative only and wanted to stress that social science concerns itself with the qualitative. He advised that people be treated as human beings when being studied, and that it was necessary to gain access to their experiences and perceptions by listening to them and by observing them (Holloway, 1997). When undertaking qualitative research, the researcher turns to the human participants for guidance, control and direction. The three most common approaches to qualitative research in healthcare are; ethnography, phenomenology and grounded theory. The difference in these three approaches is in the way the researcher approaches the research.

#### **3.4.1.1 Theory Development**

Theory testing is the primary goal of experimental type research. With this approach theory verification is undertaken using quantitative methods to test concepts and constructs which are set before a study is undertaken. With naturalistic inquiry, the researcher looks for definitions that emerge from the data collection with the aim of grounding or linking concepts and constructs to each observation and description. Glaser and Strauss (1967) described this as a way of generating theory with hypotheses and concepts that come from the data as well as being systematically worked out in relation to the data during the course of the research.

Theory development associated with grounded theory allows the researcher to develop theory based on emergent concepts and their relationships. The researcher develops theory to understand, explain, and give meaning to social and behavioural patterns (Patton, 1990). Theory has been defined as a set of interrelated constructs, definitions and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining or predicting phenomena (Kerlinger, 1973). In this definition, theory is a set of related ideas that has the potential to explain or predict human experience in an orderly fashion and is based on data (Kerlinger,

1973). For the purpose of this study the Strauss and Corbin (1990) grounded theory method was used as it allowed for the verification of current theory and further development of that theory. This method also supports the use of a preliminary literature review before beginning data collection (McCann & Clark, 2003b) as previously discussed in the introduction (section 3.1).

#### **3.4.1.2 Ethnography**

Ethnography has its roots in anthropology. The aim of this approach is to focus on the description of culture. It can be defined as a generalised approach to developing concepts to understand behaviour. Ethnography concerns itself with the study of people either individuals or groups in their natural environment. The researcher when undertaking ethnographic research is required to overtly or covertly, participate in people's daily lives (Sharkey & Larsen, 2005). It is an approach to research that focuses on the study of culture with the aim of understanding how the culture works. Data can be collected in various ways such as observation, interview and use of available records that may support the research. An ethnography is the direct description of a culture or subculture (Holloway, 1997); it is the oldest of the qualitative methods available and has been used in the description of the Greek and Romans. The word ethnography derives from the Greek, meaning "writing of culture" (Atkinson & Silverman, 1997). "Modern" ethnography transpired in the 1920s and 1930s, several researchers exploring cultural patterns and rules, explored a variety of non-western cultures (Holloway, 1997). Anthropologists argue that to understand a group of people it is necessary to engage in an extended period of observation. Anthropological fieldwork involves immersion in a culture over a period of time (Silverman, 2000). Ethnography involves the study of a particular culture (Thorne, 2000); Geertz (1973) describes culture as a system of shared beliefs, ideas, values and knowledge. An ethnography is the direct description of a culture or subculture (Holloway, 1997). Moreover, ethnography requires the researcher to get to know the participants as people (Chesney, 2001). It expects the researcher to not rely on interviews alone but to become immersed within the culture under study (Thorne, 2000).

Ethnography would answer the question; how do people 65 years of age and older understand their pain in relation to their leg ulcer? How does it shape their social interactions and functioning? How do people respond to the individual experiencing pain from chronic leg ulceration? Whilst ethnography would have the ability to answer the research questions for this study, it would not enable entire focus on the individual. The researcher wanted to focus on the individual to allow for an in-depth exploration of

the individual with pain associated with chronic leg ulceration. Furthermore, the methodology would require the researcher to undertake observational work as well as interviewing. To answer the research questions it would have been necessary to observe the patients over a 24 hour period, to capture observation of how these patients experienced and managed their pain. Ethnographic methods would have required the researcher to be present within the individuals' environment for extended periods. Participant observation is the corner stone of ethnography (Savage, 2000). It was not practical or possible for the researcher to observe patients with chronic leg ulceration over a 24 hour period, as these people were predominantly living at home. The researcher did not just want to explore how the patients managed the pain associated with their leg ulcers during dressing changes for example, but also wanted to explore how these patients managed the pain within the context of their everyday lives.

#### **3.4.1.3 Phenomenology**

Edmund Husserl (1859-1938) the German philosopher, is acknowledged as the founder of phenomenological philosophy (Mackey, 2005). The aim of his methods was to reveal knowledge, which transcended human experience. Husserl emphasis was on revealing what he called "the essence" of phenomenon, which exists independently of conscious experience. Therefore researchers will try to find answers to questions about the world and the objects within it, rather than the nature of existence of being. Heidegger challenged Husserl construction of phenomenology as a purely descriptive philosophy. Heidegger considered the actuality of any description being without interpretation. Either in the way of its telling, its recording or its re-telling, to be impossible (Benner, 1985). Heidegger sought to uncover the understanding of the meaning of being and referred to this as "hermeneutic" designating it as an interpretive rather than descriptive process (Mackey, 2005). Phenomenology has been described as being fundamentally a philosophy which was introduced into nursing by Paterson and Zderad (1976). Phenomenology is in contrast to traditional methods of experimentation, phenomenology instructs us to allow for the phenomenon to reveal itself in fullness. Phenomenology endeavours to take a fresh look at phenomena uncontaminated by a priori common sense or scientific impositions (McNamara, 2005). The aim is to capture the richness of a phenomenon as it manifests to the subject who experiences it (Moran, 2000). An aspect of phenomenology is bracketing which involves setting aside the question of the real existence of the contemplated object, as well as all other questions about its physical or objective nature. Bracketing is a term derived from Edmund Husserl (Mackey, 2005) for the act of suspending judgment

about the natural world that precedes phenomenological analysis. Bracketing would have required the researcher to put assumptions, previous knowledge and evidence from the relevant literature aside. The researcher wanted to develop theory within the context of previous knowledge and evidence. Jootun and McGhee (2009) stated that a researcher with previous experiences may provide insight about a patients' experience. This was pertinent to the study because it may have been that the researcher's bias or knowledge regarding pain allowed the researcher to understand the pain experience being described by the patients.

Phenomenology is a genre of research that renounces certain concepts associated with science – reality, objectivity, abstraction and generalisation – and instead embraces experience, meaning, subjectivity and understanding (Paley, 2005). Phenomenology study is the focus on an individual experience, often termed the lived experience. Its aim is for the researcher to discuss the phenomena of the lived experience. The aim is to capture the richness of a phenomenon as it manifests to the subject who experiences it (Moran, 2000).

Phenomenology would have provided an answer to the question; what is the lived experience of having pain associated with leg ulceration in people 65 years and older? What is the nature of the suffering experienced by people with pain from chronic leg ulceration? However, phenomenology does not allow the researcher to develop theory within the context of the available literature (McNamara, 2005). As previously discussed the aim of the research was to develop theory within the context of the current literature pertaining to the research questions. The researcher did not want to just describe the lived experience but rather wanted to explore further what the outcome of the lived experience was. There are already several phenomenological studies investigating patients with chronic leg ulceration. Whilst these studies have provided some interesting insight they did not unpack and explore the impact of the pain on the patients' lives (refer to Chapter 2, section 2.4) or provide explanatory models to guide practice.

#### **3.4.1.4 Grounded theory**

The grounded theory approach possesses methods that are unique compared with other qualitative methods, including the systematic generation of theory from data acquired by a rigorous research method (Glaser & Strauss, 1967). It differentiates from other research approaches because data collection, coding and analysis through memo writing and theoretical sampling occur concurrently. No activity is undertaken

separately and the grounded theory method dictates that all are undertaken in a cyclical fashion (Glaser, 1968a). This means that the method of data collection and data analysis should not be considered as separate procedural steps in the research process, but instead need to be considered as a continuous cycle of data collection, analysis and sampling. It also includes memo writing, as part of the theoretical development. Memo writing is important because it adds to the credibility of the theory because the researcher writes memos and records thoughts whilst collecting and analysing the data. This ensures the researchers' focus remains on the data, ensuring that the theory developed is truly grounded in the data (Eaves, 2001). The nature of carrying out the grounded theory is continuous and using the theoretical sampling and constant comparative methods allows the researcher to explore developing theory with new participants. The aim of which, is to determine if they also have similar experiences and to test if the theory being developed fits with further participants' descriptions. Moreover, unlike other qualitative methods, including ethnography and phenomenology, grounded theory involves the analysis of quantitative as well as qualitative data from review of the literature (Polit & Beck, 2006). A progressive accessing and reading of relevant literature can become a part of the data collection.

For these reasons the author undertook grounded theory as it was most appropriate to answer the research questions and allowed the researcher to verify the existing emerging theoretical insight, within the context of the available literature and further develop new theoretical models.

Grounded theory was developed by two social scientists, Glaser and Strauss whilst working at the University of California. Their first book describing, *The Discovery of Grounded Theory: Strategies for Qualitative Research* was published in 1967 (Glaser & Strauss, 1967). Two classic books were derived from their initial research both published in the 1960s, *Awareness of Dying* (Glaser & Strauss, 1968a) and *Time for Dying* (Glaser & Strauss, 1968b). The aim of grounded theory is to develop theory which is grounded in the data (Charmaz, 1990). Researchers using grounded theory develop theory to create understanding, explanation and give meaning to social and behavioural patterns presented by the cohort being studied (Glaser & Strauss, 1967). Kerlinger (1973) described a theory as a set of interrelated constructs, definitions and propositions that give a systematic perspective of specific phenomena. Therefore, the theory should present a set of related ideas which have the ability to provide an explanation or predict human experience in an orderly fashion based on the data (Kerlinger, 1973). Unlike other approaches to qualitative study, grounded theory

provides a helpful framework for guiding data collection and analysis (Charmaz, 2000). The theory was developed to explore social processes and to reveal the human characteristics of anticipating and responding to various life circumstances (Lomborg & Kirkevold, 2003). Glaser realized the need for an explicit and systematic set of techniques and procedures for both coding and testing hypotheses generated from qualitative research methods (Strauss & Corbin, 1990). Glaser (1992) provided a critique of the overspecialised deductive use of pre-established grand theories in sociology. From this pragmatic position combined with a rigorous, systematic approach, they developed their constant comparative method (Lomborg & Kirkevold, 2003). Following the development of grounded theory both Glaser and Strauss joined the nursing doctoral program at the University of California, San Francisco (Eaves, 2001). Thus, the method of grounded theory was introduced to nursing students, resulting in fairly wide spread use of grounded theory methodology in nursing research (Baker, Wuest & Stern, 1992).

The underlying assumption of grounded theory is that people make sense of and order of their social world even though, to the outsider, their world may appear irrational. Each group experiences a common social psychological problem that is not always articulated (Hutchinson, 1993). Individuals sharing common circumstances (for example, people with chronic pain) experience common perceptions, thoughts and behaviours, which are the essences of grounded theory (McCann & Clark, 2003a).

#### **3.4.1.5 Approaches to grounded theory**

There is some debate and diversity in how grounded theory methods are applied, especially the classic Glaser and Strauss version (Glaser & Strauss, 1967) and the Strauss and Corbin version (Strauss & Corbin, 1990). Essentially both versions have basic similarities as they have both evolved from the original work (McCann & Clark, 2003b).

In one paper examining the issues surrounding current changes in grounded theory it was summarised that the debate is likely to go on for some time (Eaves, 2001).

Further to this, words of wisdom from past mentors state;

*“The issue is not who is right about grounded theory and whether you agree with Glaser and Strauss, Strauss and Corbin, or Glaser. The issue is what you will take from them and do with it and how you will argue for, advocate, and defend your own position”, (Eaves, 2001, p.662).*

Charmaz (2000) believed that every researcher who uses the grounded theory method will tend to develop his or her own variations of the technique. For the purpose of this study the Strauss and Corbin (1990) grounded theory method was used because this allowed for focus on theory verification and development, within the context of the available literature. It also allowed for the researcher to use previous knowledge and experience to provide insight regarding patients' experiences. Therefore, the researcher entered the field of research as a hybrid researcher as described by Jootun and McGhee (2009). A hybrid researcher is someone who researches in familiar territory and who may have inherent biases and assumptions. Therefore the researcher's knowledge regarding pain allowed the researcher to understand the pain experience being described by the patients. Bias is not always a negative component of research, particularly in relation to the grounded theory methodology (Reed & Proctor, 1995). Furthermore, reflexivity is used within the grounded theory methodology which ensures credibility of the theory developed (refer to section 3.9).

#### **3.4.1.6 Summary**

Whilst all three methods of qualitative research could have been used to investigate the pain experiences associated with chronic leg ulceration, the researcher wanted to generate theory to answer the research questions as put forward. This could be achieved using grounded theory, as opposed to ethnography or phenomenology. Ethnographic and phenomenologic approaches do not poses the properties that would enable the researcher to develop new theory regarding the topic of interest. The purpose of this study was to develop theory to explain the experience of the pain and the consequences of the pain associated with leg ulceration with the purpose of answering questions to how, where and why this group of patients had arrived at the place or situation they described. The researcher did not seek to merely illustrate the lived experience or the culture of the group but to truly "unpack" and develop theory as to why they experienced what they described. Moreover, unlike other qualitative methods such as ethnography and phenomenology, grounded theory involves the analysis of quantitative as well as qualitative data from review of the literature (Polit & Beck, 2006). A progressive accessing and reading of relevant literature can become part of the data collection. This was especially pertinent because the researcher wanted to include and expand on the evidence within the literature regarding pain associated with leg ulceration. The researcher did not want to develop new theory that was apart from current theory, rather the aim was to develop new theory within the current evidence, i.e. verification of emerging theory from the existing literature and to further develop this theory with the findings of this research.

### **3.5 Ethical approval and consent procedures**

The participants of this current study were recruited from a primary care trust (PCT) in the north of England; patients having their leg ulcer managed by the PCT were invited to take part in the study.

Ethics committee approval was gained from the local research ethics committee and research governance was adhered to (Appendix 2). Research and development approval was applied for and gained from the local research and development unit (Appendix 3).

All district nurses were provided with information about the study and the screening forms designed to recruit participants. Possible participants were invited by the district nurse to take part in the study; a study information leaflet was given to the patients (Appendix 4). At least one week was given to potential participants for them to decide whether they would like to take part in the study. At a future meeting with their district nurse, if they wished to volunteer for the study the district nurse took personal details that were then forwarded on to the principal investigator. The researcher then made contact with the participant to arrange to obtain signed informed consent and for a time and venue to be arranged for a one to one interview.

### **3.6 Selection of participants**

#### **Inclusion criteria**

- i. Participant is aged 65 years or over.
- ii. Participant is undergoing treatment for a leg ulcer under the care of the primary care trust.
- iii. Participant has a diagnosed chronic leg ulcer below the knee and either above, on or around the malleolus.
- iv. Participant has pain associated with their leg ulcer.
- v. Participant has the cognitive ability and English language ability to undertake the interview.

#### **Exclusion criteria**

- i. Participant's leg ulcer is associated with sickle cell disease.
- ii. Participant has a terminal illness and is being cared for by a palliative care team.
- iii. Participant believes their pain is due to a condition unrelated to their leg ulcer.

Any patients with leg ulcers managed by the PCT were invited to take part in this study during the study period if they met the inclusion criteria. All participants had an active leg ulcer (below the knee and above the malleolus). Participants' medical notes were reviewed to ensure that the participant had the type of leg ulcer diagnosed appropriately using ABPI (ankle/brachial pressure index) measurements as recommended by the Royal College of Nursing (RCN, 2006). This was undertaken to ensure that the participant fitted the inclusion criteria which determined participants had to have a leg ulcer below the knee and above, on or around the malleolus. Logistics of recruitment were discussed with the tissue viability nurse specialists. The tissue viability nurse specialists suggested that community nurses' individual caseloads be screened for suitable participants by community nurses who agreed to assist with this study. The study design was developed in conjunction with the nurse specialists to allow for consideration of the logistics of recruitment and to ensure that extra work for community nurses was limited.

Participants had an opportunity to discuss the study with the researcher if they wished; contact details were provided on the study information leaflet. If participants wished to volunteer for the study, then their community nurse took their contact details and forwarded them to the researcher.

Confidentiality and anonymity of data were assured, only pseudonyms were used and participant study identification numbers were issued at the time of consent. Only study identification numbers were used for computer analysis, personal information was kept on paper and is held in a locked cabinet in the principal investigators office. All data from the study including taped interviews will be stored for five years under lock and key at the University of Leeds.

A grounded theory approach was used, thus sample size was determined once saturation had been achieved.

### **3.7 Data collection**

The researcher carried out all the interviews; which were audio taped with the participants' permission. Data collection using in-depth interviews were undertaken. The interviews were semi-structured as some control of topics to be discussed was assumed, using questions as prompts. It is expected that questions are used as prompts to encourage the participant to discuss issues that are pertinent (Bluff, 2005). During the initial phase of data collection the researcher's knowledge and experience of the topic facilitates the process (Strauss, 1987). Participants were encouraged to speak freely about their experiences and thoughts on pain and its management,

associated with their chronic leg ulcers. The prompts/questions used attempted to gain information on the pain these participants were experiencing and the impact of that pain. The focus of the prompts/questions changed throughout the grounded theory process in line with the constant comparative method.

Example of questions from interview 1

- i. *Can you talk to me about the pain from your leg ulcer?*
- ii. *What do you do to manage the pain?*

However, during the process of the data collection the interviews became more structured to allow for exploration of topics and themes that had come out of the initial interviews.

Example of questions from interview 5

- i. *Can you describe the pain you have associated with your leg ulcer?*
- ii. *Is the pain there all the time?*
- iii. *Does the pain disturb your sleep?*
- iv. *Which analgesics do you take to manage the pain?*

Toward the final interviews questions became much more specific to explore and confirm developing theories. This was undertaken to confirm or disconfirm the developing theory that; patients with pain associated with chronic leg ulceration suffer from a chronic pain condition.

Example of questions from interview 10

- i. *Do you have burning, tingling and pins and needles sensations in or around the leg ulcer and do you experience sudden changes in the pain for no obvious reason?*
- ii. *Does the compression bandaging cause you further pain?*
- iii. *How does the pain affect you psychologically?*
- iv. *What pain killers do you take and do they work?*

The length of the interview was partly dependent on the participants but tended to last between 30-60 minutes. Initially interviews were longer because the discussion covered a larger range of topics. Toward the last few interviews the time of the interview became shorter because topics to be discussed became more focused.

Demographic data were obtained at the end of the interview to be less intrusive than at the commencement of the interview. A face sheet was attached to the top of each interview after transcription to assist in retrieving demographic data. The face sheet contained information such as study number, date of the interview, interview site, age, gender, ethnicity, ulcer type and duration of chronic leg ulceration.

Not more than one interview a day was scheduled; to prevent feeling over loaded (Chenitz & Swanson, 1986) and also to allow for the constant comparison methods. The site of interview depended on the participant's preference, the major consideration being the convenience of the site. Whether the site chosen was at home or in the participant's leg ulcer clinic, privacy was maintained and disruption and interruptions were kept to a minimum.

### **3.7.1 Sampling**

Purposive sampling was used initially; this ensured that participants had knowledge of the phenomenon under investigation. During the process of the data collection using grounded theory, the researcher attempted theoretical sampling. This allows for the researcher to seek out further participants with the aim of developing emerging theories (Glaser & Strauss, 1967). Theoretical sampling was the process of data collection for generating theory. Thus the sampling process was controlled by the emerging theory. To contribute to the development of the emerging theory the researcher sought out participants or situations that both confirmed and disconfirmed the hypotheses (Marcellus, 2005). Initial sampling was determined by the choice of the research situation. Thus, initially any participants that had chronic leg ulceration with associated pain were recruited. As categories emerged from the data the researcher then sought to add to the sample with the purpose of strengthening the emerging theory by defining the properties of the category. The emerging theories could have been related to anyone with pain associated with a leg ulcer, therefore the researcher continued to recruit participants who had pain associated with their leg ulcer. The researcher attempted to specifically recruit more male participants and also participants with arterial ulcers and ulcers with mixed aetiology. However, the nurses were only able to identify a limited number of participants with these specific

characteristics. Therefore the reality was that all patients that were put forward by the nurses were included. This was because they all had pain associated with their leg ulcer, the focus of the theory development was on the chronic pain condition and all the patients put forward were relevant in determining and investigating developing themes.

### **3.7.2 Saturation**

A rule or general practice with qualitative research is that data collection ceases once saturation has been achieved that is when no new information is apparent within the data (Barroso, 2006). Unlike quantitative research there are no guidelines or tests to determine the number needed, rather it is left to the investigator to determine when saturation has been reached (Whitley & Crawford, 2005). Numbers and calculations are not relevant to qualitative research (Pope & Mays, 2000); therefore validity and reliability cannot be determined by numbers of participants. Rather the description and its apparent fit and truthfulness within the theory, relating back to the data, allows for validation (Whitley & Crawford, 2005). Essentially once the codes, which initially may have appeared disconnected and confusing, start to represent a pattern that may demonstrate a theory then saturation is likely. It is important at the beginning of data collection that all data are given equal importance and are not discarded (Morse, 1995). The quantity of data is not theoretically significant in qualitative research. For example it is not the number of times a particular aspect is described; it is the richness of the description that is relevant. It is the infrequent report that may put other data into perspective. This was apparent when some participants reported they had experienced suicidal ideation. Whilst not all of the participants described this, it was the description from some that added to the theory that these patients experienced chronic pain with associated sequelae.

During the process of saturation the report from participants may take on a sense of being predictable. The process of memoing within grounded theory assisted with this process. The researcher had a strong sense of predictability, as documented within the memoing, following the transcription of the seventh interview. The researcher had a sense that the participant would describe constant pain, chronic pain sequelae as well as pain associated with compression dressings. The researcher was cognizant of this sense of predictability and how this may impact on the data collected. Therefore, notes of this were made within the memoing and reflexivity was adhered to, to ensure that the researcher did not bias the data. Whilst this sense of predictability was attained at around participant number seven the researcher continued to recruit participants. The reality with grounded theory is that it is never possible to be entirely sure you have "got

there"; rather it is the ability of describing a theory that is grounded in the data. This is achieved by undertaking the constant comparative method. Furthermore, grounded theory represents and must satisfy four central criteria these are fit, understanding, generality and control (Strauss & Corbin, 1990) these are discussed within the credibility section (refer to Chapter 3, section 3.9). The researcher continued to recruit participants to ensure credibility, by continuing to question and test theory development. It is not possible to state or determine with grounded theory methodology that no new phenomena would be described if one went and interviewed another patient a week later, the next day, a year later etc. Rather, it is suggested that the researcher achieves saturation once a comprehensive and convincing theory has been developed (Munhall, 2006).

### **3.8 Analysis**

#### **3.8.1 Constant comparative analysis**

One way to ensure the validity of findings in grounded theory is through the use of the constant comparative analysis (Strauss & Corbin, 1998). A constant comparison method was used to enhance validity of the findings in accordance with the method of grounded theory. Thus, simultaneous collection and analysis of data and the emergent theoretical structure helped familiarize further data collection. The interviews were taped and transcribed immediately after each interview to allow for analysis of the text. The rationale for this is to allow the incoming information from participants to determine further interview prompts. All the transcription was undertaken by the researcher as this stimulated analysis of the data (Chenitz & Swanson, 1986) and allowed the researcher to become "immersed in the text".

With this approach the data collection, theoretical sampling, analysis and review of relevant literature all occurred concurrently as the study was carried out. Sampling and further data collection were based on the emerging theory (Glaser & Strauss, 1967; Strauss & Corbin, 1998). The researcher used an inductive-deductive approach (going back and forth between the data and the emerging concepts and theory) to generate and extend the theory. Data were systematically collected, organized and examined after each interview. For the first interview, the researcher was asking: What is going on here? What is the situation? Following transcription of the first interview, the second interview was coded with the first interview in mind. Subsequent interviews were then coded with the emerging theory in mind. After a time, core categories began to emerge from this process. Along with memo writing, which aided the development of the codes and emerging theory, the data were returned to and further participants were interviewed to verify the categories being developed. The literature that was relevant to

the emerging theory was also accessed and read with the aim of comparing the literature with the emerging theory, in the same way that data were compared to the emerging theory (Glaser, 1992). The process was a circular one and involved going back to the data and returning to the participants (Marcellus, 2005). The researcher started out with some questions and then based on the participants' responses, further questions focused on areas that had appeared and that had relevance to the emerging theory. The researcher looked for similarities and differences in the data and considered where to go to next to ask questions to clarify emerging theoretical concepts (Glaser & Strauss, 1967; Strauss, 1987). As an example of this process, some participants described having conditions associated with chronic pain such as depression, suicidal ideation and insomnia. In subsequent interviews these issues were further explored.

### **3.8.2 Memo writing**

Grounded theory requires the researcher to write "memos" whilst undertaking the data collection and the analysis, as a means of testing the fit and credibility of the emerging theory (Polit & Beck, 2006). Memoing occurs in parallel with data collection and analysis. A memo is a note made by the researcher to themselves about some idea or beginning hypothesis that he or she has about a property or category and particularly about how the categories relate to one another. This process was undertaken throughout all the data collection and analysis period. Memos were the written record of the researcher's inner dialogue about emerging ideas, hunches, questions and categories (Schreiber & Stern, 2001). The researcher was then able to return to the data, and collect further data, to test the fit of the emerging theory with the data and to confirm or disconfirm these ideas and thoughts. The memos served as a record of the researcher's thoughts about the study, contributed to theory development, and acted as a record of the research process itself (as an audit trail) (Marcellus, 2005).

### **3.8.3 Coding and categorizing the data**

The grounded theory model offers a framework for axial coding, which is the process of relating codes (categories, subcategories, and properties) to each other, through a combination of inductive and deductive thinking. Grounded theorists tend to emphasise causal relationships, and fit things into a basic framework of generic relationship. This framework presents the researcher with the opportunity to understand the data more readily and to develop theoretical coding from the data (McCann & Clark, 2003b).

**Initial Coding** – is the use of open coding that creates a large number of codes; the proliferation of these codes that necessitates considerable reduction. Essentially, each line, sentence and paragraph of the interview transcripts was read in search of the answer to the repeated questions: “What is this about?” “What is being referenced here?” The codes were abbreviated devices used to label, separate, compile and organize the data (Charmaz, 1983). Data analysis was started during the data collection. During the data analysis, categories of codes were identified and developed in terms of their properties and dimensions through a process involving the generation of basic ideas. It is suggested that whilst in this phase the researcher may have difficulty in understanding how the codes are connected to other codes.

**Axial Coding** – is the process of relating codes to each other; it is undertaken through a combination of inductive and deductive thinking. The data from the open coding were assembled in new ways; to allow some more central categories to become evident (Strauss & Corbin, 1998). The development of a category provided the basis for subsequent data collection. The focus of axial coding is on specifying a category in the context in which the themes first appeared (Backman & Kyngas, 1999).

**Selective Coding** – is the process of identifying a central category (occasionally more) to be the core category and relating all other categories to that category. After a time, central categories were found to emerge from the interview data with high frequency of mention, and to be connected to many of the other categories that were emerging. To settle on the final categories, the researcher returned to the data again and again and confirmed that the identified categories were based on the data and were interconnected (Strauss & Corbin, 1990). The goal of grounded theory is to generate a theory that accounts for a pattern of behaviour that is relevant for those involved (Backman & Kyngas, 1999).

To assist with coding and categorizing the data, the NVivo computer program was used. NVivo is designed to allow for inputting qualitative data and has facilities to add coding directly onto the data. It allowed for a relatively comprehensive and thorough assessment of ones data. It did not code or analyse the data for the researcher but was an aid to allow for a more straightforward analysis.

### **3.9 Credibility**

Credibility is a term that relates to ‘How vivid and faithful the description of the phenomenon is’ (Beck, 1993). Credibility relates to the trustworthiness of the findings

(Carpenter, 1995). To ensure credibility the researcher must be convinced of the description that is produced, and the supporting data should be explicit (Glaser & Strauss, 1967). Reflexivity, transparency and trustworthiness are associated with demonstrating credibility within qualitative research (Elliott, Fischer & Rennie, 1999). Reflexivity refers to the researchers acknowledging the bias they may have whilst questioning their findings within the context of their bias. It is accepted that researchers undertaking qualitative research are "co-creators" of the knowledge represented within their theory. It has been suggested that it is not possible for researchers to stand apart from their own humanity whilst creating new understanding (Russell & Kelly, 2002). Whilst undertaking the data collection, analysis and development of theory the researcher undertook a reflective approach. This was undertaken to enhance credibility, to provide assurance that the theory development was an accurate representation of what the participants were describing. Strategies for implementation of reflexivity included a self-reflection diary and the process of memoing as described above, addressed this requirement. Throughout the research process the researcher documented her thoughts, questions, statements and observations within a journal that formed a part of the data set. Furthermore, the processes of the constant comparative method added to the researcher's ability to question and develop theory and ensured that the theory was grounded within the data. Both these processes allowed and enhanced the researcher's capacity to question personal assumptions and goals (Ahern, 1999). This was undertaken to allow the researcher to gaze upon herself with the purpose of attempting to separate her bias from the data and the theory being developed (Russell & Kelly, 2002). A further strategy employed to ensure credibility was the use of an independent coder. Another experienced researcher read the interview transcripts and independently identified categories. The coding was then compared with the researchers work to increase the validity of the interpretation of the results (Appleton, 1995). This is a process that adds to diminishing investigator bias and can be seen as a qualitative form of inter-rater reliability (Mays & Pope, 1995).

Grounded theory represents and must satisfy four central criteria: fit, understanding, generality and control (Strauss & Corbin, 1990). Fit refers to whether the emerging theory fits the situation being explored. The researcher aimed to ensure that the theory was a faithful representation of the everyday reality of the area studied. To ensure fit, the researcher went back and forth from data analysis, data collection, memo writing and reading relevant literature to test out and examine the emerging theory. The researcher observed for recurring actions and interactions, and considered counter

arguments and interpretations before returning to the field thereby verifying the data (Guba & Lincoln, 1994).

Understanding, in this context, refers to the development of the theory and the ability of that theory to be understood, by the people in the situation. The aim is to help the people in the situation under study make sense of their experiences and to help them to manage better their situation (Glaser, 1992). The researcher ensured that the theory was grounded in the data and that the theory represented and gave answers to the situation being studied. For example, patients described being confused regarding the extent of the pain they had (refer to Chapter 3, section 3.10.5.1.2); the developed theory suggested that these patients may have had neuropathic pain. This notion offered an explanation for the affected patients and may serve to help them with their extreme pain.

Generality was demonstrated in the participants' shared experiences; their descriptions informed the theory developed. Again using the constant comparative method and accessing relevant literature the researcher was able to test the emerging theory for generability. For example, the participants described chronic pain sequelae (refer to Chapter 3, section 3.10.3.3), which were further confirmed with subsequent interviews and also in the relevant literature (refer to Chapter 3, section 3.12.2).

The last of the four criteria is control, in the sense of stating the conditions under which the theory applies and describing a reasonable basis for action. For example the conditions in which the theory applied related to the chronic pain condition, in that what the participants described was similar to what people with chronic pain conditions experience (refer to Chapter 3, section 3.12.2).

Another issue to discuss relating to the credibility of qualitative research is respondent validation. Unlike other types of qualitative research respondent validation is not used with grounded theory (Eaves, 2001). The purpose of respondent validation is to prevent bias and subjective rather than objective interpretation during analysis. However, it has been recognised that this form of validation produces yet another data set. This data set cannot be accepted as an absolute test of the accuracy of the findings (Murphy, Dingwall & Greatbach, 1998). Moreover, grounded theory involves itself with developing theory that represents the essence of what the participants report. During data collection the theory is constantly evolving. Thus, the grounded theory method using the cyclical process of constant comparative analysis and theoretical sampling, alongside using the literature as data, ensures a process that

encourages and supports analysing and checking the quality of the research and the emerging theory (Eaves, 2001).

### **3.10 Results**

#### **3.10.1 Study sample**

Twelve participants were recruited over a study period of six months; data collection started in February 2005 and ended in September 2005. Of the 12 people recruited, 11 participants completed the study (see Table 2). One recruit was excluded because she did not meet the study criteria; she did not have pain associated with a leg ulcer.

Initial sampling was determined by the choice of the research situation. Thus, initially any participants that had chronic leg ulceration with associated pain were recruited. Most of the participants had venous aetiology and were female. This was to be expected, as venous leg ulcers are more common in older age groups. There were more women recruited, which was to be expected as chronic leg ulcers are more common in women. Another factor that affected the sample was that not all study sites responsible for recruiting participants put patients forward. The majority did, which allowed for a wide geographical representation of participants. However, one study site did not make any further contact after the initial meeting. The researcher acknowledged that this was in part due to that particular site being under a lot of pressure. This site was under staffed and was situated in a very deprived area. It was therefore of no surprise that the district nurses working in the site did not assist with recruitment. One could suggest that it would have been impossible for the community nurses not to have influenced the selection if they were controlling the selection of participants put forward. The researcher acknowledges this but because of the ethical considerations regarding data protection; it was not possible to gain direct access to patients. This had to be considered to gain ethical approval therefore there was no other way to recruit these patients.

All study participants were white Caucasian. The ages ranged from 68 years to 100 years, with a mean age of 81 years. The chronicity of the disease was varied. However, most of the participants had chronic leg ulcers for at least 2 years with some having had the leg ulcers for 20 years (mean 7 years).

**Table 2: Demographics of Study Participants**

Study Number & Gender	Ethnicity	Age	Leg Ulcer Type	Chronicity
1 Female	White Caucasian	83	Venous	20 years
2 Male	White Caucasian	90	Venous	18 months
3 Female	White Caucasian	84	Venous	10 years
4 Female	White Caucasian	100	Venous	1 year
5 Female	White Caucasian	79	Venous	2 years
6 Female	White Caucasian	81	Venous	8 months
7 Female <i>(Patient withdrawn from study because she did not have pain related to her leg ulcer).</i>	White Caucasian	77	Venous	2 years
8 Male	White Caucasian	72	Arterial	2 years
9 Female	White Caucasian	68	Mixed aetiology Venous/arterial	3 years
10 Female	White Caucasian	77	Arterial	20 years
11 Female	White Caucasian	97	Venous	7 months
12 Female	White Caucasian	69	Mixed aetiology Venous/arterial	15 years

### 3.10.2 Description of codes

**Initial Coding** -In the stage of initial coding 34 codes were identified (see Table 3). During the data analysis, categories were identified and developed in terms of their properties and dimensions through a process involving the generation of basic categories.

**Axial Codes** – During this process seven central categories were identified (see Table 3).

Codes fitted into one or more categories.

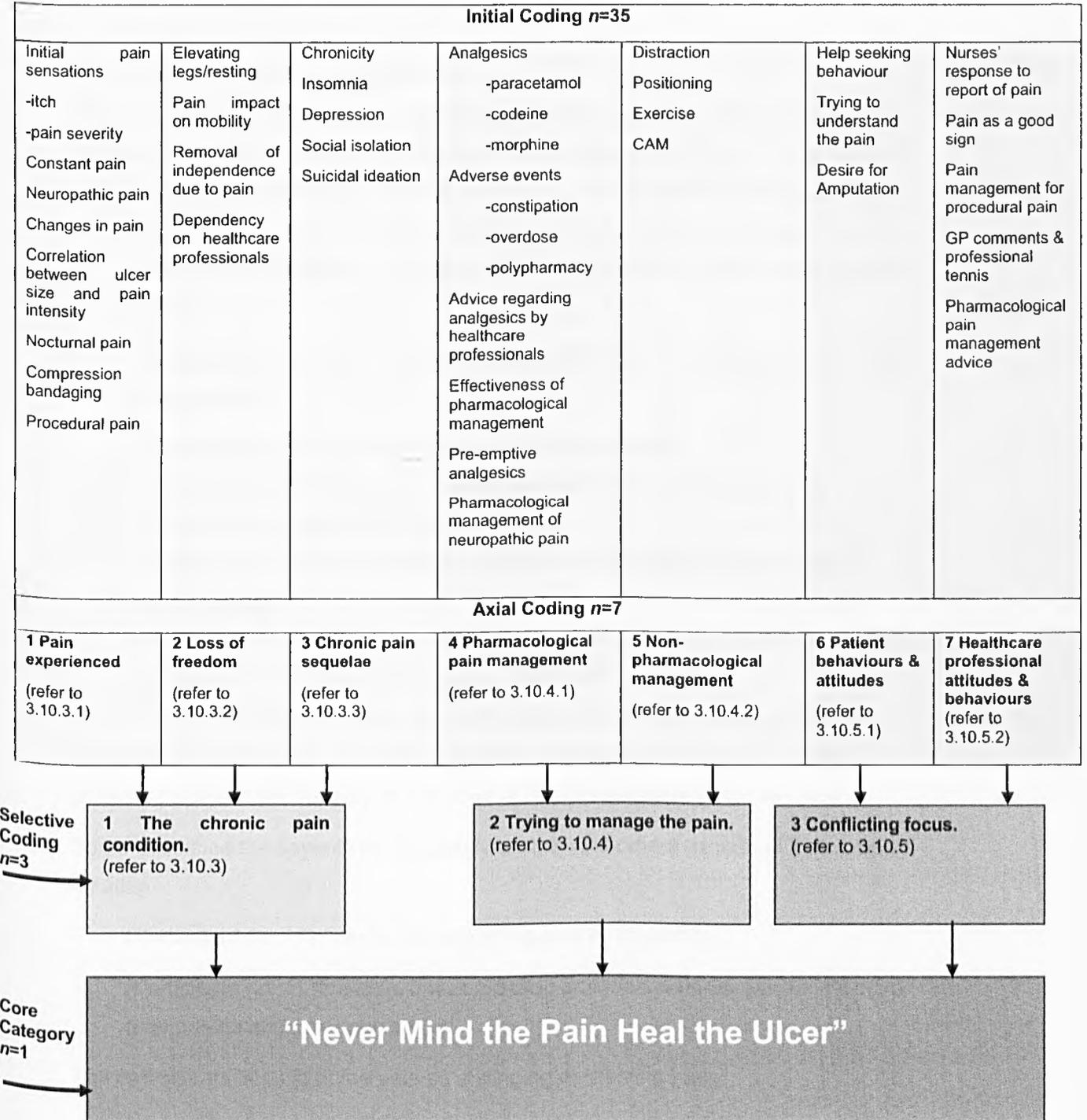
These categories were:

- i. Pain experienced.
- ii. Loss of freedom.
- iii. Chronic pain sequelae.
- iv. Pharmacological pain management.
- v. Non-pharmacological pain management.
- vi. Patient attitudes and behaviour.
- vii. Healthcare professionals' attitudes and management of pain.

Selective coding identified three central categories: the chronic pain condition, trying to manage the pain and conflicting focus.

The core category "Never mind the pain, heal the ulcer", became the core category theme that was grounded in the data.

**Table 3: Diagram of Coding**



### **3.10.3 The chronic pain condition (selective code 1)**

This selective code had 3 codes, which are described below.

#### **3.10.3.1 Pain experienced (axial code 1)**

This axial code was generated from eight initial codes.

##### **3.10.3.1.1 Initial pain sensations**

The participants gave descriptions of their pain before and when the ulcer developed. Some reported that it was the pain that led them to seek medical help. The severity of the pain was often reported as different and some patients reported itching sensations.

(Participant no. 1) *"I didn't go to the doctors at first because I thought I had been bitten by something, but as soon as it started and I felt the pain I rang the nurse"*.

(Participant no. 4) *"Once it started it hurt, it hurt then I thought you know, I went to the doctors"*.

(Participant no. 3) *"The itching was just in the beginning"*.

There was some report of the pain not being that bad initially, it was only once treatment was commenced that it became painful.

(Participant no. 6) *"It seemed to be alright when they dressed it, that night it started to sting"*.

(Participant no. 11) *"It was treated then but oh the pain it was really, it was terrific. I can't say it was ordinary it was really, really bad"*.

There was a difference in the severity of the pain reported at the point of the development of the ulcer. There was no obvious reason for this and it was not possible to predict the severity at this point of the development of the leg ulcer.

Some described the severity as absolutely terrible and others described it as simply irritating.

(Participant no. 11) *"Yes at the beginning absolutely terrible"*.

(Participant no. 4) *"Irritating, it was irritating and then became painful, it's more than painful and has been since"*.

The participants described the pain as a stinging or irritating pain;

(Participant no. 9) *"A stinging pain, like a stinging pain"*.

(Participant no. 4) *"It was just irritating"*.

Some participants connected the severity of pain with the position of the developing leg ulcer.

(Participant no. 10) *"Well I got pain almost immediately; it's very noticeable if it got anywhere near the bone. It immediately starts becoming worse the fleshy parts not too bad but when it's near the bone. On the bone I've got two leg ulcers one either side and one is a very small one and that's a painful sod, but the other ones not bad at all".*

There was some description of feeling the ulcer there even before it developed; there was some evidence that patients could predict that an ulcer was about to develop because of the sensations they were experiencing.

(Participant no. 12) *"I can feel them under the surface until they break down".*

### **3.10.3.1.2 Constant pain**

(Participant no. 2) *"Well it's painful... I think painful all the time; it's like a sore all the time".*

The participants predominantly reported that they had persistent pain, which may have changed in nature but not necessarily in severity. Some described the pain as coming and going but they reported experiencing some sort of pain all the time.

(Participant no. 8) *"I've some sort of pain all the time, it can come and go".*

(Participant no. 10) *"Then I get more constant you are aware of it, you feel it coming through".*

Others described moments of relief but these were brief and soon the pain recurred.

(Participant no. 11) *"It went off a bit and then came back again, it goes off for a bit and I think oh that's lovely but then it came back".*

### **3.10.3.1.3 Neuropathic pain.**

The participants often described their pain using neuropathic pain descriptors; some would talk about their nerve pain.

(Participant no. 1) *"No it's a sharp it's um, it's an intense pain when it's really bad it's very intense it's not sharp having said that sometimes when I am sitting there with my foot up the pain will start it jumps".*

(Participant no. 2) *"It gives me a kick it wakes me up sometimes".*

(Participant no. 4) *"As I'm sitting now my toe, my toes it's pricking".*

(Participant no. 5) *"It's the tingling and firing pain that gets on me nerves sometimes it shakes".*

(Participant no. 6) *"As though they were stinging me all the time".*

(Participant no. 8) *"It makes me jump when I'm sitting quietly, it makes me jump, it's just an annoying pain sometimes just annoying".*

(Participant no. 9) *"It feels like they are putting a bar on it, a red hot bar on it".*

(Participant no. 12) *"It's like a nerve pain really".*

(Participant no. 2) *"I can feel it sometimes shooting up my leg then it goes off again".*

(Participant no. 8) *"This is a massive hole here, but it does not hurt there. It hurts anywhere else but there. I can press here it gives pain out there".*

(Participant no. 8) *"It's all sorts of pains I can get sometime. I'm sitting in my chair and for no reason it's like a knife in me leg. After about 5 seconds it's gone and it might not reoccur again for a couple of hours. It might reoccur in a couple of minutes".*

(Participant no. 9) *"Always burning like a normal pain, but every now and then it's a burn".*

The participants also described allodynia and hyperalgesia, albeit not with those terms. Rather, their descriptions suggested occurrences of allodynia and hyperalgesia.

(Participant no. 12) *"It's like a nerve pain that never ends, that's the only thing I can describe. It's like a nerve pain that gets really bad; it comes down a bit but lasts for a long time. Um I wonder if it is a nerve pain anyone coming near me, I mean even just sit on the bed it just sets it off and I scream. It's to say that nerves just a little thing aggravates it just the pain comes on hard".*

(Participant no. 12) *"I could not stand the water on it; the pressure of the water was too much. That's why I could not have a shower on it".*

(Participant no. 3) *"It's continuous, but its considerable I can bear the impact and treatment, dressing anywhere except on one little spot".*

(Participant no. 9) *"Um, well down here it's different. Now last week and the week before, it was absolutely murder just to touch it with the gauze, but this week I could stand it".*

One participant discussed the pain caused by wearing footwear and gave a clear description of allodynia.

(Participant no. 12) *"Through the winter for two years I just wore sandals, we bought them, we bought lots of them when you find these sandals that just fit over with nothing touching it. It were amazing I'd wear them out then get another pair, but I could not stand nothing right now if I had any shoes on that came anywhere near it. Oh you can feel it that one just touching it underneath it, its pain that makes you scream".*

#### **3.10.3.1.4 Changes in pain.**

The participants reported changes in pain. These changes either had an obvious cause or no obvious cause. Often changes were associated with procedural activities such as dressing changes, management such as compression bandaging, infection and healing. There was also some report of temperature causing changes in the pain. The changes in pain that seemed to have no obvious cause were reported frequently.

Participants reported pain that would change for no obvious reason; they described pains as shooting, sudden and short sharp burst. They would voice confusion as to why this was the case.

(Participant no. 5)

(Participant) *"It will give me a bit of peace for so long and then starts up again you see".*

(Interviewer) *"Just for no reason".*

(Participant) *"Yes".*

(Participant no. 9) *"Always burning like a normal pain but every now and then it's a burn".*

[Field notes: This is confusing, but what was taken from this was; the patient was describing a really bad burn pain].

(Participant no. 8) *"It's all sorts of pains I can get sometimes. I'm sitting in this chair and for no reason it's like a knife in me leg. After about five seconds it's gone and it might not re-occur again for a couple of hours. It re-occur in a couple of minutes there's no reason for it to do this sometimes. If I change seating position it can later it, it can delay it or it can go completely there is no.*

*I've tried to get some reason so I have some form of um precedent for getting pain and relieving pain. I can't crack it; it can be any time any place".*

A lot of the pain descriptors given by the participants were neuropathic pain descriptors and of course pain arriving with no obvious cause may also be of neuropathic nature.

### **3.10.3.1.5 Correlation between ulcer size and pain Intensity.**

Some participants described having intense pain irrelevant of the size of the ulcer. Therefore, suggesting they did not experience an increase in pain if the ulcer was large or a decrease in pain once the ulcer got smaller. The participants did not report they had a reduction of pain with healing; rather they described constant pain with exacerbation of pain for no obvious reason.

*(Participant no. 4) "It's so minute; you think a bit of ointment may help".*

*(Participant no. 8) "This is a massive hole here but it does not hurt there, it hurts anywhere else but there, I can press here it gives pain out there".*

*(Participant no 6) "I couldn't manage with it really; it was from my toes to my knee, that little thing down there could do this".*

*(Participant no. 10) "I've got two leg ulcers, one either side and one is a very small one, and that's a painful sod but the other ones not bad at all".*

### **3.10.3.1.6 Nocturnal pain**

This chronic pain that participants described appeared to be especially troublesome at night, nocturnal pain was frequently reported. Patients often discussed the pain they had at night without any prompt and it appeared to be something that was very apparent in the individuals' pain experience associated with all types of chronic leg ulcers. To illustrate this type of leg ulcer has been indicated next to the patients study number.

*(Participant no. 12 mixed aetiology) "I did have a lot of pain during the night".*

*(Participant no. 8 arterial) "It's a pain that can um. I've got to be careful sleeping; I haven't slept in my bed for months and months".*

The severity of the pain was often described as getting worse at night. When analysing the data, nocturnal pain appeared to be one of the worst symptoms of

having a leg ulcer. Often the pain at night prevented the patient from sleeping or going to bed at all.

(Participant no. 5 venous) *"Well it keeps me awake sometimes at night".*

(Participant no. 6 venous) *"It was awful unrelenting. I never slept that night; I got up and sat here rather than lay in bed".*

The change in severity of pain from day to night was very obvious in one participant;

(Participant no. 8 arterial)

(Interviewer) *"The pain that you are getting at the moment can you give me a number between 0-10 that represents the pain if 0=no pain and 10=worst pain ever?"*

(Participant) *"Oh perhaps 3 or 4"*

(Interviewer) *"At night how bad is it?"*

(Participant) *"Well it goes up to about 7 or 8".*

Another described the pain as being bad and being exacerbated by change in temperature however, they depicted the pain as being especially bad during the night.

(Participant no. 11 venous) *"As soon as it got warm during the day it did hurt but not as bad as it were during the night. I don't sleep much anyway but I could not sleep at all".*

(Participant no. 1 venous)

(Interviewer) *"When you have the pain at night, you said you get pain at night? On a scale of 0 being no pain and 10 being worst pain ever how bad is that pain can you give me a number?"*

(Participant) *"Probably 7 or 8".*

The data gave a picture of these participants undertaking various strategies to deal with the nocturnal pain. They would try various activities to assist with sleeping, which involved positioning, taking analgesics and distraction.

(Participant no. 1 venous) *"The thing that strikes me about the pain when you lie in bed, you can't put your feet down to the bottom of the bed you have your knees up".*

(Participant no. 3 venous) *"Well you turn over to get rid of the pain and then you turn back the other way and you carry on like that".*

(Participant no. 5 venous) *"What I do when it starts nagging a right lot, I get up and sit at the side of me bed, put me slippers on then when I've cooled down I get back in so I can go back to sleep".*

(Participant no. 12 mixed aetiology) *"I had pillows underneath, if my husband moved in bed it was dreadful".*

(Participant no. 12 mixed aetiology) *"I'd made sure that when I went to bed on a night, I'd always left a space to take them (pain killers) and I would save them for during the night, even if it meant an hour this way".*

The picture presented from these reports was one of patients desperately trying to sleep with not much success. They show a picture of restless sleeping patterns with patients often having sleepless night after sleepless night due to their leg ulcer pain.

### **3.10.3.1.7 Compression bandaging and its effect on the pain experienced.**

All the participants apart from one reported that compression bandaging made their pain worse. They often described that the compression bandaging was the worst thing about having a leg ulcer because it made the pain so unbearable. One participant reported that the compression bandaging relieved some of the pain.

(Participant no. 1) *"I'm sort of convinced it's the four layer bandaging that hurts".*

(Participant no. 4) *"It's the bandaging that's painful".*

(Participant no. 12) *"Last time I went they put on that three, four layer bandage up to here (points to knee). I've had that, they have not been successful but I stuck it out and then last time I'd had them on a week it were absolute agony".*

One participant reported that the compression bandaging relieved some of their pain.

(Participant no. 10)

(Interviewer) *"You have compression bandaging, how does that feel, does that make it feel better or make it feel worse?"*

(Participant) *"Well it makes it feel better it contains it more, it doesn't allow freedom to wander around and rub against things".*

(Interviewer) *"Do you think the bandaging reduces the pain?"*

(Participant) *"Yes definitely".*

### 3.10.3.1.8 Procedural pain.

There was a wide variation on pain experienced during dressing changes. There was no one description that was common and participants appeared to have different experiences with regard to procedural pain.

Some participants reported a sense of relief from the pain during dressing changes as the pressure of the bandaging was removed others reported an exacerbation in the pain.

(Participant no. 2) *"It is doing the dressing it disturbs things and naturally takes a few hours to settle down again".*

(Participant no. 2) *"They wash it with warm water and some spray on disinfectant, well it stings when they put it on".*

(Participant no 3) *"When I was having aquaseptic antiseptic it was unbearable absolutely unbearable".*

(Participant no. 3) *"Of course when I have different gauze dressings that was absolutely stuck, even after soaking for 20-minutes terrible".*

(Participant no. 5)

(Interviewer) *"When they dress it does it hurt?"*

(Participant) *"Well it hurts a good bit".*

(Participant no. 2)

(Interviewer) *"When they do the dressing and take the bandaging off does that hurt?"*

(Participant) *"Yes oh yes that hurts".*

(Interviewer) *"Can you describe how that hurts?"*

(Participant) *"Not in ordinary English no, there are a few words yes".*

Two participants were able to give a graphic description to how their pain felt when their legs were touched during dressing changes.

(Participant no. 9) *"It feels like they are putting a red hot bar on that skin, a red hot bar on it".*

(Participant no. 2) *"Well imagine like you are having the skin peeled off your leg".*

This participant was suffering great increases in severity of pain during and after having the leg dressed.

(Participant no. 12) *"Sometimes it's so bad I mean, I practically not gone out completely but gone into a faint with pain. You know, I do know what it's like I have come home and screamed in this house after they have dressed it".*

A few participants reported they did not feel pain during dressing changes and reported that it was not something they considered as causing more pain.

(Participant no. 8) *"I don't get pain as they do the dressing".*

(Participant no. 1) *"Well they wash it with warm water with that um green stuff I will show you (antibacterial lotion). Doesn't hurt, I feel that it probably makes it heal better".*

Other participants felt that the actual dressing change was not painful it was the pain that came on later after the dressing change. They often associated this with what had been applied to their leg during dressing changes.

(Participant no. 8) *"I don't get pain as they do the dressing. I get the pain once the zinc oxide seems to be taking effect; it lasts for 2-3hours and then tends to go".*

(Participant no. 12) *"Well it were a good thing they put on it, sort of draw it and that's when you get a lot of the pain".*

There was some report that the dressing changes provided relief to the participants, some felt that removal of the bandage was a relief and some felt that having an ointment massaged into the leg provided some comfort.

(Participant no. 11) *"I had one of those pads, she did it very gently it was lovely it was so lovely she kept going round and round it were lovely I said keep going".*

(Participant no. 1) *"It does feel better when the nurses wash it, it does feel better, it feels better for washing".*

One participant described how itchy it felt when they took the bandage off and when it was reapplied how the itching went;

(Participant no. 11) *"That's when it really itches as soon as she starts putting it on again it goes off".*

There was no actual report of debridement pain however; there were a couple of descriptions that could be associated with debridement:

(Participant no. 11) *"It hurt at first when they pulled that little thing off; you know that little black thing".*

[Field notes: this patient was referring to necrotic tissue being removed].

(Participant no. 6) *"It just hurt sometimes when they sort of clean it, you know take swabs out".*

[Field notes: this patient was describing having a swab swiped across the wound bed to remove debris].

### **3.10.3.2 Loss of freedom (axial code 2).**

There were 4 initial codes, which contributed to this axial code.

#### **3.10.3.2.1 Elevation of legs causing further pain.**

Participants were often advised to sit with their legs elevated, some reported that they found this painful and also participants reported that this would exacerbate other painful conditions.

(Participant no. 11) *"I borrowed that stool because the one underneath is too high and I get cramps just here (behind the knee). I can't keep it up too long, I try but I can't keep it up too long, it does I get cramp its terrible pain but goes off in seconds but I can't keep my legs up".*

(Participant no. 9) *"Um, it's um to keep your leg up; it's coming up through here just now it's in my toes not hurting all the time if I put my foot down".*

(Participant no. 8) *"They said I should keep my feet up as much as possible for circulation and I understand that but they don't have the pain I've got. They are not at the sharp end business, so if I put my feet up there I can manage an hour then the pain comes and it wakes me up it's so bad it wakes me".*

#### **3.10.3.2.2 Pain impact on mobility.**

Participants reported an exacerbation in pain on mobilising; this would restrict their level of activity. Further, participants were advised to exercise to promote healing.

(Participant no. 2)

(Interviewer) *"Walking or doing anything so when your leg is down it becomes painful?"*

(Participant) *"Yes it becomes quite painful".*

(Interviewer) *"So it is affecting your day to day activities".*

(Participant) *"Oh yes quite a lot".*

This participant described a situation that would have a major impact on their ability to carry out daily activities.

(Participant no. 4) *"Not pins and needles more severe than pins and needles, like a sort of, it's affecting me back I have to sit down every two steps".*

Another expressed her regret at not being able to mobilise freely.

(Participant no. 11) *"I can't walk for long, I use a stick when I go out but I can only walk as far as that corner. I used to love going to the market and now I can't go out".*

Participant number 5 discussed how the loss of mobility affected simple day-to-day tasks such as making a cup of tea or going to the toilet.

(Participant no. 5) *"Its uncomfortable for walking, it makes a walk to the toilet or going into the kitchen to make myself a cup of tea difficult".*

This participant also stated that it was such a struggle to mobilise that they would take fewer than prescribed antidiuretics so they would not have to get up to use the toilet.

(Participant no. 5) *"It hurts a good bit you see. I also have arthritis that does not help, I'm on water tablets I'm supposed to take two but I only take one because otherwise I would go twelve times. It knocks me out going backwards and forwards".*

### **3.10.3.2.3 Removal of independence due to pain.**

Participants described losing independence and losing the ability to undertake day-to-day tasks such as housework etc... due to the pain. Participants dealt with this by employing help or moving to a residential care facility.

(Participant no. 4)

(Participant) *"Well I don't do anything really here I don't do any housework or anything I had to come here (residential care) because I was not able to do what I wanted to do".*

(Participant no. 5) *"Its uncomfortable for walking it makes a walk to the toilet or going into the kitchen to make me self a cup of tea difficult. I have a carer who*

*comes in for breakfast time and if I need a bath or a right good wash because with having bandage I can't get it in the bath and then I have someone comes who makes me dinner and at tea time I pay £73 a month for that care".*

*(Participant no. 11) "I don't do anything, I've got help I did that bit of washing there but they do me laundry, housework they do practically everything not me windows".*

#### **3.10.3.2.4 Dependency on healthcare professionals.**

Participants described entering a cycle of care to promote healing, often requiring frequent dressing changes. Participants described being dependent on healthcare professionals and also described being beholden to their nurses.

*(Participant no. 8) "To be fair they can't be exactly 5 minutes on time but most of them will try, so I'm a but reluctant. So if they say well I'll be here in the morning it's not good enough, can you give me a time, well round about, which is not easy and it's just the system, it's not, so I go down there for treatment".*

*(Participant no. 8) "Well if I wasn't retired I would have a hell of a life because I just can't see doing a full time job. Unless they let me go for half an hour a day at various times. I don't want to go every day it takes time sitting around waiting, it's a bind it's very wearing".*

This participant described being dependent on their nurses so much so that going on holiday was not possible, even though the nurses had tried to solve this problem by offering to arrange nursing care at the holiday destination.

*(Participant no. 2) "The nurses have said we can arrange for you to go on holiday and arrange for the local people to come and sort it out but how does that work? We would be sitting around waiting for them to come in our hotel".*

#### **3.10.3.3 Chronic pain sequelae (axial code 3).**

There were five initial codes, which populate this axial code.

Leg ulceration is a chronic condition therefore the pain this causes is likely to be chronic. This may not be the case for patients who have pain relief. The pain experienced and reported as such by this group has obvious similarities to other chronic pain conditions with associated outcomes. Participants reported problems associated with pain such as chronicity, neuropathic pain, insomnia, depression and suicidal ideation.

### 3.10.3.3.1 Chronicity

The pain associated with the chronic leg ulcer was reported to be as chronic as the leg ulcer. Many participants reported having their leg ulcers for many months sometimes years, with the associated pain being present alongside the presence of the chronic leg ulcers. The participants in this study reported the chronicity of their leg ulcer being between seven months to 20 years. They seemed to acknowledge that the ulcers were chronic and that once healed they would probably come back.

(Participant no. 4) *"Well it's probably a year since I noticed it was a little something a little scratch".*

(Participant no. 6) *"It started in September it's been a long time really so that's eight months".*

(Participant no. 10) *"I've been having this for about 15 to 20 years".*

(Participant no. 10) *"I just wanted it cured which it nearly is but you know that two, three, four months it will start up again".*

(Participant no. 12) *"Every photo I have on holiday last 15 year guarantee my legs are bandaged".*

(Participant no. 8) *"Like a volcano it refuses to get better".*

Participants reported that although the leg ulcer would heal it would be back, some felt that the time between healing and the leg ulcer returning was getting shorter as they became older.

(Participant no. 1) *"It healed in about 7 weeks, the doctor at the surgery thought it was marvellous but of course it is not as fast now I'm 20 years older".*

(Interviewer) *"After the ulcer heals, how long is it, before it comes back?"*

(Participant no. 1) *"Well it seems to get shorter [Field Note: period of time patient was ulcer free] over the last when I was having it done with the nurse at the surgery they did not do the four layer bandage they did probably um two layer or maybe three, but they did not do four um, I think they were very good they kept me walking and driving".*

### 3.10.3.3.2 Insomnia

The participants reported insomnia associated with the pain at night; it was one of the most frequently reported problems associated with the pain of the leg ulcer.

(Participant no. 2) *"Yes, well it's painful I think painful all the time it's like a sore all the time and then other times it gives me a kick. It wakes me up sometimes; sometimes it wakes me up at night I take some painkillers. But paracetamol before I go to bed then wake up about 2 or 3am".*

(Participant no. 8) *"I don't go to bed before 12 unless I'm really tired because I can't sleep at night".*

(Participant no. 11) *"I could not sleep at all".*

(Participant no. 12)

(Interviewer) *"How many hours sleep were you getting?"*

(Participant) *"None, well I did if I got half an hour I would be awake until three in morning. I were that exhausted I'd go off I'd be having my next day tablets before I'd even gone to sleep. Once I did get two or three hours sleep, that kept me going. I was in a position where I was in bed during the day, so I would dose of for half an hour or so that would be it".*

### **3.10.3.3 Depression and social isolation**

The participants reported feeling depressed and being isolated because of the pain of their leg ulcers.

(Participant no 2) *"It makes me depressed".*

(Participant no 12) *I've not slept and the pain is getting worse and I'm feeling down".*

Participants reported being isolated because of the pain of the leg ulcers. They described how their pain made them feel mentally and how that further exacerbated their isolation.

(Participant no. 1) *"You would just feel happy if the pain is not there".*

(Participant no. 3) *"I just get up and try to read but I can't concentrate when I have a lot of pain. You can't concentrate very well, but um you don't want to see anyone and be involved in conversation. You just want to be alone because you are a misery".*

(Participant no. 3) *"Well I haven't been out. I was too ill. When you have pain you just want to be alone... go to bed".*

### 3.10.3.3.4 Suicidal Ideation.

In some cases, the participants expressed a desire to die. They would wish for an end to their suffering by death and would express this as a desperate measure to relieve the pain.

(Participant no. 12) *"I got to put up with this pain, it were like I had to get through this pain barrier. At the end, the pain I had then you see, when it were at its worse I was quite willing, I were quite willing to die. That's how bad it were the pain, can't describe what the pain were like. It would make me mad, I was screaming with pain it were so bad it didn't go away, it were for 24 hours a day".*

(Participant no. 3) *"Last week I said to one of them I would like to have a tablet that would put me to sleep permanently".*

Once the tape recorder was turned off this patient voiced:

(Participant no. 12) *"My husband took the drugs off me otherwise I would av'e overdosed, I just had enough of the pain".*

[Field notes: the patient agreed to have this mentioned in the study but did not want it recorded].

Other participants reported a wish that they had not become old.

(Participant no. 4) *"It's not worth getting to a 100 years I wish I hadn't".*

(Participant no 2) *"Well I am coming up for 91 years, so I am restricted anyway. The only advice I would give to anyone is to die when they are about 78 or 79 to avoid old age".*

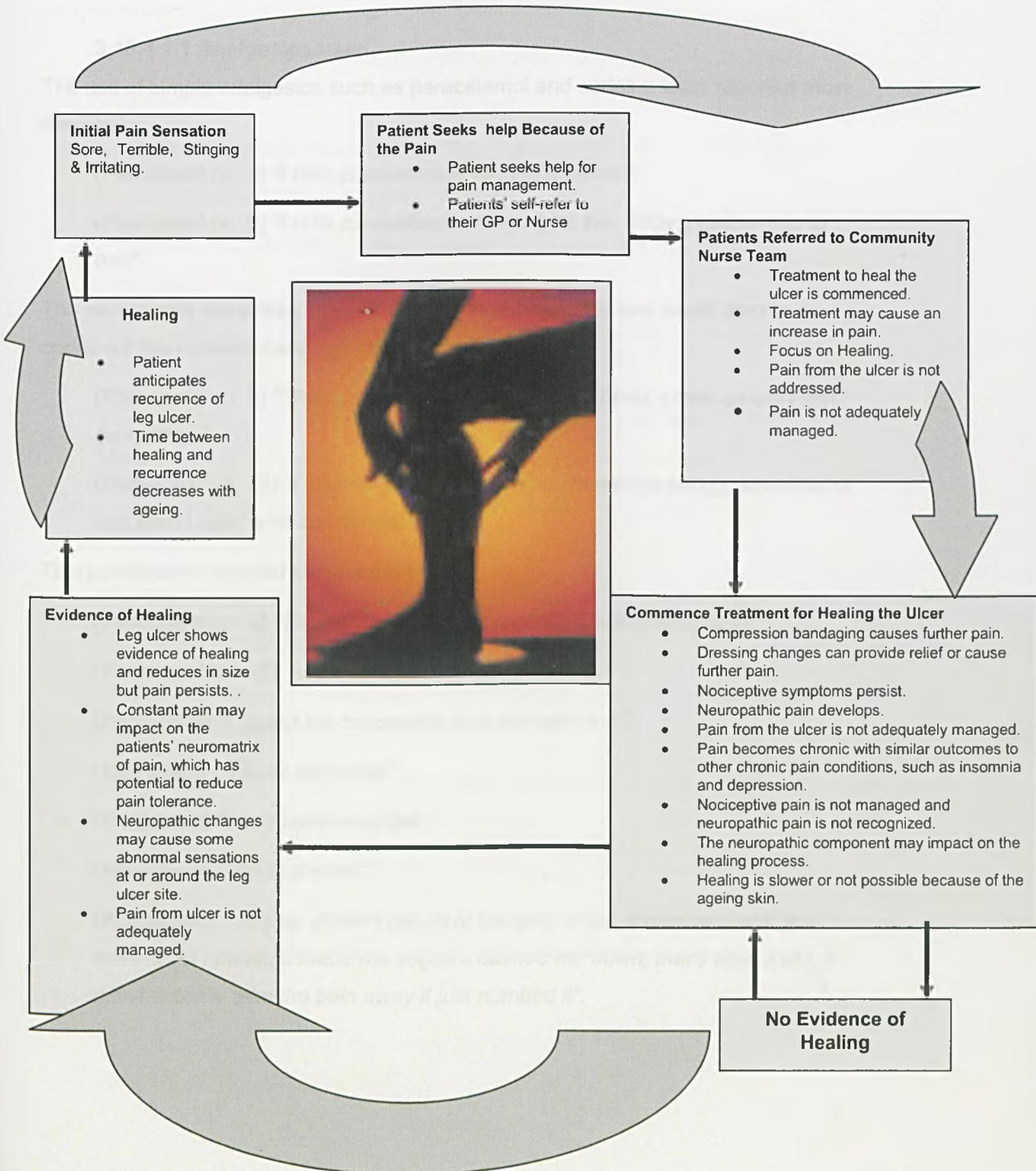
### 3.10.3.4 Summary of nature of pain experience.

The pain experience, in relation to the life cycle of the leg ulcer, is represented in the figure 1, a visual summary of the reported nature of the pain.

The participants described a wide variation in their pain experience. However, there are some themes that were commonly seen in the data. It can be summarised that the participants reported pain that was chronic and often worse at night. They described changes in the pain and most frequently sudden pain severity that could not be explained by any obvious cause. The pain they described had nociceptive and neuropathic elements. Compression therapy was commonly reported as causing further pain and in some cases the pain from compression was reported as so severe that the participant could not tolerate the treatment. Dressing changes were reported

in some cases causing further pain, but in others not, and in some cases procedural techniques were reported as providing some relief. The participants described severe pain when the ulcers were small or no pain with larger ulcers, and also described chronic pain co-morbidities, such as depression, insomnia and suicidal ideation.

**Figure 1: Participants Descriptions of the Pain in Relation to the Life Cycle of the Leg Ulcer.**



### 3.10.4 Trying to manage the pain (selective code 2).

There are two axial codes (4 and 5).

#### 3.10.4.1 Pharmacological pain management (axial code 4).

The axial code related to pharmacological pain management has six initial codes.

The pharmacological management of leg ulceration, as reported by the participants, is presented in the summary (see Figure 2).

##### 3.10.4.1.1 Analgesics used.

The use of simple analgesics such as paracetamol and codeine were reported most frequently.

(Participant no. 3) *"I took paracetamol, two paracetamol".*

(Participant no. 8) *"I take paracetamol every night, two 500mg before I go to bed".*

The participants were likely to commence with paracetamol and would then take codeine if the paracetamols was not sufficient.

(Participant no. 9) *"There is nothing I can do if it's too bad; I take an extra um, cocodamol".*

(Participant no. 12) *"I start off with paracetamol, I'm always taking paracetamol and then I went onto cocodamol".*

Two participants reported using morphine:

(Participant no. 2) *"They give me, some prescribed, some morphine".*

(Participant no. 12)

(Participant) *"I upped the cocodamol to a stronger one".*

(Interviewer) *"Liquid morphine?"*

(Participant) *"Yep I went on to that".*

(Interviewer) *"Did that work?"*

(Participant) *"Oh yes, it didn't get rid of the pain. It did, it numbed me if you know what I mean, it made me vague it calmed me down, that's what it did, it didn't actually take the pain away it just numbed it".*

### 3.10.4.1.2 Adverse events with analgesics.

The participants reported having concerns about and incidents of adverse events. The most commonly reported adverse event was constipation; some reported that this was worse than the pain.

(Participant no. 1) *"Probably I think they are constipating and I think that's worse than the pain".*

Another reported that they would not take the analgesics prescribed because of constipation.

(Participant no. 2) *"I'm a bit wary of using these things because it brings on constipation".*

Patient number 8 reported reducing his intake of codeine to prevent constipation.

(Interviewer) *"How frequently do you take it?"*

(Participant) *"As little as possible because of the side effect known as constipation".*

Only one participant reported using laxatives or being offered laxatives as a preventative measure or a curative measure.

(Participant no. 10) *"Well when I've had troubles I've gone back to the codeine phosphate and the same time taking things like fybogel (laxative)".*

Another reported that they had not been offered laxatives as a solution for the problem of constipation associated with codeine.

(Interviewer) *"Have you been offered laxatives?"*

(Participant no. 8) *"No not really"*

Polypharmacy was another concern of the participants. They were often troubled about taking too many tablets at any one time.

(Participant no. 8) *"I have one or two pain killers; I'm a bit worried about you know too many rattling around like a pill box".*

(Participant no. 8) *"I don't want to mix too many medications, I don't believe in mixing medications".*

The participants also reported concerns with overdose, either accidental overdose or purposeful overdose.

(Participant no. 2) *"Well I don't want to take them all the time, I mean doing that you get over dosed sometimes".*

(Participant no. 8) *"I don't want to overdose; I'm only taking two a day.*

There was some concern with taking opioids; some reported refusing to take opioids because of their perceived risks.

(Participant no. 10)

(Interviewer) *"Was it morphine?"*

(Participant) *"No I'd never use opiates".*

(Participant no. 5) *"I'm not going to dope myself with tablets".*

(Participant no. 12) *"I'm going to need more and I'm going to be a zombie".*

#### **3.10.4.1.3 Advice regarding analgesics by healthcare professionals.**

There did not appear to be any standardized advice with regard to analgesic use and pain management advice. The participants reported various types of advice given to them by their district/community nurse or their GP. It appeared from the patients' reports that the nurses felt at a loss as what to do about the pain.

There were some reports of participants being advised to take paracetamol.

(Participant no. 2) *"They just say take another pain killer, they prescribed paracetamol".*

There were some reports of a reluctance for the patients to take anything apart from paracetamol, the reason why was not clear.

(Participant no. 3)

(Interviewer) *"The only pain killers for the leg ulcers you have taken are paracetamol, you didn't take the codeine because you think they are too strong".*

(Participant) *"I didn't take them because the nurses recommended I stick with the paracetamols".*

(Participant no. 5) *"They told me to keep on with them paracetamols".*

There also appeared to be some reluctance from the patients' GPs to prescribe stronger analgesics; again it is not clear why.

(Participant no. 4)

(Participant) *"I've asked for stronger ones each time".*

(Interviewer) *"What did they say?"*

(Participant) *"The doctor said that I can give them to you, I can give you stronger painkillers, but I don't want to".*

(Interviewer) *"Do you know why?"*

(Participant) *"He said I don't want to, so that put me off he said he didn't want to risk it".*

Some participants reported that their GPs simply prescribed more tablets and appeared to not be able to offer much else.

(Participant no. 5) *"I've mentioned it a few times but the doctor won't come out, he just tells me that... gives me tablets... and to keep on with the good work that sort of thing".*

(Participant no. 12) *"I just tell 'em, when I go for my dressing I've not slept and the pain is getting worse. I'm coping with it and I'm feeling down I have had to say that I know they cannot do anything about it. But it's the nurse will just say, "Go see your doctor". I make an appointment to go and see the doctor and the doctor then gives me something stronger".*

There was no report that healthcare professionals were advising pre-emptive use of analgesics for dressing change. One participant reported that her community/district nurse advised her to take painkillers after dressing changes.

(Participant no. 5) *"She tells me to take the painkillers once she has been, to calm me down".*

Others reported that although they reported pain their district/community nurses did not provide further pharmacological strategies to assist with the management of the pain.

(Participant no. 6)

(Participant) *"I mention it you know but um I think they are used to it".*

(Interviewer) *"What do they say about it?"*

(Participant) *"Well they are always painful".*

(Interviewer) *"They don't recommend further painkillers?"*

(Participant) *"No".*

(Participant no. 9)

(Interviewer) *"Do you tell the nurses that it is very painful?"*

(Participant) *"Um, yes".*

(Interviewer) *"What do they say?"*

(Participant) *"They say they can't do anything about it".*

There was some report of the healthcare professionals voicing concern with their patients taking "strong", analgesics.

(Participant no. 9)

(Participant) *"I've been given the morphine but I had to cut it down".*

(Interviewer) *"Why is that?"*

(Participant) *"They didn't like me taking it".*

(Participant no. 4)

(Participant) *"The doctor said that I can give them to you, I can give you stronger painkillers, but I don't want to".*

(Interviewer) *"Do you know why?"*

(Participant) *"He said I don't want to, so that put me off, he said he didn't want to risk it".*

#### **3.10.4.1.4 Effectiveness of pharmacological management.**

Most of the reports associated with the effectiveness of the analgesics were of their inadequacy. The participants reported that they were taking their analgesics on an ad-hoc regime or they were taking them regularly and sometimes taking more than prescribed. Further, there was no report of assessment of effectiveness being undertaken by the healthcare professionals. The participants reported inappropriate use of analgesics, either due to incorrect advice or having received no advice from their healthcare professionals.

The reports of paracetamol use suggest that although it appeared to be a frequently used analgesic, it did not appear to be adequate.

(Participant no. 10) *"I also take paracetamol as well, doesn't do much good paracetamol".*

(Participant no. 11) *"I took paracetamol they didn't help; they helped a little bit and then got those co-co whatever".*

One participant reported that she had been advised to take the paracetamol regularly but she did not follow the advice. The patient understood why she should take the paracetamol regularly but had an issue with taking analgesics for the rest of her life. This participant was concerned with the effects of paracetamol on the liver.

(Participant no. 8) *"One of the nurses, God bless her, wanted me to take the paracetamols fairly regularly, to maintain the pain effect right through the day, and I understand what she is saying. But I just thought, well I'd be doing that everyday of me life because I get pain everyday of me life and I don't think it's a good thing to be taking that amount of paracetamol because it can do your liver damage can't it?"*

(Participant no. 1) *"Well, everyone says you should take them around the clock, at dermatology the staff nurse there said if you don't get the pain killers into your system then they won't work, I believe them but I don't do it. I'm sorry about that"*.

The participants reported that the analgesics worked but some reported that they would only work for a short time. There were some reports of the participants "clock watching".

(Participant no. 12) *"I do feel that you have to be in control of your pain, I didn't listen to it. I didn't look at that bottle so many in 24 hours. I counted the hours out say they were 6 hours in between and I was in dire pain 4 hours, before I would take them tablets but if the pain were not as bad I would go for a few hours over"*.  
[Field Notes: Watching the clock for time for next analgesic dose].

(Participant no. 1) *"In the night I do take the pain killers when I go to bed. I would say they take the pain off for about three and half hours to four hours"*.

(Participant no. 11)

(Participant) *"But I had to take; I think it was paracetamol mostly"*.

(Interviewer) *"Did they help?"*

(Participant) *"A little bit not much, it soon came back again"*.

(Participant no. 2)

(Participant) *"I just wait a bit and work out how many hours; it was until I last had my last painkillers, what is 10 or 9 and then take another paracetamol"*.

(Interviewer) *"And then you are able to get back to sleep?"*

(Participant) *"Sometimes"*.

### **3.10.4.1.5 Pre-emptive pain management.**

There were some reports of the participants taking analgesics pre-emptively for dressing changes. This was reported as being undertaken but with little success because of factors such as the patient not knowing the time when the district nurse would be arriving to do the dressing change.

Patient number two took oral morphine for dressing changes; he would try to take it an hour before the nurses arrived to do the dressing, but reported problems with this approach.

(Interviewer) *"How long do you take it before they get here?"*

(Participant no. 2) *"About an hour but of course I don't know when the nurses are coming you see so, I take it about 9 am but they might not come till about 12.30"*.

(Participant no. 2) *"I just use the morphine for when the nurses are coming to do the dressing"*.

There were further reports of pre-emptive analgesic use, but with little success unless the participant knew the exact time of the next dressing change. This appeared to be achieved if the participant was attended a clinic, rather than having a nurse visit them in their own home.

(Interviewer) *"Has anyone told you to take the painkillers before they arrive to do the dressing?"*

(Participant no. 5) *"I have to take them either before or just after, if I take them early morning by dinner they would have worn off so that's what happens love"*.

(Participant no. 12)

(Participant) *"I used to work it out because if I were going there I used to work out that whatever me appointment was with the nurse, I'd make sure I had took the tablets before I went so that I would because when they take it off it would (inaudible)"*.

(Interviewer) *"Did you do that from your own thinking or because someone told you to do that"*.

(Participant) *"I knew I had to, no one told me to, I worked that out meself"*.

(Participant no. 12) *"I take something before; if I have taken some already I don't wait".*

(Participant no. 12) *"I made sure that when I was going down to the doctors that I had got plenty in me".*

#### **3.10.4.1.6 Pharmacological management of neuropathic pain.**

There were no reports of using analgesics specifically for neuropathic pain such as gabapentin or amitriptylene, although there was evidence to suggest that the participants had neuropathic pain (refer to Chapter 3, section 3.10.3.3.2).

#### **3.10.4.2 Non-pharmacological pain management (axial code 5).**

This axial code had 4 initial codes and the pain management strategies that were non-pharmacological reported by the participants in this study were predominantly patient led.

##### **3.10.4.2.1 Distraction**

Distraction was described as being used by a few patients but it was not commonly used as a non-pharmacological pain management strategy. Distraction techniques being used were basic day-to-day activities such as making a cup of tea or watching television.

(Participant no. 1) *"Probably come down and make a cup of tea, it's a strange thing at the moment it's a soreness. I have not got it today, sometimes I think it goes off if something distracts".*

(Participant no. 2) *"Well I forget about it's sometimes if there is something that interests me on the TV, distraction or some visitors".*

(Participant no. 8) *"Sometimes I do activities because I've got pain, if I'm doing something it goes further back in my mind".*

##### **3.10.4.2.2 Positioning**

Many participants talked about how they used positioning as a way to relieve their pain or reduce the pain. During the day sitting with legs resting on a stool was frequently described.

(Participant no. 1) *"Well during the day I put my feet up on there".*

(Participant no. 6)

(Interviewer) *"During the day do you sit with your legs down?"*

(Participant) *"Yes but I use this (points to foot rest)".*

Another participant described trying to ease the pain by resting her leg on a stool; however she described having problems with this because it caused cramp in her thighs.

(Participant no. 5) *"Well I rest it up but if I have it up like this I get cramp, so I just have it on this low stool".*

A lot of participants used positioning to aid sleep but with limited success.

(Participant no. 1) *"I put a pillow at the bottom of the bed and try to put my foot on that, um, I don't know whether it helps but I think".*

(Participant no. 2)

(Interviewer) *"Do you use any positioning techniques to help with the pain?"*

(Participant) *"At night a pillow and during the day sitting with legs up".*

(Interviewer) *"Where do you put the pillow?"*

(Participant) *"Back of my legs".*

It appeared from the participants' dialogue that patients were spending their nights with disrupted sleep and were trying desperately to find a position that would relieve their pain to aid sleep.

(Participant no. 3) *"Well you turn over to get rid of the pain and then you turn back the other way and you carry on like that".*

(Participant no. 5)

(Interviewer) *"When you wake up in pain at night what do you do?"*

(Participant) *"I just persevere really try altering my position with my leg in bed".*

### **3.10.4.2.3 Exercise**

The participants reported that they coped with the pain by adopting various techniques such as distraction, positioning and undertaking other activities. Two participants mentioned walking as a pain relieving activity.

(Participant no. 1) *"When I'm walking around I feel I can cope with it".*

(Participant no. 8) *"I've got pain most of the day, various times in various ways, various places, mainly below me knees. I cope with it in different ways; I cope with it by walking about or not walking about".*

#### **3.10.4.2.4 Complementary and alternative medicine (CAM).**

There was some report of CAM use; most report was associated with either homemade concoctions or buying herbal and pain management devices such as copper bracelets and "pain gone" pens.

There was no report of participants using acupuncture, homeopathy or use of outside agencies for pain management.

One participant was very keen to make her own herbal concoctions; she voiced a lot of suspicion with conventional medication.

(Participant no. 3) *"Well I've never ever taken pain killers in my life, not even if I have a headache. I've never in the past, never ever taken them. I'd rather have the headache".*

(Participant no. 3) *"The one thing I used to take was nettle tea from the herbalist. That's good to purify the blood, if I could find something for pain killer, a suitable herb I would take it".*

Another participant had purchased a "pain gone" pen, from a paper supplement. A pain gone pen is a device that looks like a pen. The point part is metal which is meant to be put onto the painful part of the body. When you press the top of it a small shock is emitted. It is marketed as a device that disturbs the pain signals.

(Participant no. 8)

(Participant) *"I bought something at great expense, I'll show you (brings back pain gone pen). I wondered if it would help in any way".*

(Interviewer) *"Did it?"*

(Participant) *"No to the contrary, it were a lot of money, I got it from a magazine I thought I would give it a try. When you have pain you try anything, I put it round where I got the pain near the wound".*

(Interviewer) *"When you used the pain gone pen, did it hurt was it a sharp sensation?"*

(Participant) *"It were an electric current, um I was aware of it but it wasn't anything that painful. I did think afterwards it hurts more than it did before but it was adding pain, not the other way round"*.

One participant attempted to eliminate the pain by "freezing" the area of the ulcer.

(Participant no. 12) *"I did try once putting ice and it (laughs) I tell you what it did hurt. I should not have done it, but you know it's just that I thought if I freeze it, it would go"*.

There was no report of healthcare professionals recommending complementary and alternative medicine to manage the pain associated with pain from chronic leg ulceration.

There was some report of relatives advising the use of CAM.

(Participant no. 12) (Participant) *"My youngest daughter is into all this and she said to me why don't you go to alternative. I said I don't know why, I don't like interfering with it she said it won't harm you"*.

(Interviewer) *"Does she mean a homeopath some other alternative, what is she referring to?"*

(Participant) *"Well she is referring to, well not vitamins but the kind of thing you take, something else. Not to put something on it but to take something"*.

#### **3.10.4.3 Summary of trying to manage the pain**

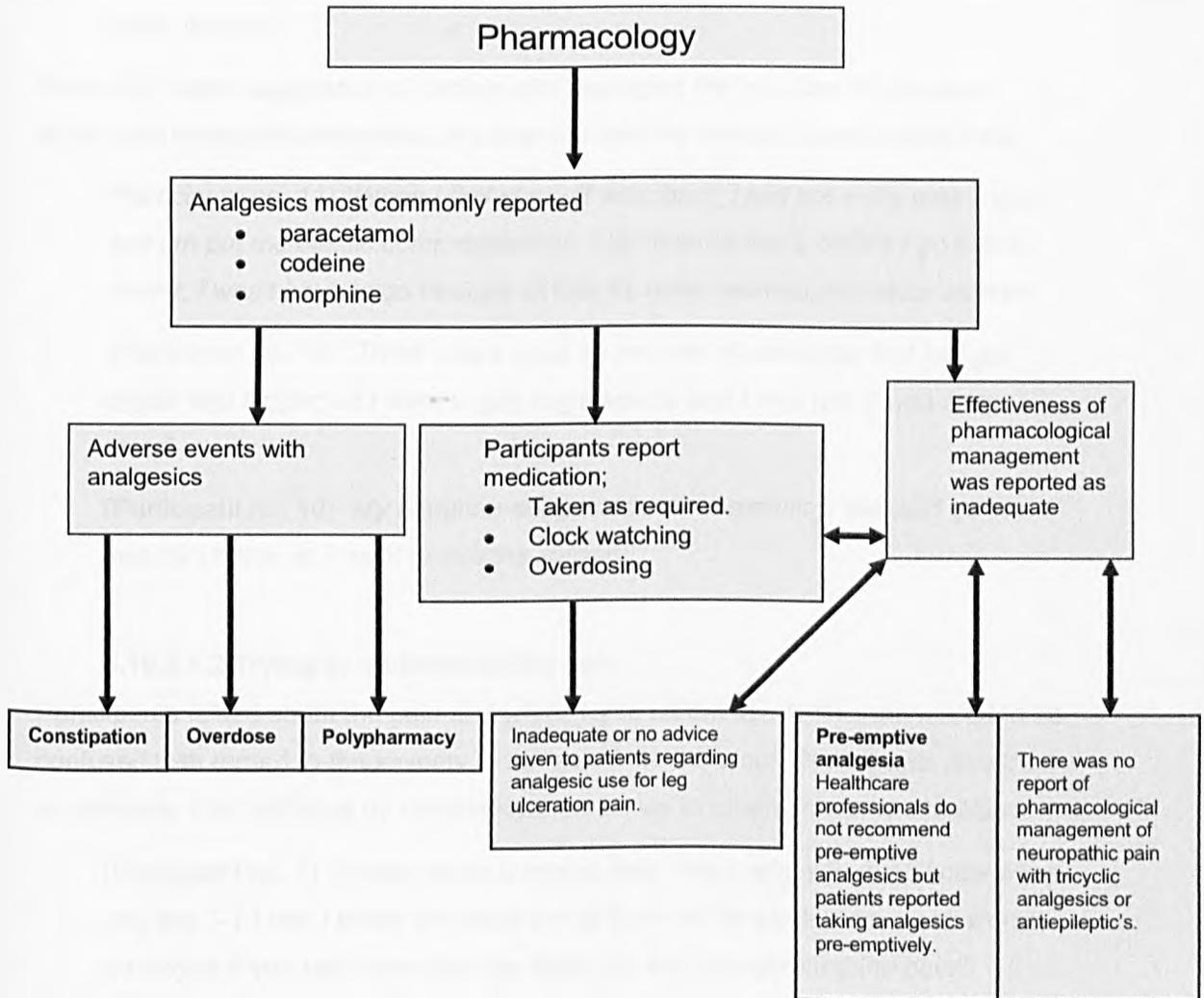
In summary (see Figure 2) participants were taking simple analgesics such as paracetamol and codeine; they also reported that these were not always adequate in managing the pain. Furthermore, analgesics were being taken as required and not regularly. Participants reported that they had problems with their medication such as constipation, polypharmacy and overdose.

Participants appeared not to have much or relevant advice given to them by healthcare professionals with regard to medication for pain management. No participant reported use of medication for neuropathic pain. Participants also reported that they would inform their community/district nurses of their pain. But the nurses appeared not to be able to provide patients with adequate pain management techniques or advice.

Participants initiated their own methods of non-pharmacological pain management and did not report that healthcare professionals were offering advice on this issue. The most commonly reported pain management techniques that did not involve

medication were distraction and positioning. There was some report of using CAM but at a basic level and no participant reported using an outside agency for pain management such as an acupuncturist. It was also reported that they had not considered this as an option. The CAM being used was either homemade concoctions or buying devices that apparently assist with elimination of pain.

**Figure 2: Pharmacological management as reported by the participants**



**3.10.5 Conflicting focus (selective code 3)**

This selective code is made up from 2 axial codes, (6 & 7).

**3.10.5.1 Patient behaviours and attitudes (axial code 6)**

Axial code 6 emerged from 3 initial codes, which are outlined below. Participants described varying and similar behaviour with managing their leg ulcers.

### 3.10.5.1.1 Help seeking behaviour

The participants described seeking healthcare professional advice because of the pain, but the focus remained on the healing and the pain was not addressed.

(Participant no. 1) *"I didn't go to the doctors at first because I thought I had been bitten by something, but as soon as it started and I felt the pain I rang the nurse"*.

(Participant no. 4) *"Once it started it hurt, it hurt then I thought you know, I went to the doctors"*.

There was some suggestion of participants managing the leg ulcer themselves, either until things became worse or a friend or relative advised them to seek help.

(Participant no. 11) *"When I first start off with them, I just put a dry dressing on and um put me elastic compressant on. I put that on that's before I go to the doctor, I won't have to go through all this it's never worked, it's never worked"*.

(Participant no. 10) *"There was a scab on the side of the ankle that just got bigger and bigger, so I went to get some advice and I was told it was a leg ulcer"*.

(Participant no. 10) *"My daughter suggested I do something, she said go and see my doctor, so I went to into the surgery"*.

### 3.10.5.1.2 Trying to understand the pain.

Participants talked about the pain and would try to rationalise it. They appeared to be confused with regard to the severity of the pain from the ulcer. Participants also tried to downplay their suffering by comparing themselves to others in worse situations.

(Participant no. 1) *"I mean there is worse pain, this is why you don't know when you say 1-10 um. I mean um there are all kinds of things that are much worse, so maybe if you only have had the ulcer you are exaggerating the pain"*.

(Participant no. 2) *"I feel I exaggerate what is pain? It's not like that's red and that's white, it might be to someone just a little discomfort but to me its pain like burning"*.

There was a real sense of participants feeling they exaggerated the pain because they just could not comprehend why such a little thing (the ulcer) could hurt so much. There was almost a sense of not deserving pain management. This one participant demonstrated this attitude with the following comment;

(Participant no. 12) *"Yes, I see it as a little thing; I think I should not be complaining even though I've got all that pain. I shouldn't be complaining, I think I've got to get on with it".*

Participant number 12 felt that other conditions were far more deserving of pain complaint and felt that pain caused by cancer in particular must be far worse.

(Participant no. 12) *"When I see other people in how much pain they are, that help me through as well because I think all these people that are in pain, all these people that have cancer and all these people that have amputation you know um".*

Participant number 2, felt that at times he must have dreamt the pain, it made him reflect on his experiences in the war.

(Participant no. 2) *"I get pain further up here, mainly down here (the ulcer). I can feel it sometimes shooting up my leg then it goes off again. Some days I think have I dreamt it. I broke this knee that was very painful in the war, I was very lucky some of the people had their legs blown off, how is it that I got away with it?"*

One participant would convince herself it could not be that bad, by comparing her situation with people in the third world. She felt that she had to put up with it as to do otherwise would be making a fuss.

(Participant no. 12) *"Well I don't know what their pain is but I think these foreign countries these third world countries, it made me sort of put up with that pain more. I've got to put up with it because there are people a lot worse than me, it takes you through it. I think about people pain and suffering and that helps me a lot when it comes down and it starts to feel better. I think all that fuss over and there's all these people suffering in the world and I'm here complaining about a little thing".*

Another participant explained that if you were not easy going you would make a fuss.

(Participant no. 1) *"My temperament is easy going that's probably why if you are not easy going you maybe make more fuss".*

One participant talked about discussing the suffering of the leg ulcer with another person who had them. They suggest that this was helpful and that they gained some support from other sufferers.

(Participant no. 12) *"I had someone that went to a pensioners club with me and she had them, she were bandaged, we used to say I'll get mine off before you do. Things like you know, it were amazing how we both helped each other, like you know because we both knew what we were both going through like you know"*.

Some participants would put on a brave face and did not want to discuss the pain with family or friends.

(Participant no. 2)

(Interviewer) *"Have you talked to your family or friends about the pain?"*

(Participant) *"Not really, I usually try to put on a brave face; it's a bit deceptive I'm a miserable old man"*.

(Participant no. 10)

*"Grin and bear it, just get on with it"*.

#### **3.10.5.1.3 Desire for leg amputation.**

Participants reported feelings of desperation associated with the pain. In some cases participants expressed a desire for amputation of the affected leg.

(Participant no. 10) *"I asked about taking the leg off"*.

(Participant no. 12) *"I have it all night long when it's at it's worse it's just it's, it's, you get so all you want to do is take it off, you just wish they would take the leg off"*.

#### **3.10.5.2 Healthcare professional attitudes and behaviours (axial code 7).**

This axial code is generated from 5 initial codes, which are described below.

##### **3.10.5.2.1 Nurses' response to report of pain**

Participants reported that although they told their nurse and doctors about the pain it was rarely managed. There was a sense of nurses not knowing what to do with the pain so they focused on the one thing they could manage, which was the healing.

(Participant no. 6)

(Participant) *"I mention it (the pain) you know but um I think they are used to it."*

(Interviewer) *"What do they say about the pain?"*

(Participant) *"Well they are always painful".*

(Participant no. 9)

(Interviewer) *"Do you tell the nurses that it is very painful?"*

(Participant) *"Um yes"*

(Interviewer) *"What do they say?"*

(Participant) *"They say they can't do anything about it".*

(Participant no. 6)

(Interviewer) *"What do the nurses say about the pain?"*

(Participant) *"Not much I mention it to Sister but it's just in passing, not much is said".*

(Interviewer) *"Does she make any recommendations on what to do if it's painful".*

(Participant) *"No".*

One participant who expressed to her nurse that the bandage was painful commented;

(Participant no. 1) *"The nurse said we blame everything on the bandage".*

### **3.10.5.2.2 Pain as a good sign**

There also seemed to be some confusion with diagnosing the cause of the pain. The participants reported that their nurses suggested the pain was a good thing. Whether or not this was because the nurses genuinely believed that the pain was a good thing and part of the healing process or, they went along with this, as that was easier than admitting they did not know what to do about the pain. It is not possible to ascertain.

(Participant no. 3) *"Well I ask each time what is down there; they usually say well it's a little uncertain. I ask them to explain why the pain is there and they say it must be near a nerve or something".*

(Participant no. 2)

(Interviewer) *"When you speak to the community nurses about the pain what do they say?"*

(Participant) *"That's all part of the healing process".*

(Participant no. 5)

(Interviewer) *"When the nurses come and do the dressings do they ask you about the pain?"*

(Participant) *"Well I tell them about it every time they come and they say well it's a good sign".*

(Interviewer) *"They tell you it's a good sign?"*

(Participant) *"It's a good sign because it shows me tendons are good or something I don't know".*

The same participant went onto say;

*"They keep telling me and that the pain is because it's knitting and me tendons are all, it's good to have pain, better than not having pain it's working".*

### **3.10.5.2.3 Pain management for procedural pain.**

The participants mentioned that they were advised in various ways on how to manage the procedural pain. There was no frequent mention of a particular strategy being utilised.

(Participant no. 12) *"When they come to do it they say right brace yourself".*

Another participant described a slightly more sympathetic scenario.

(Participant no. 2)

(Interviewer) *"So whilst they do the dressing change it is painful".*

(Participant) *"Yes".*

(Interviewer) *"Do the nurses know that?"*

(Participant) *"Oh yes, they say I'll wait a bit have a rest but I'd rather they would get it done, they are concerned".*

This participant was told to take her painkillers after having her leg dressed to "calm her down".

(Participant no. 3)

(Participant) *"She tells me to take the pain killers once she has been to calm me down".*

(Interviewer) *"After she has been?"*

(Participant) *"Yes to calm me down".*

(Interviewer) *"Do you find that once she has been your pain is more severe?"*

(Participant) *"Yes, that's why she tells me to take the pain killers; she's disturbed it all you see".*

#### **3.10.5.2.4 GP comments and professional tennis.**

The participants reported that they would seek pain management from their doctors. However, the response did not appear to promote adequate pain management. There was also some suggestion that patients were referred to the doctors for pain management. However, the doctors' referred the patient back to the nurses as the nurses were considered experts on leg ulcer management.

(Participant no. 9)

(Interviewer) *"When you see the doctor what does the doctor say about the pain?"*

(Participant) *"He gives me antibiotics; he says there is nothing he can do about it he says, the district nurses know a lot more about ulcers than I do".*

(Participant no. 1) *"I know the lady doctor when it first started, I used to complain about the pain they never suggested pain killers, no one ever, never took pain killers no one said I should".*

(Participant no. 5) *"Well I've mentioned it a few times, but the doctor won't come out, he just tells me to keep on with the good work, that sort of thing".*

#### **3.10.5.2.5 Pharmacological pain management advice.**

There was very little mention of pharmacological advice being given to patients to manage their pain. Participants reported that the only drug the nurses advised them to use was paracetamol.

(Participant no. 2) *"They just say take another painkiller they prescribed this paracetamol".*

There also appeared to be unwillingness for the nurses to want the patients to take anything else for the pain apart from paracetamol.

(Participant no. 3)

(Interviewer) *"The only painkillers for the leg ulcers you have taken are paracetamol you didn't take the codeine because you think they are too strong".*

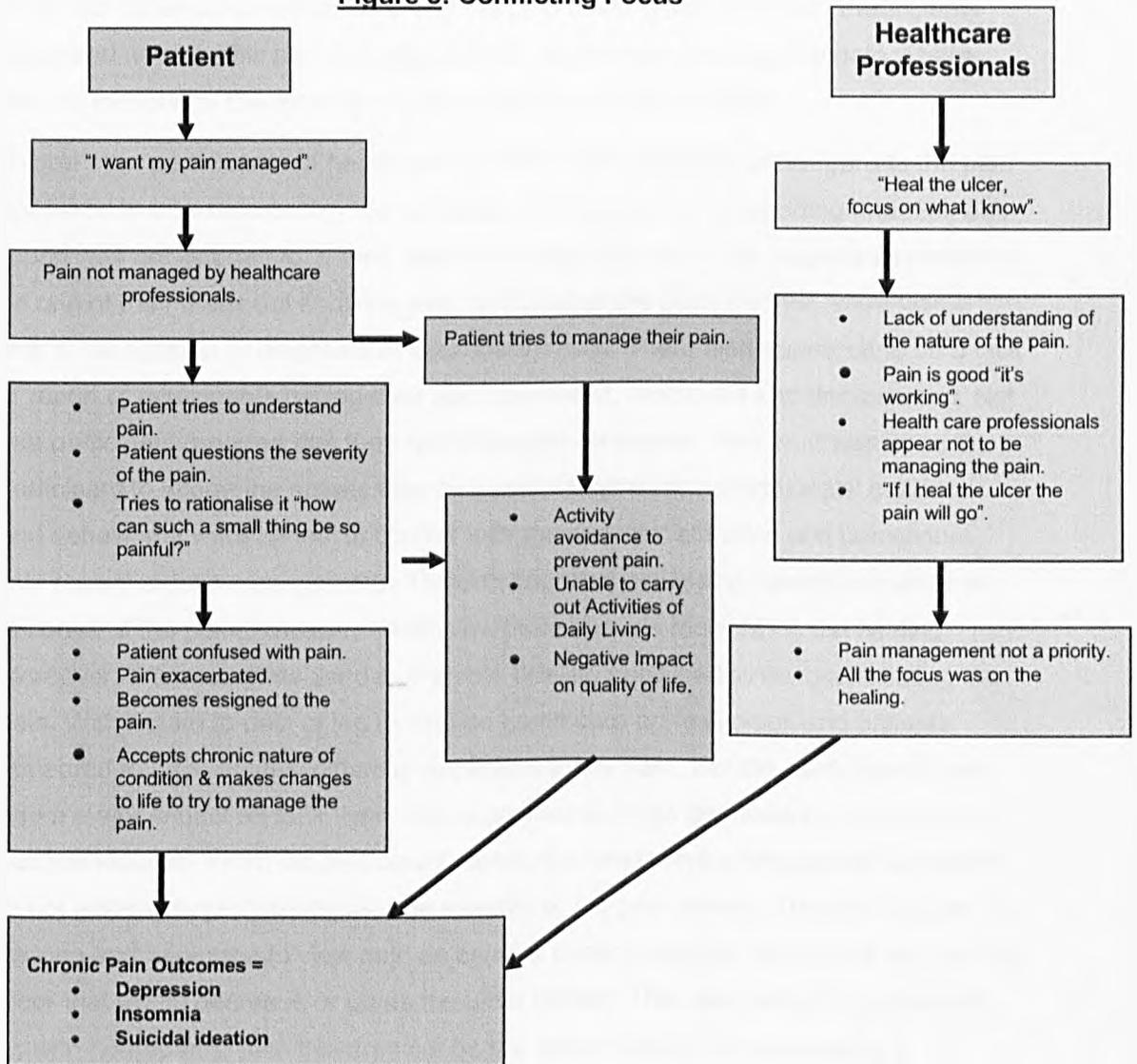
(Participant) *"I didn't take them because the nurses recommended I stick with the paracetamol"*.

### **3.10.5.3 Summary of patient and healthcare professionals' attitudes and behaviours.**

The participants reported seeking healthcare assistance either because of the pain or because their efforts to heal the ulcer did not work. They then entered a path of care that was entirely focused on the healing of the leg ulcer (see Figure 3).

Participants in this study expressed their confusion with the severity of the pain and appeared to view their pain as being more severe than it should have been. The end point as reported by the participants appeared to be one of continued chronic pain leading to depression, insomnia and suicidal ideation. In some cases participants were so desperate to eliminate their pain they desired amputation of the affected limb.

The report from the participants suggested that the focus from the healthcare professionals was on the healing. Participants reported they informed their healthcare providers of their pain but that it was rarely managed appropriately. There appeared to be some suggestion that the nurses viewed the pain as a positive symptom. The pharmacological advice given to participants appeared to be inadequate. Paracetamol was the most frequently mentioned drug and was quoted by participants as being recommended by the nurses. Further there was some evidence to suggest that the doctors were reluctant to prescribe opioids to this group of patients.

**Figure 3: Conflicting Focus**

### 3.11 Summary of findings

From the participant report the picture that was given was one of patients being trapped in a cycle of healing which was exacerbating their pain. Further, the participants described reporting their pain to the nurses, but also described inadequate pain management. Participants were trying various different measures to alleviate their pain with not much success, such as positioning, self-medication and distraction. They were also making changes to their lives to manage their pain. The pain impact on activities of daily living and quality of life was reported as quite substantial. Notably, one participant reported they had moved into residential care because they could not cope with the pain caused by their leg ulcers.

There also appeared to be an element of trying to understand the pain, participants really did not seem to understand why the pain severity was so great. Participants described neuropathic pain but they did not use the term neuropathic pain. There was no mention of the term neuropathic pain by any participants.

Report from participants of healthcare professionals' attitudes with regard to the pain appeared to be exacerbating the condition. Participants were reporting that their pain report was not listened to. If their pain report was listened to the response seemed to be one of the nurses not knowing what to do about the pain. Further, there was a lack of recognition or diagnosis of neuropathic pain. There also appeared to be a lack of report of participants having their pain measured, monitored and documented. Not one participant reported that they had their pain measured. Rather, it was up to the participant to inform the nurses they had pain. Healthcare professionals' attitudes and behaviours were almost in conflict with the patients' attitudes and behaviours with regard to pain management. Patients reported accessing healthcare services because of the pain, however, healthcare professionals focused on the healing. Moreover, the treatments used to promote healing appeared to be exacerbating the pain. With regard to pain of leg ulceration healthcare professionals and patients appeared to have entirely differing responses to the pain. For the participants, pain had a major impact on their lives, with outcomes such as depression, insomnia and suicidal ideation. From the participant report, the healthcare professionals appeared to not acknowledge or recognise the severity of the pain impact. They focused on the healing and appeared to view pain as being a minor symptom associated with the leg ulcer that would decrease or go as the ulcer healed. This was certainly problematic as with neuropathic pain this may not be the case; there is not necessarily a decrease in pain with healing and/or a decrease in the size of a wound. Further, healing may not always be possible. Participants in this study demonstrated this, as they reported having had their leg ulcers for many months, sometimes years.

### **3.12 Discussion of study 1**

This section discusses the findings of the study within the context of the available literature. A combined overall theoretical discussion and conclusion of study one and study two is then presented with recommendations for practice, further research, national guidelines and educational requirements in chapter 5.

### 3.12.1 Study 1 aim

A comprehensive literature review failed to identify any research that aimed to understand why patients with leg ulceration continued to have pain, despite evidence that this patient group have pain and despite the availability of pain management techniques. Hence this grounded theory study aimed to understand the experience of having pain from leg ulcers and to develop theories about why the pain relief for people with leg ulcers appeared to be inadequate. This study aimed to provide new insights and theory regarding the experience of pain associated with leg ulceration and the impact the pain experience has on the individual.

#### Research questions

- i. What is the nature of pain associated with chronic leg ulceration?
- ii. What are the outcomes for patients with pain associated with their chronic leg ulcers?
- iii. What are people with pain associated with leg ulcers doing to manage their pain?
- iv. What reasons are there for inappropriate pain management?

Selective coding identified three central categories, which will be discussed. These were the chronic pain condition, trying to manage pain and conflicting focus. Together these indicated an overarching theoretical statement that encompassed the patient experience. This statement was "Never mind the pain, heal the ulcer".

### 3.12.2 Chronic pain condition

There was a disparity between patients severity of pain at the point of the development of the ulcer. Some described the pain as absolutely terrible and others described it as just irritating. The fact that patients experienced differing severity of pain was to be expected. Pain is a personal experience that results from both the invasiveness of the painful stimulus and how that stimulus is modulated by factors both external and internal to the individual (Stevens, Watt-Watson & Gibbins, 2003). Melzack and Dennis (1978) state that painful stimuli enter an already active nervous system that is a substrate of past experience, culture, anticipation and emotions. As a result there is no single standard experience for any given painful stimulus. Moreover, if these patients have had several episodes of leg ulceration with poor pain management they may have an increased pain response because of changes to their pain neuromatrix. Furthermore, if they have developed neuropathic pain previously this will further affect

their pain intensity. Neuropathic pain intensity does not necessarily correlate with wound size and does not always decline with healing (McQuay, 2002). Evidence also suggested that neuropathic pain can be more severe than nociceptive pain (Caraceni & Portenoy, 1999).

Some participants in this study reported itch as a sensation from the ulcer. In a study measuring the impact of venous leg ulcers on quality of life, 69.4% of participants experienced itching (Hopkins, 2004; Hareendran *et al.* 2005). It was not surprising that some participants reported itch as a sensation associated with their developing leg ulcer. Itch, along with pain is a major part of nociception and an important symptom of systemic problems (Yosipovitch, Greaves & Schmelz, 2003). This finding has been repeated in other qualitative studies where itch has been identified as a problem for patients with chronic leg ulceration (Chase, Melloni & Savage, 1997; Hareendran *et al.* 2005). There was also further evidence of this from quantitative studies investigating chronic leg ulceration (Phillips *et al.* 1994; Heinen, 2006). Furthermore, itch was also associated with neuropathic pain sensations (Boureau, Doubrere & Luu, 1990).

Some participants could predict the development of the leg ulcer by sensations they were experiencing. Some participants reported that it was the pain that led them to seek medical help. However, they went on to report that the pain was not addressed and the focus of treatment was on the healing. Moreover, the treatment to heal the ulcer in most cases caused further pain. In previous studies it has been shown that treatment administered to promote healing has exacerbated pain (Cullum & Roe, 1995; Ebbeskog & Ekman, 2001). Further, various reviews investigating patients with chronic leg ulceration have reported that treatment exacerbated pain (Heinen *et al.* 2004; Persoon *et al.* 2004; Hareendran *et al.* 2005; Briggs & Flemming, 2007).

All participants who had compression bandaging, except one reported that the compression bandaging caused further pain. They often described that the compression bandaging was the worst aspect about having a leg ulcer because it made the pain so unbearable. There was additional evidence in the literature that supported this finding. Mallett (1999) observed in one particular clinic, that many patients, because of the unacceptable levels of pain, could not use compression therapy. In recent studies using quantitative and qualitative methods compression therapy was shown to cause further pain (Edwards, 2003; Heinen *et al.* 2007). Various qualitative and quantitative studies have provided evidence that compression bandaging in some cases was so painful that the patients were unable to tolerate it (Ebbeskog & Emami, 2005; Briggs & Closs, 2006; Mudge *et al.* 2006; Heinen *et al.* 2007). Participants in this study have also reported that in some cases they were unable to tolerate compression therapy. Despite most of the participants reporting that

compression therapy exacerbated their pain the nurses appeared to persevere with this technique. This was understandable as compression therapy is the mainstay of treatment and prevention of ulcers with venous aetiology (RCN, 1998; Cullum & Roe, 1995; Mekkes *et al.* 2003; RCN. 2006; O'Meara, Cullum & Nelson, 2009). The pain with compression therapy was to be expected if these patients were also reporting neuropathic pain. Allodynia is a likely characteristic of neuropathic pain (Wall, 1991). Allodynia can be described as pains that are provoked by normally innocuous stimuli, thus applying a tight heavily layered bandage can be expected to cause further pain. For the nurses managing these patients it is a difficult situation, as they are expected and encouraged to use compression therapy. It is a dilemma as the one treatment that may heal the ulcer, for some causes further suffering.

There was a wide variation in pain experienced during dressing changes. There was no one description that was common and participants appeared to have differing experiences. There was no actual report of debridement pain. However, there were a couple of descriptions that suggest mechanical debridement. Of course the fact that surgical/mechanical debridement caused pain to the two participants that described debridement was no surprise, with an already painful and inflamed wound, stimuli of this form was likely to cause a substantial amount of pain. The pain whilst undergoing surgical/mechanical debridement has been reported in previous studies as being extreme (Krasner, 1998). Not only was the pain severe whilst the procedure was being carried out but the on going pain continued for hours post debridement (Vanscheidt 2001).

The literature and current research investigating pain management of leg ulceration concentrates on procedural pain (Hansson, Holm & Lillieborg, 1993; Lok *et al.* 1999; Stymne & Lillieborg, 2001; Briggs *et al.* 2004; Heinen *et al.* 2004; Briggs & Nelson, 2010). However, the participants in this study described that constant pain was far more troublesome.

In this study some of the participants either did not feel pain or felt better with dressing changes. Others did feel pain when their legs were touched during dressing changes. It appeared that participants from this study had constant pain that did or did not change in nature over a 24-hour period. The theme derived from this data suggested that it was the constant pain that was a problem to the majority of participants who took part in the study. Recent studies reported pain as a major problem to this patient group, but they did not make the distinction between constant and procedural pain (Hareendran *et al.* 2005; Heinen *et al.* 2007). Participants also described persistent pain despite a reduction in the ulcer size as well as severe pain when the ulcers were small or no pain with larger ulcers. Therefore, suggesting that

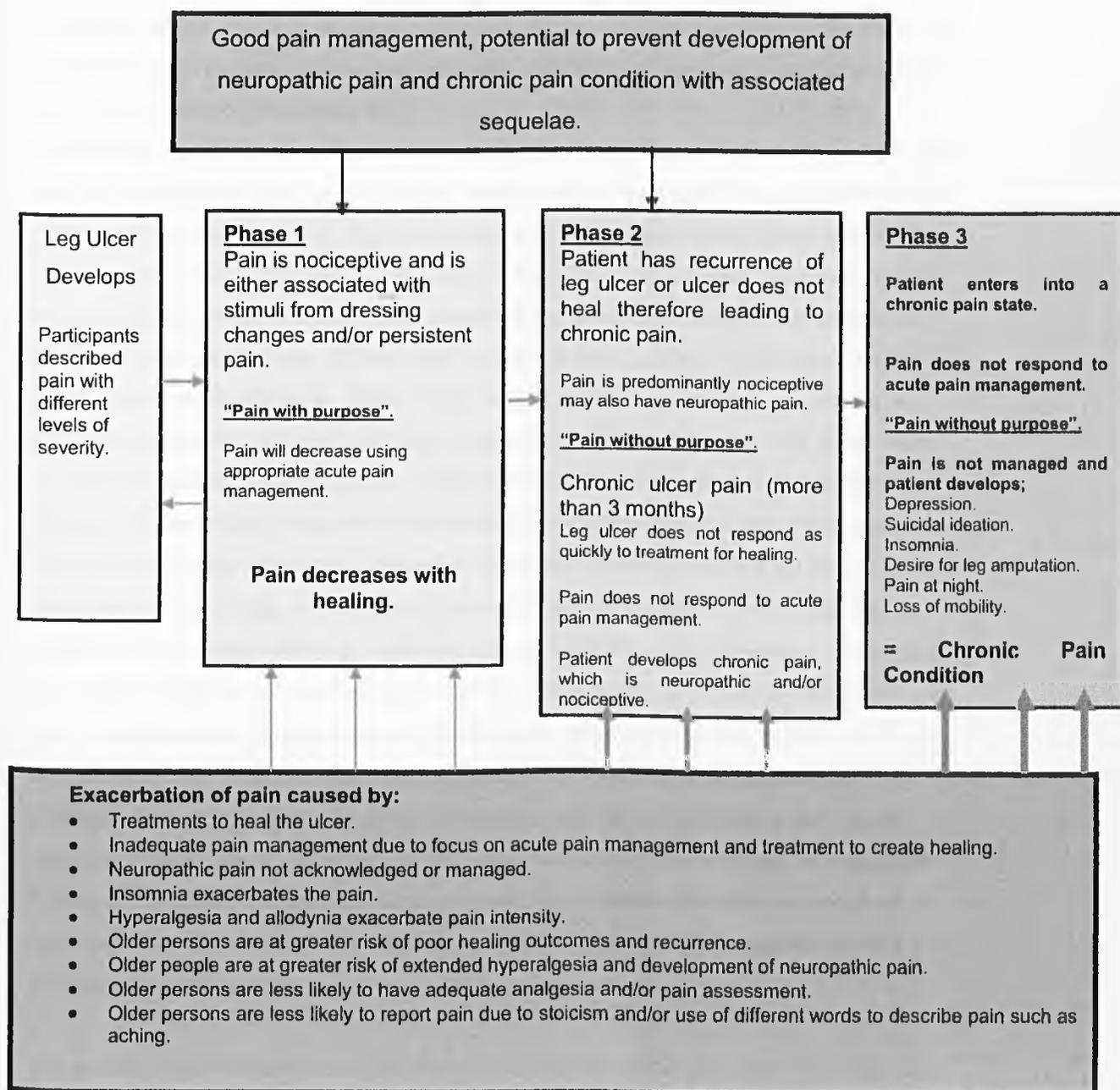
there was not necessarily a correlation between pain intensity, healing and/or size of the leg ulcer. This finding was also demonstrated in quantitative studies undertaken by Briggs *et al.* (2007) and Park, Ferreira and Santos (2008). Briggs *et al.* (2007) undertook a prospective, longitudinal cohort study investigating painful leg ulceration. The findings reported that leg ulcer characteristics such as ulcer type, size nor duration of the leg ulcer, could be used to infer the pain severity an individual may experience. Park, Ferreira, and Santos (2008) determined that age, number, duration and frequency of wounds had no impact on pain intensity. The fact that size and level of healing may not determine pain severity was to be expected if patients have associated neuropathic pain. Neuropathic pain is more likely to persist and does not always decline with healing (McQuay, 2002).

There were many descriptors given that suggested neuropathic pain. The pain associated with neuropathic mechanisms is often described as a continuous burning pain, or spontaneous lancinating or electrical pain (Rasmussen *et al.* 2004; Bennett, 2006). In various studies reporting pain associated with leg ulcers, it was shown that pain descriptors such as burning, shooting, tingling were used by patients describing their pain (Walshe, 1995; Noonan & Burge, 1998; Krasner, 1998; Douglas, 2001; Nemeth *et al.* 2004). Participants in this study did not use the word neuropathic but they certainly used pain descriptors that suggested they may have neuropathic symptoms. In Brigg's *et al.* (2007) study investigating pain mechanism and intensity it was found that 45.3% of the participants had signs of neuropathic pain. None of the participants in this study reported that they had been diagnosed as having neuropathic pain and they were not receiving treatment for neuropathic pain. The evidence from this study further supports the evidence from Briggs's *et al.* (2007) and Park, Ferreira and Santos (2008) studies and the evidence of descriptors used by patients from various qualitative studies, (Krasner 1998; Douglas 2001; Nemeth *et al.* 2004) that patients with chronic leg ulcers are at risk of neuropathic pain.

Participants in this study suffered from chronic pain and described associated sequelae such as sleep disturbance, depression, social isolation and suicidal ideation. There was a considerable amount of literature reporting that; many patients with chronic pain will go on to develop depression, insomnia and suicidal ideation. Psychological co-factors exist alongside chronic pain, which make coping with chronic pain so difficult. Among these co-morbidities was inadequate sleep due to the pain and the anxiety and depression that stem from the stressful negative consequences of living with pain (Nicholson & Verma, 2004).

The description of the pain and its outcomes from participants in this study suggested that they had developed chronic pain with chronic pain sequelae. It is proposed that this was because they had not had their initial pain managed appropriately. Figure 4 illustrates this finding.

**Figure 4:** A theoretical model depicting the journey from development of leg ulceration to development of a chronic pain condition with associated pain sequelae, as reported by patients with leg ulceration 65 years and over.



It is proposed that these patients on initial development of leg ulceration entered the leg ulcer management trajectory with acute pain, which may have responded to an acute pain model (Phase 1). Acute pain is a typical sensory experience that can be described as an unpleasant awareness of a noxious stimulus or bodily harm (Appendix 1, pain terms and physiology). Acute pain responds to acute pain management using analgesics such as paracetamol, codeine and ibuprofen. Stronger analgesics may be required depending on the level of pain intensity. Acute pain from leg ulceration is either associated with stimuli from dressing changes or constant pain associated with inflammation. Acute nociceptive pain has a function it serves to aid tissue repair (Johnson, 2006). The role of acute pain is not only to alert the individual to the cause of the pain but the hyperalgesia associated with inflammatory responses encourages the individual to protect the painful area.

The term "pain with purpose" provides a good description of acute pain. Acute pain can last for seconds and may last for longer, even months. Acute pain has a cause that the patient and the clinician can diagnose. It also has a trajectory that ensures with healing comes a reduction of pain and eventually no pain. Thus, its purpose is not only to alert the person to harm or disease but also informs the person of healing. The inability to feel pain for some patients with diabetic foot ulcers and the loss of pain as a warning can be problematic (Sibbald, 2009). To provide a compelling example of why acute pain has a purpose we need only look at the outcomes for individuals who suffer from congenital insensitivity to pain (CIP). Congenital insensitivity to pain is a rare inherited disease characterized by a lack of pain sensation and thermoregulation (Manfredi *et al.* 1981). For patients with this condition it is unusual for them to reach adult hood because of their inability to feel pain. We rely on pain as an alert to inform us that we are either being subjected to an external noxious stimulus such as burning, or we have an internal illness which is causing an internal noxious stimulus such as infection. If we are unable to detect these we are unable to either remove ourselves from the external noxious stimulus or obtain treatment for the internal noxious stimulus. Without awareness of noxious stimulus illness or trauma may not be identified which would eventually lead to death (Manfredi *et al.* 1981). This is why the term pain with purpose has been described for patients with acute pain associated with initial development of their leg ulcer. It is the bodies' normal mechanism which manifests as pain, alerting the individual to their leg ulcer.

It is said that pain becomes chronic when it lasts for 3 months or longer (Torrance *et al.* 2006). However, this is ambiguous as with some pain it is clear it is a chronic problem before 3 months (Lander, 2007).

Participants in this study described recurrence or they described their leg ulcers not healing. This may have put them at risk of developing chronic pain with a neuropathic pain component because of the physiological processes associated with inflammation and neuropathic pain (refer to Chapter 2, section 2.4). This was because they either did not heal and therefore they continued to have inflammatory pain or because they had recurrence within a few weeks. Compounding this, participants described that the time in-between healing and recurrence became shorter as they got older. Chronic neuropathic pain often serves no useful purpose and the nociceptive system itself has become dysfunctional (Johnson, 2006). The term "pain without purpose" provides a good description of chronic neuropathic pain. It is becoming clearer that unrelieved acute post-traumatic pains or postoperative pains are risk factors in the development of chronic pain, although psychological and environmental factors are at work as well (Shipton & Tait, 2005). It is speculated that pain is more likely to persist following trauma when central sensitization is encouraged. This happens if the patient receives inadequate analgesia and if complications such as infection are present or the extent of the peripheral ectopic activity is prolonged or magnified. Patients with pain associated with leg ulceration are likely to have chronic pain because of the inflammatory processes and because the length of time the ulcer can take to heal. Therefore, they are at risk of central sensitization. Central sensitization may be triggered by primary nociceptive stimulation or by on going peripheral ectopic activity or both (Treede *et al.* 2004). If such a state persists patients are at risk of developing neuropathic pain. There is evidence to suggest that patients who have unrelieved acute pain either following trauma or surgery or following conditions such as shingles, are at risk of developing neuropathic pain and chronic pain syndromes (Hayes & Molloy, 1997; Brown, 2004; Wu, Marsh & Dworkin, 2000). Furthermore, older people are at greater risk of extended hyperalgesia which may put them at greater risk of neuropathic changes (Zheng *et al.* 2000). Brown (2004) state that each year, between 0.05% and 1.5% of post-surgical patients continue to have pain after 1 year. Hayes and Molloy (1997) found that 14% of patients presenting to a pain clinic with pain problems believed that previous surgery was the initiating factor. Further, evidence of appropriately managed acute pain preventing chronic pain has been demonstrated with conditions such as shingles and development of post herpetic neuralgia. Reduction of acute pain and prevention of postherpetic neuralgia are linked, in that any treatment reducing the intensity or the duration of the acute pain, has the potential to prevent or reduce the severity of postherpetic neuralgia, by preventing central sensitization (Wu, Marsh & Dworkin, 2000). Bonezzi and Demartini (1999) suggest that there is a possible window of opportunity for preventing central sensitization early in

the course of shingles. Thus, it may be possible to prevent patients with pain associated with chronic leg ulceration from developing neuropathic pain. It is proposed that if the participants of the study whilst in phase 1 had received adequate pain management and assessment, central sensitisation may have been prevented. This may have prevented them from developing neuropathic pain. Unfortunately participants from this study described receiving inadequate pain management which may have caused them to develop chronic neuropathic pain. Participants described being in phase 3 because they did not have their pain acknowledged or managed appropriately. Therefore, they had chronic pain which had not been managed which led them to develop chronic pain sequelae. They were at greater risk of entering into phase 2 and 3 because they were older, older people are less likely to heal and are at greater risk of recurrence (refer to Chapter 2, sections 2.3). They were also at greater risk of developing neuropathic pain due to unrelieved acute pain (Shipton & Tait, 2005). It is suggested that whilst the participants were in phase 2 their pain may have been predominantly nociceptive but may also have had a neuropathic element. Whilst in phase 2 they may not have responded to acute pain management and may also not have necessarily experienced a reduction in pain with healing, in part due to the developing neuropathic pain component. The focus remained on the healing despite poor healing outcomes. The participants demonstrated poor healing outcomes because they reported having had their leg ulcers for months sometimes years. The patient entered into phase 3 where they had chronic pain with chronic pain outcomes. Moreover, it has been shown that once patients have developed neuropathic chronic pain it is difficult to manage (Bonezzi & Demartini, 1999). No phase was exclusive and rather, phases 1, 2 and 3 describe the participants' journey from the development of acute pain associated with their leg ulcer to the development of a chronic pain condition. Any patient that has a chronic pain condition would have had to go through specific physiological pain processes, which would involve inflammatory responses and development of neuropathic pain (see Appendix 1, Pain terms and physiology). Therefore, whilst participants interviewed in this study described being in phase 3, they would have had to go through phases 1 and 2, before getting to phase 3. The theory developed from this study provides an explanation to why the participants described a chronic pain condition. Once participants had developed a chronic pain condition their quality of life was compromised and they did not respond to acute pain management and were less likely to heal. Reduction of healing associated with neuropathic pain in patients with leg ulcers was demonstrated by Briggs *et al.* (2007). They reported that patients with neuropathic signs and symptoms were less likely to heal. The participants in this study described becoming trapped in a cycle of "Never mind the pain, heal the

ulcer". Moreover, the treatment to heal the ulcer added further to their suffering by causing an increase in their pain. This was especially apparent with compression therapy and as discussed this was to be expected due to the neuropathic component. The pain associated with the chronic leg ulcer was reported to be as chronic as the leg ulcer. Leg ulceration is a chronic condition therefore if the pain from the leg ulceration is not managed the patient is likely to develop a chronic pain condition. The pain experience reported by participants of this study had obvious similarities to other chronic pain conditions. Rheumatoid arthritis (RA) is a good example. Both conditions are chronic and have visual physiological indicators involving inflammatory processes. Patients with RA and leg ulceration are at risk of chronic pain. Further, if the pain is not managed they are at risk of developing chronic pain sequelae. The difference between the management of these conditions is that focus on pain management associated with RA is apparent. Whilst there is some focus on reduction of the symptoms associated with RA it is managed using a chronic disease management model (Majithia & Geraci, 2007). Moreover, the treatments to manage the symptoms associated with RA do not exacerbate the pain. In contrast treatments associated with management of leg ulceration have been shown to exacerbate the pain. Rheumatoid arthritis is recognized as a chronic disease without a cure and its main treatment strategies are managing the associated pain and preventing the future destruction of the joints (O'Dell, 2004). Rheumatoid arthritis is recognised within the literature as a disease with associated chronic pain and has clinical drug trials that demonstrate effectiveness of drugs used to manage neuropathic pain (Rani *et al.* 1996). Leg ulceration management in contrast to RA management emphasises strategies to heal the leg ulcer, therefore focus is on "curing" the patient from the leg ulcer and associated symptoms. Unfortunately the literature has demonstrated that this is not always possible and for some is an unrealistic goal, particularly for older adults (refer to Chapter 2, section 2.3.3).

### **3.12.2.1 Insomnia**

Insomnia can be defined as the perception or complaint of inadequate or poor quality sleep because of one or more of the following: difficulty falling asleep; waking up frequently during the night with difficulty returning to sleep; waking up too early in the morning; or unrefreshing sleep. Insomnia is not defined by the number of hours of sleep a person gets as requirements can vary from person to person. Consequences of insomnia can be behavioural, fatigue, memory difficulties, concentration problems, car accidents, psychiatric problems – depression, anxiety conditions, alcohol and other substance abuse, medical – cardiovascular, respiratory, renal, gastrointestinal,

musculoskeletal disorders, impaired immune system function and an increased risk of mortality (WHO, 2004).

The chronic pain that participants portrayed appeared to be especially troublesome at night. This was something that was very apparent in the individuals' experience and was associated with all types of leg ulceration. The literature suggested that pain at night was problematic for this patient group, regardless of type of leg ulcer. Guarnera *et al.* (2007) undertook a quantitative study investigating pain in patients with either venous, arterial or ulcers of mixed aetiology. They found that nocturnal pain was reported more frequently regardless of ulcer type. Others have also reported this finding (Hofman *et al.* 1997; Noonan & Burge, 1998; Wissing & Unosson, 2002). The picture presented from this study was one of patients desperately trying to sleep with not much success. They presented an impression of restless sleeping patterns with patients often having sleepless night after sleepless night, due to their leg ulcer pain. Patients who have insomnia associated with their leg ulcer pain may fit into phases 1, 2 or 3. This is because all patients in these groups may have pain, which may cause insomnia. However, patients in phase 1 may respond to an acute pain model, which would allow them some pain relief that may lead to sleep. Patients in phases 2 and 3 are not likely to respond to the acute pain model, in part because of the neuropathic pain element. Therefore, their ability to sleep was limited. The lack of sleep adds to the patients suffering, insomnia is a symptom associated with chronic pain sequelae. Insomnia in people with chronic pain is well documented. Patients who suffer from chronic pain experience difficulties in initiating and maintaining sleep. Sleep deprivation has been associated with a decreased pain threshold, muscle aches and stiffness in normal volunteers (Nicholson & Verma, 2004). Patients with chronic pain report that their insomnia started after they began experiencing chronic pain (Morin, Gibson & Wade, 1998; Smith *et al.* 2000). Pilowsky, Crettenden and Townley (1985) carried out a study on 100 individuals referred to a multidisciplinary out patients chronic pain clinic, 70% reported "poor" sleep, while another 20% reported "fair" sleep. Haythornthwaite, Sieber, and Kerns (1991) studied 46 individuals with chronic pain referred to an in-patient rehabilitation pain program. Patients were required to complete sleep diaries for an average of 5 days. Pain related variables (e.g. the duration of pain and pain intensity) were significantly positively correlated with delayed sleep onset, lower quality of sleep and fewer hours of sleep. Sleep disturbance as measured by sleep diary items, was positively correlated with measures of depression and anxiety. Other studies have reported similar prevalence of insomnia in chronic pain patients, (Pilowsky, Crettenden & Townley, 1985). Morin, Gibson, and Wade (1998) found that 65% of patients referred to a multidisciplinary pain clinic described themselves as 'poor

sleepers'. Wittig *et al.* (1982) measured objective sleep using polysomnographic recordings. They compared objective sleep in patients with chronic pain ( $n=26$ ), patients with insomnia and psychiatric disorder ( $n=12$ ) and insomnia ( $n=16$ ). The results revealed that patients with chronic pain had evidence of disturbed sleep efficiency and increased waking time during the night compared to individuals with subjective insomnia. Further, the authors suggested that pain tolerance decreases with lack of sleep and may partially account for reports of increased pain perception (Wittig *et al.* 1982). The finding that insomnia may cause a lower intolerance to pain has also been reported by Nicholson and Verma (2004). They suggested that patients who suffer from chronic pain experience difficulties in initiating and maintaining sleep. Research investigating chronic leg ulceration suggested insomnia maybe a problem these patients suffer. A quantitative study that investigated sleep as part of the study, was undertaken by Heinen *et al.* (2007), using a descriptive cross sectional design. A sample of 141 patients taken from the population of outpatients' clinics of seven hospitals in the Netherlands had their sleep quality measured using a subjective sleep quality scale (SSQS). The mean sleep quality score of all the patients was 9.4 on a 0-15 scale, where 15 stood for excellent sleep. The mean score of the patients who had sleeping problems was 6.7, 45% ( $n=63$ ) of the participants had sleeping problems. Findings from this grounded theory study add further to the evidence that pain associated with leg ulceration may cause insomnia. Moreover, the findings suggested that patients who have chronic pain associated with leg ulceration develop a chronic pain condition. Participants in this study frequently reported problems with sleeping and reported depression. The participants appeared to be in phase 3 (see Figure 4) where their pain had developed into a chronic pain condition. Pain at night and problems associated with sleeping as well as depression were apparent from the participant report. The interrelationship of depression and insomnia and pain is complex; many chronic pain patients are depressed and anxious; sleep deprivation can lead to anxiety; depression can be both the cause and the result of sleep disturbances (Nicholson & Verma, 2004). In Pilowsky, Crettenden and Townley (1985) study patients who reported more sleep disturbance also reported higher scores on measures of depression and anxiety. This finding was repeated by Haythornwaite, Sieber and Kerns (1991); sleep disturbance as measured by sleep diary items, was positively correlated with measures of depression and anxiety. Further evidence for this is given by Nicassio and Wallston (1992) who studied 242 people with rheumatoid arthritis (RA) over a 2-year period. Cross-sectional regression revealed that sleep difficulties, measured by several questions, were independently associated with depression. Interactions of pain and

sleep problems were independently associated with depression from the beginning of the study to follow up. The authors suggested that pain exacerbated sleep disturbance and that, over time, both pain and sleep disturbance may be associated with depression.

The qualitative studies investigating living with chronic leg ulceration provide further evidence of insomnia in this patient group (see Table 4). The pain of the leg ulcer appeared to be the main factor for the cause of the insomnia in participants from this study. It was not possible to state if it was the insomnia or the pain that caused the apparent depression. However, it was the pain that caused the insomnia. There is a strong correlation between insomnia, pain and depression and this has been discussed in the thesis (refer to Chapter 3, section 3.12.2.4).

**Table 4: Evidence of Insomnia, Depression and Suicidal Ideation in Patients from Qualitative Studies Investigating Living with Leg Ulceration**

Author and Methods	Results
Mudge <i>et al.</i> (2006) UK Phenomenological focus group <i>n</i> =6	<i>"I kept it (the compression bandage) on for a week and never slept for the whole week, it was terrible"</i> (p.1169).
Hareendran <i>et al.</i> (2005) UK Transcribed interviews <i>n</i> =38	Some patients described waking up when the effect of the painkillers had lessened.  Itching was also contributed to patients waking up during the night as was stated during interviews.  44.4% felt low or depressed, feeling sad, helpless, and hopeless, losing interest and not liking themselves.
Hopkins (2004) UK Phenomenological unstructured interviews and patient diaries <i>n</i> =5	<i>"I cannot explain why yesterday was nearly a pain free day until 4am, when a very severe pain occurred, waking me from a good sleep not often enjoyed"</i> (p.558).  (Participant quote)
Rich and McLachlan (2003) UK Descriptive phenomenology <i>n</i> =8	<i>"I've got no social life at all, I don't go out... I lay on this bed"</i> (p.53).  <i>"The worst thing is the healing process. Once you've got it, it takes a long time to heal. I could cheerfully chop the leg off...."</i> (p.53).
Douglas (2001) UK Grounded theory transcribed interviews <i>n</i> =8	Lack of sleep created a negative state of well-being.
Ebbeskog and Ekman (2001) Sweden Phenomenological-hermeneutic approach. <i>n</i> =15	Participants said they did not want to show that they were feeling depressed and so they put on a cheerful face when they met friends or were visiting the clinic. They went home and cried in their loneliness and it took a lot of effort not to show what they felt. <i>"It is often so that you make yourself look nice when you go there, you do that, look alert and cheerful. And you look nice today. You could have put on some makeup when you go down there. And when you go home and feel even unhappy"</i> . (p.241). Having no pain was described as a feeling of happiness. <i>"The times when I've been completely out of it, I think I have been in heaven"</i> (p.241).
Husband (2001b) UK Grounded theory. <i>n</i> =39	Pain at night causing sleeping problems was a frequent finding. <i>"At first because it was so bad, I never slept hardly at all"</i> (p.37).. <i>"Oh, I couldn't sleep-I couldn't walk-I couldn't sleep at night"</i> (p.37). <i>"I sat up in bed and cried with pain"</i> (p.37). <i>"They are VERY, VERY painful, I didn't have a full night's sleep for ages"</i> (p.37).
Hyde <i>et al.</i> (1999) Australia Grounded theory. Transcribed interviews <i>n</i> =12	Leg ulcer pain often occurred at night.
Krasner (1998) US Phenomenological <i>n</i> =14	Many women identified that the pain was most evident at night, when it interfered with their sleep. On-going frustration led some patients to feel depressed. One participant described suicidal ideation with regard to her dressing changes.  <i>"I'm getting a little tired. I really am tired of this... Sit me in the middle of the road and let some truck hit me"</i> (P.164).
Walshe (1995) UK Phenomenological transcribed interviews <i>n</i> =13	Pain was reported as preventing patients from getting full night's sleep.

### 3.12.2.2 Depression

Participants in this study reported feelings of depression (refer to Chapter 3, section 3.10.3.3.3) and behaviour associated with depression (WHO, 2007). The WHO (2007) define depression as a disorder that presents with depressed mood, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, low energy and poor concentration. The participants from this study described the experience of their pain that reflected a chronic pain condition. Others have also reported depression amongst leg ulcer sufferers. In a study undertaken by Hareendran *et al.* (2005) measuring the impact of venous leg ulceration on quality of life 44.4% ( $n=38$ ) of participants reported feeling low or depressed. Jones *et al.* (2006) examined 190 patients with chronic venous leg ulceration. Using the HADS scale, 52 patients reported depression.

Depression has been documented as a frequent concomitant of chronic pain (Roy, Thomas & Matas, 1984). Further, reports of the incidence of depression among pain patients have ranged from 10% (Pilowsky, Chapman & Bonica, 1977) to 100% (Turkington, 1980). Many studies and reviews have documented the high degree of co-morbidity between depression and chronic pain disorders (Romano & Turner, 1985; Magni *et al.* 1990; Gallagher & Verma, 1999). The majority of the studies reported the coexistence of depression in over 50% of chronic pain patients sampled (Kramlinger, Swanson & Maruta, 1975; Lindsay & Wyckoff, 1981; Kerns, Turk & Rudy, 1985). Moreover, some evidence showed that the incidence of depression among persons with chronic pain was higher than for other chronic medical conditions (Banks & Kerns, 1996). Ohayon (2004) carried out a study to evaluate how the presence of a chronic painful condition (CPC) lasting 6-months or more influences the frequency and severity of depressive symptoms in subjects with major depressive disorder (MDD). This study took participants from the general population of 4 countries (UK, Germany, Portugal and Spain) ( $n=18,980$ ). Researchers interviewed participants by the phone between 1994 and 1999; nearly one half of the subjects with MDD (43.4%) also had CPC. Subjects with CPC had a longer duration of depressive symptoms (seven months or longer) and were more likely to report severe fatigue, insomnia nearly every night, severe psychomotor retardation, weight gain, severe difficulty concentrating and severe feelings of sadness or depressed mood. In another study Haythornthwaite, Sieber, and Kerns (1991) examined the relationship between depression and pain related variables. Thirty-seven depressed and 32 non-depressed heterogeneous chronic pain patients were identified through structured interviews. The depressed chronic pain patients reported greater pain

intensity, greater interference due to pain and more pain behaviours than the non-depressed group. It is well established and widely accepted that depression amongst chronic pain sufferers is frequent (Kramlinger, Swanson & Maruta, 1975, Pilowsky, Chapman & Bonica, 1977, Turkington 1980, Lindsay & Wyckoff, 1981, Roy, Thomas & Matas, 1984, Turner & Romano, 1984, Kerns, Turk & Rudy, 1985, Magni *et al.* 1990, Banks & Kerns, 1996, Gallagher & Verma, 1999, Ohayon 2004) depression is also likely in older people (Turk, Okifuji & Scharff, 1995; Laidlaw 1997; Lenze, Rogers & Mortire, 2001, Audit Commission, 2002). Therefore, people who are older and have chronic pain could be described as being at high risk for depression.

Depression in older people is common and appears to be associated with increased mortality (Laidlaw, 1997). The main risk factor for depression in older people is poor physical health (Lenze, Rogers & Mortire, 2001). Further, depression in older people is under-diagnosed and can have prevalence rates as high as 16% (Audit Commission 2002). Turk, Okifuji and Scharff, (1995) carried out a study to evaluate relationships among pain, cognitive appraisal variables and depressive affect in the older chronic pain population. One hundred chronic pain patients were divided into two age groups (<69-years ( $n=73$ ) and >70-years ( $n=27$ ). Results showed that younger patients demonstrated a low non-significant correlation between pain and depression. Conversely, a strong direct association was observed in the older patients between these variables. These results suggested that the relationship between pain and depression varies substantially depending upon age cohort.

### **3.12.2.3 Suicidal ideation**

Participants in this study as well as expressing depression also articulated suicidal ideation. Suicidal ideation amongst people with leg ulcer pain was reported but was not discussed in the literature. Krasner (1998) cited a quote from a patient that suggested suicidal ideation (see Table 4). However, Krasner (1998) did not discuss suicidal ideation within the discussion. Risk factors of suicidal ideation were discussed in the literature, such as social isolation (Hopkins, 2004; Hareendran *et al.* 2005) and insomnia (Hopkins, 2004). The literature informs us that patients who have chronic pain are at risk of suicidal ideation. It has been shown that increased pain intensity and longer duration of pain have been positively associated with suicidal ideation (Hinkley & Jaremko, 1994). Ratcliffe *et al.* (2008) undertook a study that accounted for the effect of mental disorder. They used a large population based sample ( $n=36,984$ ) to investigate the association between chronic pain and suicidal ideation and suicide attempts. They demonstrated that there was an association

between chronic pain and suicidal ideation and suicidal attempt, whilst adjusting for mental disorders.

The findings from this study suggested that patients with chronic leg ulcer pain are at risk of developing chronic pain sequelae such as suicidal ideation. The findings propose that without adequate pain management the patient is at risk of being caught in a cycle of failed healing and constant chronic pain with associated chronic pain sequelae (see Figure 4). Patients in the study described chronic pain with neuropathic pain symptoms. However, they described their pain management as acute, which they reported as ineffective. Thus, they continued on a trajectory of inappropriate pain management, with the focus of treatment remaining on the healing aspect. This led the patient to develop chronic pain sequelae with insomnia and depression leading to suicidal ideation.

Strictly speaking, suicidal ideation means wanting to take one's own life or thinking about suicide without actually making plans to commit suicide. Depression is often accompanied by thoughts of suicide; indeed such suicidal ideation is seen as an important element in the diagnosis of depression. The deeper the depression, the more likely it is that a person will experience suicidal ideation. Although suicidal ideation does not necessarily lead to suicide, risk of suicide must be considered. Although suicide rates in older people of both sexes have dropped considerably since the 1950s, they are still high, with older men showing the highest rates. Rates of suicide for the age group 65 years and over were 300 per 1 million in the 1960s and in 1997 this rate had come down to 190 per 1 million (McClure, 2000). Suicide in older people is strongly associated with depression, physical pain or illness, living alone and feelings of hopelessness and guilt. Community surveys suggest that from 10% to over 20% of older people may be experiencing depression, but that only a fraction of these may be known to GP and psychiatric services (DoH, 2001). About 60% of all suicides in older people are associated with depression compared with 30% of 21-35 year olds. Moreover, chronic pains as well as being male, living alone, bereavement, psychiatric illness and depression are risk factors (Kelly & Bunting, 1998). A study undertaken by Smith *et al.* (2004) described suicidal behaviour in a cross-sectional sample of chronic pain patients and evaluated factors associated with increased risk for suicidal ideation. Nineteen percent reported current passive suicidal ideation, 13% had active thoughts of committing suicide, 5% had a current suicide plan, and 5% reported a previous suicide attempt.

Relative to the general population, patients with chronic pain have a heightened degree of suicidal thoughts (Chaturvedi, 1989; Breslau, 1992; Hitchcock, Ferrell &

McCaffery, 1994; Latham & Davis, 1994). Higher rates of suicide attempts (Venkoba, 1990; Stenager, Stenager & Jensen, 1994) and an increased rate of suicide completions (Fishbain, 1996). Further, increases in pain intensity and longer duration of pain have been positively associated with suicidal ideation (Hinkley & Jaremko, 1994). Thus, we can assume from the findings of this study that patients with poorly managed pain associated with leg ulceration are at risk of chronic pain sequelae and therefore are also at risk of suicidal ideation (see Figure 4).

Studies investigating depression in patients living with leg ulceration have demonstrated that depression was a risk. However, there was very little discussion of suicidal ideation in the leg ulceration literature. There was one qualitative study investigating people living with leg ulceration, which demonstrated a patient with suicidal ideation (Krasner, 1998) (see Table 4). Further to this there was one example of a patient desiring amputation, as part of a qualitative study undertaken by Rich and McLachlan (2003) (see Table 4).

The results of this study suggest that patients with chronic pain associated with chronic leg ulceration are at risk of suicidal ideation. The participants described their pain as one of the worst aspects of having a leg ulcer. They also described not having their pain managed. They described receiving acute pain management and the neuropathic component to their pain was not acknowledged or managed. Therefore, their pain continued and the focus remained on healing the ulcer, although the treatments used to promote healing predominantly caused further pain. Some participants demonstrated a wish for an end to their suffering by death and would advocate death as a desperate measure to stop the pain. These patients also articulated a desire for amputation of the affected limb. This is in contrast to the aims of the treatment, which were to protect and preserve the limb. The focus from the leg ulcer guidelines and the focus of the care that the participants described were associated with preservation of the limb. However, some participants focused predominantly on their pain, so much so that some of them desired amputation or death to relieve their suffering.

#### **3.12.2.4 Inter-relationships between insomnia, depression and suicidal ideation**

Chronic pain, insomnia, depression and suicidal ideation are inextricably linked. The evidence in the literature demonstrates that patients with chronic pain are at risk of co-morbidities such as insomnia, depression and suicidal ideation. The

interrelationship of depression and insomnia and pain is complex; many chronic pain patients are depressed and anxious; sleep deprivation can lead to anxiety; depression can be both the cause and the result of sleep disturbances (Nicholson & Verma, 2004). Depression amongst patients with chronic pain has been demonstrated. Moreover, the main risk factor for depression in older people is poor physical health. Patients with chronic leg ulceration are at risk of chronic pain, which has been shown to cause insomnia. Insomnia has been associated as a risk factor of depression that can lead to suicidal ideation. Thus, we can assume that patients with leg ulceration who are 65 years and over are at risk of chronic pain sequelae and the incidence of this has been demonstrated by this study. Therefore, providing further support to the affirmation, pain associated with leg ulceration in some cases is a chronic pain problem and should be managed as such. Patients who have developed chronic pain associated with their leg ulcer are unlikely to respond to acute pain management. Their pain is likely to have nociceptive properties as well as neuropathic properties. If their pain is not managed as a chronic pain condition, acknowledging neuropathic as well as nociceptive pain mechanisms, they are at risk of developing a chronic pain condition with associated sequelae (see Figure 4). Despite requiring chronic pain management the evidence from the literature and from this study suggested that the pain management patients received was acute pain management. Moreover, their treatment continued to focus on the healing of the ulcer. Quality of life was reported as poor and they appeared to be trapped in a cycle of poor healing outcomes and constant severe, untreated pain. The core category "Never mind the pain heal the ulcer", was grounded in the data and summarises the experience that these patients have described (see Figure 4).

### **3.12.3 Trying to manage the pain.**

#### **3.12.3.1 Pharmacological pain management**

Participants reported that their pain management was not effective. They reported continued chronic pain despite taking analgesics. The most frequently reported analgesics being used were paracetamol and codeine. Previous quantitative studies have suggested that paracetamol and codeine are the most common analgesics used by this patient group (Ebbeskog, Lindholm & Ohman, 1996; Guarnera *et al.* 2007). Only two qualitative studies included analgesic type (Chase, Melloni & Savage, 1997; Husband, 2001b), these were paracetamol, tylenol (paracetamol is marketed as tylenol in North America) and codeine. Participants reported that they used opioids, but type and name of drug was not specified. There was only one study available in the

literature that reported the use of opioids (Nemeth *et al.* 2004). However, type of opioid used was not given. Two participants from this study mentioned the use of morphine, but no details on frequency of taking the drug were given. Although participants from the study suggested and described pain that may be neuropathic they did not report that they were taking any drugs for the management of neuropathic pain. There was much evidence available suggesting that tricyclic analgesics are effective for neuropathic pain management (MacPherson, 2000). Amitriptylene appears to be the most common tricyclic analgesic being prescribed by pain experts for the management of neuropathic pain (Maxwell, 2000). However, tricyclic analgesics are not recommended for older adults because of adverse effects (Dworkin, Backonja & Rowbotham, 2003). Further, anticonvulsants such as gabapentin and pregabalin have been shown to be effective for managing neuropathic pain. In a systematic review undertaken by Wiffen *et al.* (2004), 23 trials of 6 anticonvulsants were investigated ( $n=1,074$ ). The type of pain that responded well to anticonvulsants was neuropathic pain. The review suggested that approximately two thirds of the patients who took either carbamazepine or gabapentin could be expected to achieve good pain relief. A newer antiepileptic called pregabalin is now available; it is similar to gabapentin but has been shown to have less severe side effects and does not require titration to the individual patient (Rice & Maton, 2001). Pregabalin has been shown to be as effective as gabapentin but with fewer side effects in several studies investigating its use for neuropathic pain (Rosenstock *et al.* 2004; Sabatowski, Galvez & Cherry, 2004). Participants in this study did not report they were taking any drugs to manage their neuropathic pain. This may be because the participants did not report having had their neuropathic pain diagnosed. They did not report that they had neuropathic pain and also reported that their pain was not measured or assessed. Therefore, if patients were not diagnosed with neuropathic pain it was not surprising that they were not receiving medication to manage neuropathic pain. Further, there was no evidence in the literature that patients who have pain associated with leg ulceration were receiving medication for neuropathic pain. It is not possible to state whether this was because patients were not getting diagnosed with neuropathic pain or the nurses caring for these patients were not aware of medication available to manage neuropathic pain. Some of the participants suggested that they took their medication as required, rather than taking analgesics regularly. However, taking analgesics regularly is a more effective way of managing chronic pain. Participants who did report taking their analgesics regularly also reported that they did not gain effective pain management. This was particularly apparent with one participant who described clock watching (refer to Chapter 3, section 3.10.4.1.3). Guarnera *et al.* (2007) undertook a multicentre cross

sectional study ( $n=381$ ) investigating patients with leg ulceration, they reported that 66% of participants used analgesics as required. Participants also voiced concern with polypharmacy and overdose. It was understandable that participants were concerned with polypharmacy and overdose. Multiple drug use in elderly persons is the most important risk factor for adverse reactions (ADR's) and increases the risk of drug interactions and compliance. ADR's are responsible for about 10% of all hospital admissions of elderly persons. The drugs most commonly involved are cardiovascular, psychotropic's and anti-inflammatory agents (Gaddi, Cicero & Pedro, 2004). There was some report from this study of participants taking analgesics pre-emptively for dressing changes. However, they go onto say that this was not successful, as the nurses did not arrive at regular times. Evidence of pre-emptive analgesic use was not presented in the chronic leg ulceration literature. However, the use of topical local anaesthetic and topical ibuprofen for the management of procedural pain was. Briggs and Nelson (2010) carried out a systematic review; they found that the use of EMLA 5% could be considered to reduce the pain of sharp debridement. They suggest that the main concern with using topical LA for the management of pain associated with leg ulcers appears to be the unknown potential effect that these LA will have on healing. There was no report from the participants that they were having sharp debridement, this may offer an explanation as to why patients in this study did not report the use of LA. Participants in this study also did not report that local applications of ibuprofen were being administered. Application of local ibuprofen was a relatively new concept at the time of data collection and this may offer an explanation to why it was not reported as being used. Thus, we can surmise simple analgesics such as paracetamol and codeine were commonly used. Neuropathic pain did not appear to be managed using appropriate medication such as tricyclic analgesics or antiepileptic's. Moreover, there was also no report of medication being used for procedural pain.

Much of the report associated with effectiveness of analgesics was of analgesics being inadequate. This perhaps was not surprising considering that the participants reported they took analgesics as required and did not take appropriate analgesics. Lack of effective prescribing regimens and medication administration have also been reported in the literature (refer to Chapter 2, section 1.6). Participants reported that paracetamol, although used as a regular analgesic, was not that effective. Paracetamol is a mild analgesic and can be used alone to manage mild pain (Schug, Sidebotham & Guinney, 1998) or as an adjunct to other analgesics, its use is limited by an analgesic ceiling (Maxwell, 2000). Therefore, the fact that patients in this study and also in other studies, reported that it was ineffective for leg ulcer pain was not surprising.

Most of the studies investigating pain management of leg ulceration did not report on effectiveness of analgesics. Heinen *et al.* (2007), Nemeth, Harrison and Graham (2003) and Price *et al.* (2008) reported the effectiveness of the analgesia. Price *et al.* (2008) reported fifty six percent of respondents indicated they took analgesics. However, 21% of this group indicated their analgesics were not effective. Heinen *et al.* (2007) reported that 70% of patients using analgesics indicated they experienced acceptable pain after taking them. However, 25% of the study participants with pain did not use analgesics and 25% used analgesics only occasionally. Nemeth, Harrison and Graham (2003) reported similar findings with 75% of participants finding their analgesics effective. However, 48% of the participants reported that they did not use analgesics. These studies did not report on type of analgesics used. Douglas (2001), Husband (2001b) and Walshe (1995) in their qualitative studies suggested that participants reported analgesics as being ineffective. This qualitative study confirmed this finding with the majority of participants reporting that their analgesics were not adequate.

There was also a suggestion that patients were not taking certain analgesics because of fear of side effects, especially constipation. Constipation was the most frequently reported side effect associated with codeine from participants in this study. Codeine is a low potency opioid and is often used in combination with paracetamol. Constipation is a side effect of all opioids and occurs as a result of opiate binding to the gastrointestinal tract, which leads to decreased peristalsis, reduced intestinal secretions and increased re-absorption of fluids from the colon (McQuay, 1999). This is a side effect that requires particular attention especially in the older person. It is recommended that upon initiation of opioids certain measures should be taken. Use of a stimulation laxative, adequate fluid intake, ambulation and exercise should be encouraged (Gloth, 1996; Maxwell, 2000). Only one participant in this study reported the use of laxatives. There was evidence in the chronic leg ulceration literature of codeine being used for associated pain. However, there was no report of constipation and its management in patients with pain associated with chronic leg ulceration. Participants in this study also appeared to have an aversion to taking opioids due to over-exaggerated fears associated with taking these drugs. The healthcare professionals reinforced these attitudes for these patients. This study confirms further the evidence of misconceptions held by patients and healthcare professionals. These common misconceptions include opiates are dangerous in older people and addiction results from opiate use (AGS 2002; Gagliese & Melzack, 2003; Macintyre, Upton & Ludbrook, 2003). Polypharmacy came across as a frequent concern to participants from this study. This was a genuine concern as multiple drug use in older people is the

most important risk factor for adverse reactions (ADR's). It has been stated by some that an elderly person taking six medications is 14 times more likely to have an adverse reaction than a younger person on the same number of medications (Gloth, 1996).

Healthcare professional advice regarding analgesic use appeared to be limited and did not appear to be standardised. The participants reported that they were advised to take paracetamol and anything stronger was advised against. There appeared to be reluctance in prescribing stronger analgesics, it was not clear why. The findings from this study suggested that patients were managed using an acute pain management model. This may have been appropriate for acute pain that was either mild or moderate. However, these patients described severe chronic pain with a neuropathic element. The participants reported that the focus of care remained on the healing. For patients who have developed chronic pain and fit into phases 2 or 3 (see Figure 4) with a neuropathic component, their pain would not necessarily be relieved by a reduction in size of the ulcer. Participants reported that pain was not in relation to ulcer size, they also did not report a reduction in pain over time. Moreover, they were less likely to heal because of the neuropathic component and other factors such as age. Participants in this study reported their pain to the nurses but also reported that they were given limited guidance or no guidance regarding pain management.

Not one participant described having their pain measured or documented. They also did not report that they had neuropathic pain, which would suggest that the nurses caring for them were not carrying out assessment for neuropathic pain. Thus, ensuring the patients continued to receive acute pain management and did not receive appropriate pain management that may have managed their chronic pain. The provision of appropriate pain-relieving interventions depends on accurate assessment (Closs, 2005). There was further evidence of the lack of pain assessment and measurement in the chronic leg ulceration literature and community nursing literature (Roe *et al.* 1993; Hollinworth, 1995; Kammerlander & Eberlein, 2002; Lorimer, Harrison & Graham, 2003; Breivik *et al.* 2006). These studies suggested that pain assessment was not a routine activity amongst community nurses, despite International wound pain assessment recommendations. The European Wound Management Association and the World Union of Wound Healing Societies have both produced position and consensus documents to address the importance of wound associated pain (EWMA, 2002; World Union of Wound Healing Society, 2004). There are further pain management recommendations published in the wound literature (Woo *et al.* 2008; Fogh *et al.* 2008), these articles discuss wound pain and emphasise the importance of pain assessment. However, the recommendation of pain assessment and

management is a comparatively new development in the wound literature and this may offer an explanation. Hollinworth (1995), Kammerlander and Eberlein (2002); Lorimer, Harrison and Graham (2003) and Breivik *et al.* (2006), reported that community nurses often failed to assess pain verbally or to use pain assessment tools. This is unfortunate as researchers have highlighted the inconsistencies that exist between nurses and patients interpretations of pain (Field 1996; Briggs & Dean, 1998; Harmer & Davies, 1998; Idvall, Hamrin & Rooke, 1999; Nash, Yates & Edwards, 1999; Dahlman *et al.* 1999; Sjostrom, Dahlgren & Halijam, 2000; Idvall, 2004). There was evidence in the literature that suggests older people are not provided with adequate pain management and much of the problem is associated with the failure of appropriate assessment. Without a comprehensive pain assessment, the judgment of the professionals dictates how, what and when analgesia is administered. Older adults are less likely to have their pain accurately assessed due to a multitude of factors (Closs *et al.* 2002; Closs, 1994; Brockopp *et al.* 1996; Herr & Garand, 2001; Kovack *et al.* 1999; Closs & Briggs, 2002) which are; older people being less likely to report pain, older people expect to have pain, older people have been found not to describe the pain sensations as pain but rather discomfort, ache, soreness and other descriptors. Moreover, common misconceptions amongst healthcare professionals create further problems with pain assessment and management, these include pain is a normal part of ageing, perception of pain decreases with age, older people not complaining of pain are not in pain, opiates are dangerous in older people, pain reports can be an attention seeking device in older people and addiction results from opiate use (AGS, 2002; Gagliese & Melzack, 2003; Macintyre, Upton & Ludbrook, 2003).

It can be assumed that older adults can provide self-report of pain (Ferrell, Ferrell & Osterweil, 1990; Weiner, Peterson & Ladd, 1999b). There is evidence that indicates older people are able to use pain measurement scales such as the verbal rating scale and the numerical rating scale (Closs *et al.* 2004). Therefore, it was not the inability of the professional to assess the older person's pain; it was the apparent lack of pain assessment activity for this patient group that may have ensured they did not receive adequate pain assessment and therefore management. This was particularly relevant with regard to lack of assessment and measurement for neuropathic pain. Participants described being managed using an acute pain management model. This had not taken into account the true nature of their pain, which they described as being chronic with a neuropathic pain component.

In summary this study has suggested that patients with pain associated with chronic leg ulceration take simple analgesics. These analgesics such as paracetamol and codeine were not taken regularly and were not reported as providing good pain relief.

The medications used by the participants may have been suitable for an acute pain state that had a pain intensity that could be described as mild to moderate. However, the participants described pain that was severe and chronic. The study showed no evidence of a multimodal pain management approach and their appeared to be reluctance from patients to take analgesics. Moreover, there was no evidence of topical analgesics being used. There was no evidence of pharmacological neuropathic pain management amongst this group. Further, there was no evidence of patients having their pain measured, assessed or documented. Participants described having poor or no communication with their healthcare providers regarding pain management. The theme derived from the data with regard to pharmacological management was of patients having inadequate analgesics, alongside a lack of adequate pain assessment. Despite pain being an obvious problem for patients with chronic leg ulceration, this study suggests that pharmacological pain management was inadequate. Participants described receiving acute pain management, which may have been suitable if they fitted into phase 1 (see Figure 4). However, the participants' descriptions of their pain and the outcomes from that pain would suggest that they fitted into phase 3. Therefore, the pain management they had received was not adequate and was not appropriate for the type and nature of the pain they described.

### **3.12.3.2 Non-Pharmacological pain management**

The non-pharmacological methods of pain relief reported by participants in this study were predominantly patient-led. The most frequently reported method of non-pharmacological pain management as reported by the participants was positioning. This was also reported on in the literature, Ebbeskog and Ekman (2001) reported that different positions were something that relieved the pain.

However, there was limited report in the literature of non-pharmacological pain management for this patient group. Only three qualitative studies could be located that mention non-pharmacological strategies. Positioning as a pain management strategy has been discussed in previous qualitative studies (Hyde *et al.* 1999; Ebbeskog & Ekman, 2001; Hareendran *et al.* 2005). However, success of this strategy has not been investigated in the literature for this patient group.

Despite positioning being used as a strategy, its success appeared limited. This was especially apparent during the night; dialogue from participants suggested that they were spending their nights with disrupted sleep, trying desperately to find a position that would relieve their pain. Much of the positioning involved using various devices,

such as pillows and bed cradles with the aim of reducing pressure on the ulcer. This was perhaps to be expected considering that these patients are at risk of allodynia and hyperalgesia associated with neuropathic pain mechanisms. Therefore, it could be surmised that they were trying to reduce any stimulus on the affected area. However, if they had neuropathic and nociceptive pain positioning may offer some relief but would be unlikely to eliminate the pain. This was especially pertinent if the patient had neuropathic pain, as pain can be present without any stimulus. The pain intensity of neuropathic pain does not necessarily relate to activity. However, if the patient also had allodynia and hyperalgesia it was of no surprise that they would use positioning to try to reduce any stimulus. The constant activity of the patient trying to reduce their pain, to allow them to sleep, by using positioning, may have in-fact added further to their inability to sleep. Participants described scenarios of restless nights where they would spend the night trying to get into a position that would reduce their pain. With little or no success, in part due to the neuropathic element and the inappropriate pharmacological management they were receiving. There were a few participants from this study that suggested distraction techniques were used for pain relief. These techniques consisted of watching television and trying to remove their focus from their pain. This was described as providing some relief. However, their pain was described as being worse at night and the distraction techniques that they may have used during the day, could not be used when their pain was at its worse. There were no studies investigating the use of distraction for pain associated with chronic leg ulceration. However, there were numerous studies investigating distraction for procedural related pain and chronic pain. Common sense suggests that an effective way to cope with pain is to distract oneself from the sensations or emotional responses resulting from painful stimulus. Distraction, like relaxation, can take on many active and passive forms. Commonly, individuals engage in relaxing activities such as reading, watching television, playing computer games, walking, or talking with care givers or families to distract themselves from their pain (Stevens *et al.* 2003). Non-pharmacological practices, such as guided imagery, hypnosis and distraction have been effective in improving patient experiences during stressful or painful procedures (Lang *et al.* 1996). A number of studies support the effectiveness of distraction as a treatment for children experiencing acute medical pain (Powers, 1999; Zelikovsky, Rodrigue & Gidycz, 2000; Dahlquist *et al.* 2002).

There was some suggestion from participants that they used complementary and alternative medicine (CAM). However, most of the report was associated with homemade concoctions or buying herbal and pain management devices. There was

scant evidence in the literature of the use of CAM to manage pain associated with chronic leg ulceration.

The findings suggested that participants developed their own methods of non-pharmacological pain management. There was no report of healthcare professionals giving advice on non-pharmacological methods. Participants also reported that the non-pharmacological methods they employed were not that successful, especially relating to positioning to relieve the pain at night. This was not surprising considering they described their pain as severe with neuropathic symptoms. Moreover, participants also described the compression therapy as causing an increase in pain. Therefore, perhaps no amount of positioning or distraction could reduce their pain because of the severity and the on going focus on the healing, which they described as causing further pain and perhaps encouraged a lack of focus from the health care professionals on managing the pain.

#### **3.12.4 Conflicting focus**

Participants in this study described seeking healthcare assistance either because of the pain or because their efforts to heal the ulcer had failed. Findings from this study support findings from Husband's (2001a) work in her qualitative grounded theory study, investigating people with chronic leg ulceration, Husband reported that the main factor for participants to approach their GP was pain.

Participants' reports suggested they attended their GPs because of the pain. They reported that the pain was not managed and they were then referred to the community nurses. It is to be expected that patients with leg ulcers be cared for by community nursing teams (Dowsett, 2005). Once they became a patient of the community nursing team the emphasis of care appeared to focus on the healing of the ulcer and participants reported that their pain was not addressed. This was to be expected because leg ulceration guidelines emphasise a focus on the healing (RCN, 2006). Furthermore, work undertaken on the topic of leg ulceration has mainly concentrated on healing rather than symptom control. The participants described that the nurses gave very little advice on pain management. Participants went on to describe entering a cycle of care that promoted healing, requiring frequent attention from the nursing teams. This led to a dependence on the nursing teams and a loss of independence by the patients. Jobling (1988) describes some chronic disease management as hard work. Sufferers find they are caught in the "Sisyphus syndrome". In Greek mythology Sisyphus was condemned by the Gods for his misdemeanours to roll a huge boulder to

the top of the mountain; as he approached the summit, the boulder would always slip and fall to the bottom, and he would be forced to begin again. So too with patients, they work hard with various treatment regimens, only to find that their condition has changed very little. This working hard attitude to heal the ulcer appears to be further enforced by the healthcare professionals. One participant in this study described the GP telling him to "keep on with the good work" to heal his ulcer, despite the patient going to him for pain management. Participants described seeking pain management from their GPs who either prescribed antibiotics or appeared to dismiss the pain. Husband (2001a) found that healthcare professionals would often ascribe pain to infection and would prescribe antibiotics in response to a patient expressing pain. The evidence in the literature that pain can be used as an indicator for leg ulcer infection is ambiguous (Gardner, Frantz & Doebbeling, 2001). Evidence from a few qualitative studies exists but only one study describes patients that suggested an increase in their pain was caused by infection (Hyde *et al.* 1999). Participants in this study described accommodating their lives around dressing changes and nurse visits in the belief that this would cure their ulcers, which would relieve their pain. However, most of the patients in this study had suffered from their leg ulcers for months and in some cases years. Participants described losing independence and their ability to undertake day-to-day tasks such as housework limited, due to the pain. Other qualitative studies investigating living with leg ulceration have reported that restrictions in activities of daily living occur due to the pain (Hyland, Lay & Thomson, 1994; Ebbeskog, 2001). Participants described dealing with their loss of independence and ability to undertake day-to-day tasks by employing outside help. One participant in this study was so disabled by the pain from her leg ulcers that she moved into residential care.

Participants also described confusion with regard to the extent of their pain. They just did not appear to understand why 'such a little thing' could hurt so much. This perhaps was to be expected considering they did not appear to have an understanding of the pain mechanisms associated with neuropathic pain. Further, severity of pain was not always dependent on wound size. Pain severity and its experience is an individual, unique and distinctive phenomenon for each individual irrespective of cause (Jacox, 1977; Craig, 1978; Melzack, 1982; Melzack, 1999). Perhaps due to the lack of understanding with regard to the severity of the pain participants described, there was also a sense of guilt and down-playing. There was a real sense of participants feeling they exaggerated the pain because they just could not comprehend why they hurt so much. This was further compounded by the nurses' apparent lack of pain assessment and appropriate management. Participants did not describe having any diagnosis of

neuropathic pain and therefore were not offered an explanation of the nature of their pain from the healthcare professionals. This perhaps caused the patient to feel confused with regard to the severity of their pain. The leg ulcer literature did not appear to have any further evidence of this patient behaviour. However, there was evidence of healthcare professionals holding the belief that leg ulceration causes minor pain and irritation (Porter, 1979; Bennett *et al.* 1985; Cornwall, 1986; Buxton, 1987; Vallencia, Falabella & Kirsner, 2001). It could be surmised that healthcare attitudes have affected patient beliefs around their pain experience. Thus, ensuring patients with severe pain found it difficult and confusing to understand the extent of their pain. As they perhaps have been led to believe that leg ulcer pain is not usually painful (Vallencia, Falabella & Kirsner, 2001). Despite work suggesting that leg ulceration is in fact painful, participants appear to hold onto the belief that they should not cause so much pain. It must be remembered that the majority of the participants in this study have had leg ulceration for many years. Thus, we can assume that some of their understanding of their condition and its symptoms will be based on information gained at initial diagnosis and commencement of treatment. The literature concerning leg ulceration has acknowledged the pain component within the past 10-15 years. However, there was little evidence of change in practice. Moreover, the neuropathic aspect of the pain did not appear to be understood or acknowledged by the patients. There was no report of the patients receiving any information from the nurses with regard to the possibility of neuropathic pain. Participants appeared to receive pain management that may have been appropriate to patients who had acute pain with nociceptive properties and could be described as fitting into phase 1 (see Figure 4). However, the patients in this study described pain that was chronic with a neuropathic element. They described a pain experience that would suggest they predominantly fitted into phase 3 as they also described suffering with chronic pain sequelae (see Figure 4). Participants reported that the healthcare professionals continued to focus on the healing aspect and although they acknowledged the pain, they tried to manage the pain using an acute pain model. Furthermore, there was some report that the nurses viewed the pain as a positive aspect, suggesting that the pain was good because it indicated sensation and or healing. The patients reported the pain but because the nurses focus was on healing the ulcer they perceived pain as a good symptom. It appeared that the nurses were so focused on the ulcer that they were unable to remove that focus and manage the patient using a more holistic approach. Nurses viewing pain as a good sign has not been discussed in the wounds literature. However, previous studies have identified professionals incorrect attitude to pain (Lebovits, Florence & Bathina, 1997; Levin, Berry & Leiter, 1998; Ponte & Johnson-Tribino, 2005) and have shown that this

impacts negatively on the pain management ability of the clinician. Furthermore, the leg ulcer literature encourages the use of pain as an indicator to infection/sensation or arterial involvement (RCN, 1998; RCN, 2006). Therefore, it is understandable that nurses might use pain as an indicator. However, it is not clear why nurses perceived pain as a positive symptom associated with healing.

The reported healthcare professionals' attitudes and behaviours appeared to be in conflict with the patients' attitudes and behaviours. Patients described focusing on their pain experience and trying to manage their pain. According to the participant report healthcare professionals focus remained on the healing of the ulcer. They approached the management of the ulcer using an acute care model that may have been appropriate for patients who were in phase 1 (see Figure 4). This is because patients in phase 1 have nociceptive pain that may respond well to an acute pain model. Moreover, the pain is likely to reduce with healing. However, patients that are in phases 2 and 3 are unlikely to respond to an acute care model and require chronic pain assessment and management that considers the neuropathic element. It could be proposed if this were undertaken for patients in phase 2 the risk of patients developing chronic pain sequelae would be reduced. This would prevent patients from entering phase 3 where they develop a chronic pain state with the outcome of a poor quality of life. The patient enters a cycle of chronic pain that impacts on every aspect of their life causing misery and ensuring they enter a cycle of "Never mind the pain, heal the ulcer".

### **3.13 Limitations of the study**

It can be acknowledged that there are factors that may decrease the credibility and reliability of this study.

The community nurses were responsible for putting participants forward thus they were gate keepers and may or may not put some control on who was put forward. The researcher was dependent on the nurses for selecting the sample and it is possible the variation of the data may have been limited (Bluff, 2005). It is not possible to state that all of the patients who would have been potentially suitable for this study were approached and invited to participate. One could suggest that it would be impossible for the community nurses not to influence the selection if they are controlling the selection of participants put forward. The majority of the participants were female with venous leg ulceration, whilst this reflects the higher prevalence of leg ulceration amongst women and the higher prevalence of venous aetiology, the theory developed may not be a true representation of the male

experience or the experience associated with arterial aetiology. However, data from the men and data from participants with arterial or mixed aetiology demonstrated a similar experience to what was described by the majority. Furthermore, using theoretical sampling the researcher did try to recruit more men and more participants with arterial or mixed aetiology, but none came forward. Whilst this may cause a weakness in the study findings, it was the pain experience and its outcomes, irrelevant of the aetiology that was the focus. Therefore, the study participants were a reflection of the patient group that suffer from leg ulceration. It is accepted that patients 65 years and over with leg ulceration are most likely to be female and are most likely to have a venous ulcer (refer to Chapter 2, section 2.3).

Another factor to consider with regard to the nurses being responsible for inviting patients to participate is that the nurses may not have been aware of all patients who were in pain because of two factors, first nurses may not have had adequate knowledge and education in pain management that allowed them to understand that some patients had pain associated with their leg ulceration. Second, if patients were not having their pain assessed adequately, some patients with pain may not have been known to the nurses looking after them. Therefore, it is possible that not all patients who experienced pain associated with their leg ulcers were invited to participate.

Another factor that may have impacted on the data was one study site did not recruit any patients possibly due to lack of resources and staff shortages. However, there was a good geographical representation from across the area being investigated. The above factors may create a slightly inaccurate picture, but because of the ethical considerations regarding data protection, it was not possible to gain direct access to patients. This had to be considered to gain ethical approval. Therefore, there was no other way to recruit these patients. Thus, the experiences that the patients described may not be wholly representative of all patients with pain associated with leg ulceration. However, this is the nature of qualitative research. It is the ability of the theory to fit and make sense to people involved in the area of research that reflects its truthfulness, fit and credibility.

All participants that were recruited were Caucasian; this is probably because inclusion criteria dictated that all participants were required to undertake an interview in English. Due to lack of resources it was not possible to use translators for non-English speaking participants. Therefore, this study does not represent ethnic minorities from the area involved in the study.

Another consideration that may impact on the internal credibility, or the degree to which the findings represent the reality of the experience of pain and its management associated with chronic leg ulceration, can be distorted by sources of subjectivity from the researcher and the participant.

The researcher is a pain specialist and has worked predominantly in pain management; therefore there is a possible bias towards the pain subject. However, the grounded theory method ensures a process where this is considered. Using reflexivity along with memo writing and the constant comparative method possible bias were acknowledged and addressed.

Credibility may also be decreased by the respondents' inability to accurately recall perceptions of events and responses to those events. Therefore this study developed theory based on patients' perceptions and report of what they had experienced and were experiencing not necessarily on what they had actually experienced.

### **3.14 Summary**

Figure 4 is a model of the theory developed from this study. From the participant report the picture that was given was one of patients being trapped in a cycle of "Never mind the pain, heal the ulcer". This was especially pertinent, as the majority of these patients reported having had their leg ulcers for months if not years. The literature and evidence from this study suggested that patients with chronic leg ulceration may suffer from chronic pain and are at risk of chronic pain sequelae. The participants from this study demonstrated that they were indeed suffering from chronic pain sequelae. The treatment they were receiving to heal the ulcer in some cases was exacerbating their pain. There were clear similarities with the outcomes for these patients compared with outcomes for patients who have other chronic pain conditions.

Participants reported trying various different measures to alleviate their pain with not much success, such as positioning, self-medication and distraction. They also made changes to their lives to manage their pain. The pain impact on activities of daily living and quality of life was reported as quite substantial. With one participant moving into residential care because she could not cope, due to the pain caused by the leg ulcers.

The patients reported focusing on the pain, as it was the pain that caused them the most disruption to their quality of life. Yet the emphasis from the healthcare professionals remained on the healing. The theory developed describes the pain

journey the patients experienced which accounted for them developing a chronic pain condition. It was surmised from this study that these patients, on development of their leg ulcer had acute pain with nociceptive processes including inflammation. Whilst in phase 1 they may have responded well to an acute care model, this was because they would not have had neuropathic pain at this stage. They may also have responded well to the acute care model because there was a likely reduction of pain with healing. At this stage they were more likely to heal and therefore "perform" in a way that was expected by the clinicians. However, if the ulcer did not heal or there was a recurrence of the ulcer the patient was at risk of developing chronic pain. Thus, leading onto the second phase, pain became chronic with associated nociceptive pain, increased allodynia and development of neuropathic pain. Whilst in phase 2 patients may not have received adequate pain management in part because of the lack of recognition of the neuropathic pain. Whilst in phase two they were at risk of entering into phase 3 where the pain was constant with a neuropathic component that just added to the confusion and lack of effective pain management. The treatment continued to focus on the healing of the ulcer. The patients described chronic pain sequelae such as depression, suicidal ideation and insomnia. Quality of life was poor and they were trapped in a cycle of poor healing outcomes and constant severe, untreated pain. For all phases the focus remained on the healing, despite the fact that patients who have developed neuropathic pain and who are older are less likely to heal. Participants did not suggest they had been diagnosed or were being treated for neuropathic pain. Patients with chronic pain with a neuropathic element will not respond to an acute care model. These patients required chronic pain management that considered the nature of that pain. The patients in this study described a pain experience that would suggest they were in phase 3 (see Figure 4). However, they described having treatment that may have been appropriate for them whilst in phase 1 but were not suitable for them whilst in phases 2 and 3. Perhaps it would be more appropriate to manage these patients using a symptom management approach. This would allow the shift of focus from healing to symptom management, with the aim of creating a better quality of life for the patient.

## **Chapter 4**

### **Study 2: A Feasibility Study.**

#### **Painful Leg Ulcers: Community Nurses' Views.**

##### **4.1 Aim**

This study aimed to provide insight regarding community nurses' views regarding painful leg ulcers. Nurses predominantly care for this patient group therefore; investigation about nurses' attitudes and knowledge regarding pain management of patients with leg ulceration was required. This allowed for further understanding of what was happening with regard to pain management for this patient group.

- iv. What reasons are there for inappropriate pain management?
- v. What do nurses looking after these patients understand about the pain?
- vi. What strategies do nurses use to manage their patients' pain?
- vii. Do nurses have confidence in managing pain for this group of patients?

##### **4.2 Study 2 Objectives**

- i. To explore community nurses' perceptions of the nature of the pain from chronic leg ulceration.
- ii. To describe current strategies used by community nurses to manage pain in this patient group.
- iii. To survey nurses' attitudes in relation to providing pain management for this group.

##### **4.3 Method**

###### **4.3.1 Sample**

This was a feasibility and pilot survey of the population of community nurses employed by a primary care trust (PCT) in the North of England. All community nurses were invited to participate from the PCT. Community nurses including healthcare assistants in the trust were sent questionnaires individually and asked to complete them independently. The logistics of the study and how to identify study participants were

discussed with lead nurses of the PCT. Once ethics approval was gained, lead nurses agreed to provide a list of names of nurses employed and where they worked.

#### **4.3.2 Inclusion criteria**

- i. Qualified nurses and health care assistants.
- ii. Community nurses employed by the primary care trust.
- iii. Community nurses caring for patients with chronic leg ulceration within their caseload.

#### **4.3.3 Exclusion criteria**

- i. Nurses working within the primary care trust (PCT) but not employed by the PCT i.e. student nurses and agency nurses.
- ii. Nurses whom the PCT employed but who did not look after patients with chronic leg ulceration.

#### **4.3.4 Ethical approval**

Ethics committee approval was gained from the local research ethics Committee. Local research ethics committee and research governance procedures were adhered to (Appendix 6). Research and development approval was applied for and gained from the local research and development unit (Appendix 7).

#### **4.3.5 Implied consent**

Consent was implied if the nurses completed and sent back the questionnaire. Covering letters (Appendix 8) and study information leaflets (Appendix 9) were sent with questionnaires. They included information regarding confidentiality and it was made very clear that the study was entirely voluntary.

#### **4.3.6 Data collection**

Data were collected using a questionnaire (Appendix 10); this allowed for access to the whole sample, which aimed to assess the nurses' knowledge about the nature of leg ulcer pain and attitudes about pain management associated with chronic leg ulcers. Data were also collected relating to pain management provision and support within the individuals' clinical area of work.

A questionnaire was used, as it is ideal for large sample sizes (Walonick, 2004). A cover letter was enclosed with the questionnaires in order to increase response rate (Walonick, 2004). It allowed the researcher to explain the purpose and nature of the

research and requested that the respondent completed the questionnaire.

Questionnaires were sent to places of work.

Confidentiality of data was assured. An anonymous study is one in which nobody (not even the researcher) can identify who provided the data. It is difficult to conduct an anonymous questionnaire through the mail because of the need to follow-up on non-responders. The only way to do a follow-up is to mail another questionnaire or reminder postcard to the entire sample. However, it was possible to guarantee confidentiality, where those conducting the study promised not to reveal the information to anyone. Each questionnaire was given a study number and to whom it was sent recorded. This was necessary for follow up procedures. One of the most powerful tools for increasing response is to use follow-ups or reminders (Edwards *et al.* 2002). For the purpose of follow-up, identifying numbers on questionnaires is generally preferred to using respondents' names (Walonick, 2004). A further strategy used to increase response rate is the use of an incentive (Edwards *et al.* 2002). A wrapped chocolate was sent along with the questionnaire and the cover letter. A meta-analysis of 38 studies that used some form of incentive revealed that monetary and non-monetary incentives were effective only when enclosed with the survey (McColl *et al.* 2001). The average increase in response rate for monetary and non-monetary incentives was 19.1% and 7.9% respectively (Walonick, 2004). Three weeks were allowed for return of the questionnaire, for non-responders a second questionnaire with a covering letter was sent. Although a cut off of three weeks was used before sending out further questionnaires a deadline for returning was not given to the responders. Notification of a cut off date have been shown to reduce response rates (McColl *et al.* 2001). Once the follow up questionnaires had been sent, list of names and places of work were destroyed to protect anonymity. Stamped addressed envelopes were provided to return the completed questionnaires. This was to ensure that the questionnaire was easy and convenient to return. Mail surveys that include a self-addressed stamped reply envelope get better response than business reply envelopes (Walonick, 2004). All data from the study will be stored for 5 years under lock and key at the University of Leeds.

#### **4.3.7 Questionnaire development**

Whilst there were a limited number of studies relating to pain and leg ulcer management, these studies only asked questions relating to pain assessment. They did not ask questions about the nature of the pain or the management of the pain (Roe *et al.* 1993; Moffatt, Franks & Hollinworth, 2002; Kammerlander & Eberlain,

2002; Lorimer, Harrison & Graham, 2003). Hollinworth (1995); Moffatt, Franks & Hollinworth, (2002); Kammerlander & Eberlein, (2002) papers focused on dressing types used to prevent pain. Lorimer, Harrison and Graham (2003) audited practice of care given to a cohort of clients with venous leg ulcers from one nursing agency. This was the only paper that discussed and investigated pain assessment as well as management activity. However, the researchers' aims were to assess and audit nursing practices in all aspects of caring for patients with leg ulceration, so the main focus was on dressings used and practices carried out relating to the wound care. Therefore, they did not measure attitudes of community nurses with regard to pain associated with leg ulceration. Hollinworth's (1995) and Kammerlander and Eberlain (2002) papers used postal questionnaires. Kammerlander and Eberlain (2002) sent questionnaires to 3,300 nursing and medical practitioners. They did ask questions regarding pain assessment but again their focus of questioning was on the dressing types used to prevent pain and trauma. Hollinworth's (1995) study also focused on the dressings rather than activity of pain assessment. Moffatt, Franks and Hollinworth (2002) investigated nurses' views regarding pain and trauma at dressing changes across 11 different countries. They did not ask direct questions regarding pain assessment and again the focus was on the dressings used. However, they did establish that the nurses were not using pain assessment before or after the dressing change. Roe *et al.* (1993) study design had groups of nurses answering questions at team meetings. Therefore, their responses may not reflect individual practice and instead may reflect the groups' perceptions on what they thought they should be doing. This study did not use direct questioning regarding pain management practices but rather questions relating to assessment, which obtained answers from the respondents regarding pain management. The questionnaire they used was a semi-structured questionnaire and each question was asked in a number of ways to ensure that respondents had more than one opportunity to describe their practice. Roe *et al.* (1993) study was the only study that discussed and provided evidence of reliability and validity of their questionnaire. They ascertained face validity during a pilot of the questionnaire and then tested their questionnaire responses using inter-rater reliability on a 10% ( $n=15$ ) random sample. The purpose of the inter-rater reliability check was to ensure that the codes and scores given for type of data collected were reliable. Reliability checks were undertaken on 204 items and the percentage agreement did not fall below 79% for any item.

Previous studies that have used validated questionnaires to assess pain knowledge and attitudes have been undertaken (McCaffery & Ferrell, 1992). However,

McCaffery and Ferrell's (1992) validated questionnaire would not have been suitable for this study as it did not have questions relating specifically to the management of chronic pain associated with leg ulceration. Therefore, it was necessary to develop a questionnaire that could be used to investigate the objectives of the study. The development of the questionnaire followed the identification of relevant issues and situations described by the respondents from study 1. Furthermore, items and domains were appropriated from the relevant literature.

The questionnaire was piloted among community nurses working for a separate primary care trust in the South of England. Seven community nurses completed the questionnaire and were given opportunity to make comments on the lay out and content of the questionnaire.

Some of the respondents in the pilot suggested the reasons for pain with compression; therefore, question 11 was added to the questionnaire.

Question 11 "If you have ticked all or some patients, why do you think it causes or worsens pain?"

The respondents in the pilot had no problems with answering the questionnaire and feedback was positive. They suggested the questionnaire was presented in an A4 booklet format as this made it easier to complete and ensured the pages stayed together, therefore preventing loss of data.

This study was a feasibility and pilot of the use of the newly developed questionnaire, to investigate community nurses' views regarding pain and its management of chronic leg ulceration. However, the validated Clinical Decision Making Questionnaire was incorporated, with permission, from the authors (Brockopp *et al.* 2004). The aim of this was to examine if the community nurses manage pain of equivalent severity with equal time and energy regardless of condition. The authors had validated this questionnaire; a panel of experts established content validity and test re-test reliability was undertaken on a separate sample (Brockopp, Ryan & Warden, 2003). Categories were selected based on the literature as well as consideration for the group of nurses being surveyed.

#### **4.3.8 Reliability and validity of the questionnaire**

The ideal questionnaire would be one that had been developed, tested and validated previously. However, as discussed there were no available questionnaires relating to the topic of investigation that could have been utilised, apart from the inclusion of the

Brockopp *et al.* (2004) questionnaire. However, Brockopp's *et al.* (2004) questionnaire only established if the nurses were using preconceived ideas rather than just patient report to manage patients' pain.

#### 4.3.8.1 Reliability

Reliability refers to the measure of how stable, dependable, trustworthy, and consistent a test is in measuring the same thing each time (Campbell & Machin, 1993). A measure is considered reliable if it gives the same result over and over again (assuming that what is being measured isn't changing). Reliability is defined as the degree to which a measure gives consistent or reproducible values when applied in different situations e.g. on different occasions on the same individual (test re-test reliability).

It was possible to test the reliability of the survey by undertaking internal consistency testing of the items within the survey. Internal consistency refers to the degree to which the items that make up the scale "hang together". In other words, are they all measuring the same underlying construct? (Pallant, 2003). The most commonly used indicator of internal consistency is the Cronbach alpha coefficient. It is a particularly useful test because it can be used when it is impractical or undesirable to assess reliability with two tests or to have two test administrations (because of limited time or money) (Cohen, Swedlik & Smith, 1992). When considering reliability, the most important output is the alpha value. The value given will be between 0-1. A value of 0.5 or above is considered acceptable (Bowling, 2005) and if a value of 0.7 or above is established then the test can be considered to have strong reliability (Pallant, 2003). The Cronbach alpha scores for this survey are presented in the results section (section 4.4.1).

To obtain further reliability of the questionnaire a test, re-test would have been required. Due to the time and financial limits of the PhD it was not possible to carry out test re-test reliability, although this may not always yield reliability. There are two issues with test re-test; the first is if re-testing is undertaken too soon it may produce a false reliability as the respondents may have memorized the questions (Heffner, 2004). If the re-test is carried out at a much later date then there is no control on what the respondents may have experienced between the tests. For example they may have attended in house training or they may have experienced something that may make them respond differently to the questions. Test re-test reliability is best used for things that are stable over time, such as intelligence (Trochim, 2006).

The other forms of reliability testing for surveys are inter-observer reliability and internal consistency reliability. It was not possible to undertake inter-observer reliability as this was a survey that did not include interviewing techniques or observations by more than one researcher (Heffner, 2004). Internal consistency reliability is used to judge the consistency of results across items on the same test. To do this you would need to ask two questions for each item you were testing (Trochim, 2006). The reliability of the instrument is judged by estimating how well the items gain similar results. This was not undertaken as the study was a feasibility and pilot study. As previously mentioned due to the time and budget constraints of the PhD, it was not possible to carry out some types of reliability.

#### **4.3.8.2 Validity**

##### **4.3.8.2.1 Content validity**

Content validity refers to the validity of the content of the questionnaire. Content validity is not determined using a statistical test, rather it involves the systematic examination of the test content. The examination of the test is undertaken to ensure that the content covers adequately the activity and behaviours being measured (Anastasi & Urbina, 1997). It can be achieved using review of experts in the subject domain. The content of the questionnaire was assessed and designed by the researcher and two other researchers with relevant expertise. The researcher had worked as a pain specialist for many years and had specialist expertise in the topic of pain. One of the researchers who informed the questionnaire was an expert in questionnaire design relating to nurses and pain management. The other researcher was an expert in wounds and pain management. Furthermore, the content of the questionnaire was informed by the participants report from study 1. The themes and the theory developed from study 1 informed some of the content of the survey. Therefore, the content of this survey was developed using rich description from people living with painful chronic leg ulceration. A rationale for the inclusion of each question is provided in this thesis (refer to Chapter 4, section 4.3.8.3). The final questionnaire was designed and decided upon, following several discussions of content.

##### **4.3.8.2.2 Face validity**

Face validity is if a test is thought to look like it will work and will measure what it was designed to measure. Face validity can be achieved by piloting the questionnaire in a similar group that the questionnaire had been designed to be used for. Face validity can also be achieved by asking an expert in the topic of the questionnaire to provide

feed back (Anastasi, 1988). Thus, face validation was achieved not only with the nurses who formed the group that undertook the initial pilot, but also amongst the author and the author's supervisors, during the process of questionnaire design.

#### **4.3.8.2.3 Construct validity**

Construct validity may be defined as the extent to which a test measures theoretical content. To obtain construct validity a gradual accumulation of evidence that demonstrates the tests responses, related to other variables is required. The judgement is based on the accumulation of correlations from numerous studies using the instrument being evaluated (Trochim, 2006). It was not possible to demonstrate construct validity because this was a pilot and feasibility study of the newly developed questionnaire.

#### **4.3.8.2.4 Concurrent validity**

Concurrent validity is the measure of the agreement between a newly developed test compared with a "gold standard" test (Campbell & Machin, 1993). Essentially concurrent validity is determined if a test correlates well with a measure that has previously been validated.

It was not possible to test for concurrent validity with the newly developed survey because there were no "gold standard" surveys measuring community nurses' views regarding painful leg ulceration.

#### **4.3.8.3 Questions with rationale**

A copy of the questionnaire is provided in Appendix 10. Section one (questions 1-4) collected data on the background of the participant, including their gender and date of birth, level of training, job title, year of qualifying and whether or not the respondent had attended any formal pain management training. This was undertaken to determine if any of these variables significantly impacted on the nurses' responses to the questions asked. Age, level of training and year of qualifying have all been shown to have an impact on the practitioners' ability to manage patients' pain. Studies have identified that insufficient knowledge and training have been a barrier for nurses in providing effective pain management (Elliott & Elliot, 1992; McCaffery *et al.* 1990; Coulling, 2005). Studies have also identified that nurses with a higher degree were more able and competent at managing pain using pharmacological and non-pharmacological techniques (Vortherms, Ryan & Ward, 1992; Clarke *et al.* 1996; McCaffery & Robinson, 2002). Age has been shown to impact on nurses' pain management attitudes; younger nurses have attitudes that promote more effective

pain management. Younger nurses were more likely to convey more importance to the patients' pain (Jastrab *et al.* 2003). Furthermore, year of qualifying may indicate if the nurse had pain management training within their initial nurse training.

Gender, job title and age characteristics were also obtained to determine if there was an adequate representation of nurses from each group compared with an average community nurse team working in the North of England<sup>2</sup>. Respondents' age and gender characteristics were compared with characteristics of nurses registered with the Nursing and Midwifery council (NMC, 2006). Job title characteristics of the respondents were compared with the job titles of the typical community nurse team (Appendix 12). This was undertaken to determine response bias. Response bias can occur if the respondents' characteristics are found to be different to non-responders' characteristics (Dickinson, 2002).

The section entitled; the nature of pain from leg ulcers and management of pain associated with chronic leg ulcers, (questions 5-20) aimed to survey the nurses understanding and knowledge of the nature of pain from leg ulcers and also their current management of painful leg ulcers.

Questions and rationale for each question are as follows;

- please tick which box you think is the correct answer to the following statements.*

#### Question 5

*Pain associated with leg ulcers can be described as*

*Chronic*  *Acute*  *Chronic & Acute*  *Unsure* .

#### Rationale

It was clear from study 1 that participants were describing pain that was chronic. However, the pain management they described receiving would have been more appropriate for acute pain management. Therefore, this question aimed to examine if community nurses viewed leg ulcer pain as chronic or acute as this would have an impact on the management of that pain.

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<sup>2</sup> Teams involved in recruiting participants were asked about team skill mix, a typical team in the PCT had larger numbers of staff nurses, senior staff nurses and case load holders. With fewer matrons, nurse specialists, healthcare assistants and enrolled nurses.

## Question 6

*Leg ulcer pain maybe neuropathic as well as nociceptive*

True  False  Unsure

## Rationale

To ascertain if community nurses recognised the pain, as potentially having a neuropathic component. Neuropathic pain has been shown to be a risk to patients with pain from chronic leg ulceration (Briggs *et al.* 2007). Patients from study 1 often used descriptors that appeared to describe neuropathic pain but they did not describe receiving pain management for neuropathic pain. It was not clear whether this was due to a lack of recognition from the nurses or under-reporting from patients.

## Question 7

*Pain severity is directly proportional to the amount of tissue involvement.*

True  False  Unsure

## Rationale

Participants in study 1 and evidence from the literature (refer to Chapter 2, section 2.4.1) suggested that pain was not directly proportional to tissue involvement. Therefore, this question aimed to investigate the level of awareness amongst the cohort being surveyed.

Questions 8, 9 and 10 aimed to explore how the nurses use the information gained from reports of pain severity and type.

## Question 8

*Pain in these patients is a good sign as it indicates*

*Sensation*  True  False  Unsure

*Healing*  True  False  Unsure

*Infection*  True  False  Unsure

## Rationale

This relates to another theme identified from study 1 (refer to Chapter 3, section 3.10.5.2.2). Participants spoke of nurses who told them their pain was a good thing to have, as it was better than no sensation. Further, there was some evidence in the literature that pain is used as an indication of infection (SIGN, 1998; RCN, 1998;

RCN, 2006). This question was designed to estimate how prevalent these opinions were.

#### Question 9

*Patients' reports of pain intensity (e.g. mild, moderate, severe) can help in diagnosing type of leg ulcer.*  True  False  Unsure

#### Rationale

There was some evidence in the literature that severity of pain was used to diagnose type of leg ulcer (Phillips, 2004; Dowsett, 2005; Reichenberg & Davis, 2005). This question aimed to identify if the community nurses use pain intensity as a diagnostic tool.

#### Question 10

*Patients' reports of pain triggers e.g. elevating legs, standing and pain at night can help in diagnosing type of leg ulcer.*  True  False  Unsure

#### Rationale

There was evidence in the literature that report of pain triggers were used to help diagnose type of leg ulcer (Phillips, 2004; Reichenberg & Davis, 2005). This question aimed to identify if the community nurses use pain triggers as a diagnostic tool.

#### Question 11

*Compression bandaging may cause or worsen pain.*

In all patients  In some patients  In no patients

*If you ticked in all or some patients why do you think it causes or worsens pain?*

#### Rationale

Compression bandaging was reported as painful by the majority of the participants who had experienced it, from study 1. There was also further evidence of this in the literature (refer to Chapter 2, section 2.5.3). The open question was used to determine what nurses thought caused the pain associated with compression and to see if they identified neuropathic pain as a cause.

#### Question 12

*Leg ulcer pain may lead to (you may tick more than one)*

Insomnia  Depression  Loss of mobility  Pain at night

Suicidal ideation  Social isolation  Desire for amputation of affected limb

Rationale

Evidence of the above was apparent from study 1; there was further evidence of these chronic pain sequelae in the literature (refer to Chapter 3, section 3.12.2).

Question 13

*Which analgesics do you routinely recommend for leg ulcer pain?*

*(A grey box has indicated the correct answer).*

*Names of the drugs are the names used clinically within the PCT; these drugs have other names (see Appendix 14).*

	<i>Always</i>	<i>Sometimes</i>	<i>Never</i>
<i>Paracetamol</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Codeine</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Ibuprofen</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Diclofenac</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Tramadol</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Pethidine</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/> <i>(should not be used for chronic pain)</i>
<i>Morphine</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Amitriptylene</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <i>(used for neuropathic pain)</i>
<i>Gabapentin</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <i>(used for neuropathic pain)</i>
<i>Pregabalin</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <i>(used for neuropathic pain)</i>
<i>Oxycontin</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Fentanyl Patch</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

*Other (please specify).....*

Rationale

Participants in study 1 predominantly mentioned paracetamol as the drug they used for pain. Pharmacological pain management appeared to be inadequate for this patient group. This question aimed to gain insight concerning what the nurses were recommending for pain. Drugs used to manage neuropathic pain were included to

ascertain if nurses were recommending these drugs for patients with chronic leg ulceration.

Question 14 and 15

14 I am a nurse prescriber  Yes  No

15 I routinely prescribe analgesics for patients with chronic leg ulcer pain.

Always  Sometimes  Never

Rationale

Nurse prescribing is a relatively recent activity taken on by community nurses, it was of interest to see if the nurses who could prescribe, prescribed analgesics.

Question 16 and 17

How do you assess pain?.....

Do you measure and document pain:

On every visit  On admission to the community nurse team

Never  Only if the patient reports pain

Rationale

Pain measurement and assessment is a crucial part of effective pain management. There was very little evidence of this activity for this patient group from the literature (refer to Chapter 2, section 2.7.1). Participants from study 1 did not report that their pain was assessed and documented.

Question 18

For pain at dressing changes do you use:

(The correct answer has been indicated by a grey box).

	Always	Sometimes	Never
Analgesia before dressing change	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Extra analgesics post dressing change	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Non-pharmacological techniques (E.g. TENS, relaxation, distraction etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Gentle dressing technique	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify).....			

### Rationale

The aim of this question was to identify what the nurses were doing for procedural pain; the literature has focused on pain management of procedural pain (refer to Chapter 2, section 2.7.3). However, the evidence in the literature suggests the nurses focus on dressing type to manage the pain associated with dressing changes (refer to Chapter 2, section 2.5.2.1).

### Question 19

*Do you recommend the use of non-pharmacological methods of pain management to patients in this group?*

Always  Sometimes  Never

### Rationale

Participants from study 1 described using non-pharmacological methods of pain management. However, there did not appear to be any suggestion that the nurses were recommending or promoting non-pharmacological methods.

### Question 20

*If always or sometimes, what non-pharmacological pain management methods do you recommend for use in this patient group?*

### Rationale

To determine what the community nurses recommend to their patients for non-pharmacological pain management.

The section entitled "Professional attitudes" was designed to explore community nurses attitudes to managing pain for this group of patients.

### Question 21

*Patients on my case list with pain from leg ulcers have been referred to pain specialists.*

Agree  Disagree  Unsure

### Rationale

Pain specialists who are referred patients from the community predominantly deal with patients with chronic pain conditions. Therefore, this question was asked to

determine if the nurses perceived patients' pain associated with leg ulceration, as a chronic pain condition which may benefit from a pain specialist consult.

#### Question 22

*Healing is the primary goal for all patients with leg ulcers regardless of recurrence rates and history.*

Agree  Disagree  Unsure

#### Rationale

The literature (refer to Chapter 2, section 2.5) and patient description from study 1 (refer to Chapter 3, section 3.10.5.2) suggested that the focus was on the treatment to heal the leg ulcer rather than symptom management. Furthermore, healing maybe an unrealistic aim considering the evidence that suggests older people have poor healing rates and high rates of recurrence (refer Chapter 2, to section 2.3).

#### Question 23

*Pain is a normal part of ageing.*

Agree  Disagree  Unsure

#### Rationale

The literature suggested that healthcare professionals and older people believe that pain is a normal part of ageing; this question aimed to determine if this attitude existed within this nursing group. It has been shown that when healthcare professionals and the older person view pain as a normal part of ageing, this attitude can be counterproductive to effective pain management (refer to Chapter 2, sections 2.6 and 2.7.1).

#### Question 24

*With repeated exposure some nurses may become desensitised to patients expressing pain during dressing changes.*  Agree  Disagree  Unsure

#### Rationale

There was some evidence in the literature that nurses who are exposed frequently to patients in pain can become desensitised (Grootenhuis, 1996; Nagy, 1999), which may impact on how they manage the pain. Therefore, this question was included to determine if the community nurses had an awareness of this.

#### Question 25

*Patients with pain from leg ulcers have a right to expect pain relief.*

Agree    Disagree    Unsure

Rationale

The literature (refer to Chapter 2, section 2.7) and patient report from study 1 suggested that patients with pain from leg ulceration do not receive adequate pain management. This question aimed to explore if the nurses caring for patients with chronic leg ulceration had a right to expect adequate pain management.

Question 26

*In general, I am hesitant to give opioids to older patients (65 years and over) with leg ulcers.*

Agree    Disagree    Unsure

Rationale

Inadequate pain management in patients 65 years and over is partly due to lack of knowledge and fear of side effects of opioids (refer to Chapter 2, section 2.6.3). This question aimed to establish if this unfounded fear was apparent amongst this nursing group.

Question 27

*I am confident in managing pain for this patient group.*

Agree    Disagree    Unsure

Rationale

To examine if community nurses were confident in managing pain for chronic leg ulceration.

Question 28

*I would like more training in managing pain for this patient group*

Agree    Disagree    Unsure

Rationale

To examine if community nurses would like more training on pain management.

Question 29

*I feel well supported by the multidisciplinary team when managing pain for this patient group.*

Agree    Disagree    Unsure

#### Rationale

To examine if the community nurses, feel well supported by the multidisciplinary team.

#### Question 30

*I sometimes avoid asking the patients about their pain when I am not sure how to manage it.*

Agree    Disagree    Unsure

#### Rationale

The literature reviewed suggested that community nurses focus on the healing aspect of the leg ulcer and appear not to acknowledge or address the symptom of pain (refer to Chapter 2, section 2.7). This question aimed to determine if this was because they did not know what to do about pain?

#### Question 31

The validated clinical decision making questionnaire was incorporated, with permission, from the authors (Brockopp *et al.* 2004). The authors had validated this questionnaire; a panel of experts established content validity and test re-test reliability was undertaken on a separate sample (Brockopp, Ryan & Warden, 2003). Categories were selected based on the literature as well as consideration for the group of nurses being surveyed.

*Given that all the patients have the same degree of pain using the following scale (1-5) rate the time and energy you would choose to spend managing the pain of the following patients. (1=little time and energy, 5=maximum time and energy) circle one number for each condition.*

#### Patient conditions

Cancer	1 2 3 4 5
Substance abuse	1 2 3 4 5
AIDS	1 2 3 4 5
Multiple trauma	1 2 3 4 5
Suicide attempt	1 2 3 4 5
Elderly patients	1 2 3 4 5

<i>Renal patients</i>	1 2 3 4 5
<i>Diabetes</i>	1 2 3 4 5
<i>General surgery</i>	1 2 3 4 5
<i>Chronic pain</i>	1 2 3 4 5
<i>Laparoscopic surgery</i>	1 2 3 4 5
<i>Chronic wound</i>	1 2 3 4 5

#### Rationale

The aim of this questionnaire was to investigate if the nurses use factors (such as preconceived notions) other than reported pain to decide pain management practices.

#### 4.3.9 Analysis

To analyse quantitative data SPSS quantitative data analysis computer software was used (SPSS 13.0 for Windows)..

All questions were numbered and coded to allow for easy input onto the SPSS spreadsheet. The researcher undertook all data input. The ID number of each respondent was the same as the number of the questionnaire they completed. This formed the study number that was automatically allocated when sending out a questionnaire.

There were two questions that were open. The responses to these questions were analysed for frequency of similarities that were then coded and analysed using quantitative methods. A statistician from the University of Leeds provided advice with regard to the correct statistical tests to use for the presentation of the data.

The majority of the data collected were nominal meaning they fell into mutually exclusive categories with no logical order, such as gender. The Chi-square test compares the frequency of observed results against the frequency that would be expected if there were no difference between the groups. The Chi-square is used to explore the relationship between two categorical variables; the variables can have more than two categories (Pallant, 2003). Using the Chi-square statistic and its associated degrees of freedom, the computer software (SPSS) reports the probability that the differences between the observed and expected frequencies occurred by chance. A probability of 0.05 or less is considered to be a significant difference.

In cases where numbers were small a Fisher's exact test was used to ensure the p value was valid. Fisher's exact test is a statistical significance test used in the analysis of contingency tables where sample sizes are small (Pallant, 2003). If the expected values in any of the cells in the Chi-square were less than 10 then the p value may not be accurate (Cambell & Machin, 1993). Thus, Fisher's exact was used instead, it is as its name suggests exact, and it can be used regardless of the sample characteristics. With the SPSS computer software Fisher's exact probability test was displayed as part of the output from the Chi-square test.

With many studies multiple testing of data is undertaken. Some believe that if multiple testing is undertaken the p value should be adjusted upward, to reduce the chance of claiming a statistical significance when in fact there is none. This view is based on the theory that if you test data frequently you will inevitably come up with a statistical significance. Therefore, there may be a risk of creating a type I error (Tukey, 1977; Ludbrook, 1998), type I error refers to rejection of the null hypothesis when in fact it is true (Campbell & Machin, 1993). It is not possible to determine with absolute proof a null hypothesis or otherwise, because studies are only able to investigate a sample of the population and not the whole population.

It is standard within scientific practice to have a cut-off point of 0.05 to determine statistical significance. Therefore, one in 20 tests will appear to be significant when it really is coincidence (type I error). To prevent a type I error the p value of each individual test can be adjusted upward. The Bonferroni correction is the classical method to adjust the p value upward. It involves setting a more tough alpha level for each comparison. This was done if multiple testing of a variable was undertaken, by dividing the alpha level (0.05) by the number of comparisons made (Tabanick & Fidell, 1996). This has been described throughout the results section.

Whilst the Bonferroni correction prevents a type I error, it is often considered to be overly conservative and can cause type II errors (Feise, 2002). A type II error refers to acceptance of the null hypothesis when in fact it is false. The researcher considered this and was aware of this possibility during analysis of the data.

Furthermore, the statistical significance has also been discussed within the context of the literature. It has been suggested that a studies statistical significance needs to be interpreted within not only the context of the quality of the study but within the context of findings of other studies (Feise, 2002). Also this was a feasibility and pilot study and the researcher acknowledges that the findings from this study will require further testing.

Descriptive statistics have been used to assess knowledge with regard to the nature of leg ulcer pain. Frequency of use of interventions has been measured and presented in the results. The ID number was put onto the SPSS spreadsheet to allow for comparisons with different variables relevant to individual participants such as pain management training, level of qualification, job title, gender, year of qualifying and age.

#### **4.3.10 Ethical implications**

The first concern that became apparent was that whilst completing the questionnaire the community nurses may have had to make a statement of not feeling competent when managing pain for this patient group.

There was also a question asking the nurses if they believed they become desensitised to people's pain, this may have prompted recognition and therefore caused distress.

This was addressed by providing the contact number of the researcher who discussed this if required. Information on accessing pain education was provided on request.

During the study, only one nurse contacted the researcher. This was to establish the confidentiality as the nurse had a query and thought that the study should be anonymous. The reasons for the study being confidential rather than anonymous were explained.

The second concern was that aspects of poor practice could be identified from the questionnaires e.g. use of pethidine for chronic pain. If this was the case then lead nurses were notified about the particular practice with recommendations for improvements and support from pain specialists. At no point were any individuals identified. The names of the respondents were destroyed so anonymity was assured. Anonymity is essential for professional security and honesty. The staff nurses were not identified but the clinical behaviour was highlighted if necessary.

It was made very clear that the questionnaire was confidential and only the researcher and her supervisors had access to the data.

#### **4.4 Results**

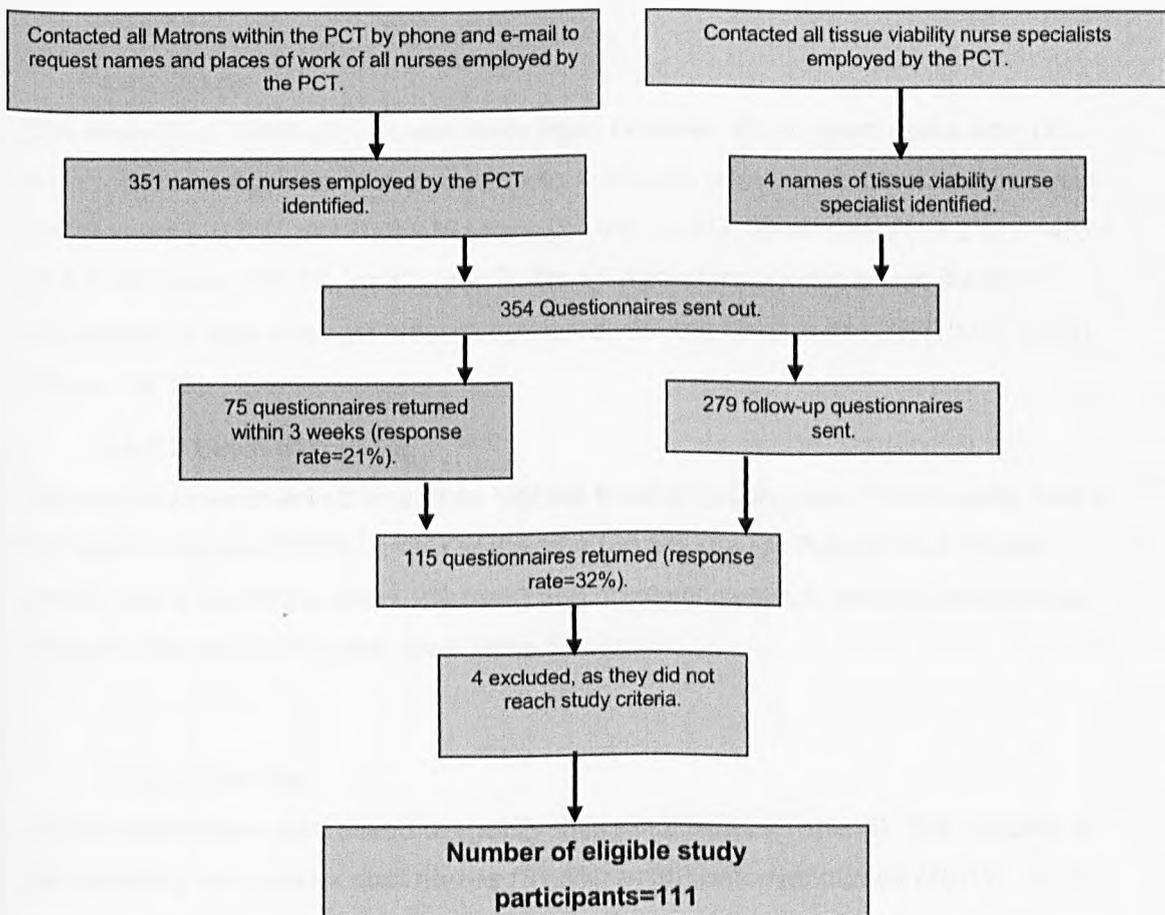
One hundred and fifteen completed questionnaires out of the 354 sent out were returned (see Figure 5). Four were excluded, as the participants did not meet the study inclusion criteria, in that they did not care for patients with chronic leg

ulceration. The response rate was 32% ( $n=111$ ). It is acknowledged that the response rate to this survey was low, and therefore this may have introduced a self-selection bias which is inherent when using postal questionnaires. It is not possible to state if the low response rate from this survey resulted in a response bias. Response bias can occur if the respondent characteristics are found to be different to the non-respondents characteristics (Dickinson, 2002). Evidence suggests that non-response is determined by several factors including characteristics of the sample and level of interest that individuals within the sample have in the topic under investigation (Dillman & Frey, 1974). Others have found that healthcare professionals who respond to surveys are better qualified, better educated and hold more senior positions (Cartwright, 1978; Clarke & Rees, 1989). Therefore, the nurses who responded to the survey may have a higher level of interest in the survey topic and may also be better qualified and better educated. This may have biased the survey results as nurses who did not have an interest in pain management, who were less educated and qualified and who held junior positions may have been under represented. Methods that are considered acceptable in obtaining information to inform differences between responders and non-responders include telephone follow up (Carifo, Biron & Shwedel, 1991). Telephone follow up to non-responders would have required contacting individuals who had chosen not to participate in the study. This was not possible because of ethical considerations concerning obtaining individuals' telephone numbers and time and money constraints. However, whilst it was not possible to obtain any data from the non-respondents, it was possible to compare characteristics of the respondents with characteristics of nurses registered with the Nursing and Midwifery council (NMC, 2006). Age and gender characteristics were found to be similar to the characteristics of nurses registered with the NMC (2006) (Appendix 13). Furthermore, job title distribution amongst the respondents represented a typical community nurse team working in the PCT studied. This was determined by obtaining information regarding distribution of job titles within each team included in the survey (Appendix 12).

Low response rates are typical with postal questionnaires, especially when they are aimed at healthcare professionals. Many studies, testify to the fact that healthcare professionals are poor responders to questionnaires (Cartwright, 1978; Bowling *et al.* 1991; Myerson, 1993). The response rate that this study achieved was greater or similar compared with other published studies that used postal questionnaires with community nurses (Hollinworth, 1995; Moffatt, Franks & Hollinworth, 2002; Kammerlander & Eberlain, 2002). Hollinworth had a 37% response rate with her postal

questionnaire to 1000 nurses, 61% of which were community nurses. Moffatt, Franks and Hollinworth (2002) had a response rate of 27% when questionnaires were disseminated to community nurses. Kammerlander and Eberlain (2002) had a 15% response rate for their postal questionnaire sent to nursing and medical practitioners. Furthermore, in surveys completed by healthcare professionals it has been demonstrated that low response rates do not always cause bias (O'Neill, Marsden & Silman, 1995; Asch, Jedrzejewski & Christakis, 1997). Cull *et al.* (2005) measured the impact of response rate bias amongst 50 different healthcare surveys. They found that in surveys with the lowest response rates <50%, the response rate bias was minimal. In a review of non-responders to surveys posted to nurses (Ford & Bammer, 2009) it was found that the non-responders most common reason for non response was not finding the time or losing the questionnaires. There is evidence that in general, response rates to postal questionnaires are falling (Office for National Statistics, 2004). However, there is no agreed level of acceptable response in postal surveys (Birnbaum & Hoch, 2004; Hock, 2004).

**Figure 5: Flow Diagram of Recruitment**



#### **4.4.1 Reliability**

To determine internal consistency reliability the Cronbach alpha statistic was used. A Cronbach alpha score was calculated for each section within the survey and for the survey as a whole. The first part of the survey asked questions relating to the nature of the pain from leg ulcers. The Cronbach score for this section was 0.63. The second section of the survey asked questions relating to the management of pain associated with chronic leg ulceration, the Cronbach score for this section was high (0.92). The final section asked questions relating to professional attitudes, the Cronbach alpha score for this section was lowest (0.54). The Cronbach score for the survey overall was 0.89.

#### **4.4.2 Background of study participants**

##### **4.4.2.1 Gender**

The majority of the respondents were female (91.8%,  $n=102$ ), which reflected the gender mix amongst nurse groups within the UK (NMC, 2006) (Appendix 13). A very small minority were male (4.5%,  $n=5$ ) and four respondents did not specify their gender (see Table 5).

##### **4.4.2.2 Age**

The majority of community nurses were aged between 40-49 years at the time of data collection. Age was broken down into 4-decade groups to enable data analysis, 20-29 years (10.8%,  $n=12$ ), 30-39 years (21.6%,  $n=24$ ), 40-49 years (43.2%,  $n=48$ ) and 50-60 years (19.8%,  $n=22$ ) (see Table 5). Age of respondents was similar to breakdown of age amongst nurses registered with the NMC in the UK (NMC, 2006), (Appendix 13).

##### **4.4.2.3 Level of training**

Respondents were asked what their highest level of training was. The majority had a bachelor's degree (30.6%,  $n=34$ ) or diploma (30.6% ( $n=34$ )). Twenty four percent ( $n=27$ ) had a certificate and 7.2% ( $n=8$ ) had no qualification. A small number had a master's degree (7.2%,  $n=8$ ) (see Table 5).

##### **4.4.2.4 Job title**

Respondents were also asked to specify their job title (see Table 5). The majority of respondents were senior staff nurses (31.5%,  $n=35$ ) and staff nurses (26.1%,  $n=29$ ) and a significant number of respondents were caseload holders (22.5%,  $n=25$ ).

There were a small number of matrons (8%,  $n=9$ ) and smaller numbers of nurse specialists (3.6%,  $n=4$ ). Only one stated they were an enrolled nurse and 7.2% ( $n=8$ ) of respondents were healthcare assistants (see Table 5). With a typical community nurse team (Appendix 12) we can expect the largest numbers of nurses to be staff nurses, senior staff nurses and caseload holders. The smallest numbers were matrons, tissue viability nurse specialists and healthcare assistants. This may be slightly different for some teams, depending on the area they are serving and patient need. Thus, the sample that responded was a good representation of the study sample. A description of the various job roles is also provided in the appendix (Appendix 11).

**Table 5: Study participant characteristics.**

Study participant characteristics						
Gender	Male 4.5% ( $n=5$ ).	Female 91.8% ( $n=102$ )	Not specified 3.5% ( $n=4$ )			
Age	20-29 years 10.8% ( $n=12$ )	30-39 years 21.6% ( $n=24$ )	40-49 years 43.2% ( $n=48$ )	50-60 years 19.8% ( $n=22$ )		
Level of Training	Master's Degree 7.2% ( $n=8$ )	Bachelor's Degree 30.6% ( $n=34$ )	Diploma 30.6% ( $n=34$ )	Certificate 24% ( $n=27$ )	No Qualification 7.2% ( $n=8$ )	
Year of Qualifying	2000-2007 27.9% ( $n=31$ )	1990-1999 21.6% ( $n=24$ )	1980-1989 29.7% ( $n=33$ )	1970-1979 13.5% ( $n=15$ )	No year of Qualifying 7.2% ( $n=8$ )	
Job Title	Nurse specialist 3.6% ( $n=4$ )	Matron 8% ( $n=9$ )	Caseload holder 22.5% ( $n=25$ )	Senior staff nurse 31.5% ( $n=35$ )	Staff nurse 26.1% ( $n=29$ )	Healthcare assistant 7.2% ( $n=8$ )
Formal Training in Pain Management	Included in initial nurse training 26.1% ( $n=28$ )	In house training 36% ( $n=40$ )	Pain management study day 27.9% ( $n=31$ )	Module for diploma/ degree 9.9% ( $n=11$ )	Pain management degree/ diploma 0.9% ( $n=1$ )	

#### 4.4.2.5 Year of qualifying

Data regarding year of qualifying were also collected, 27.9% ( $n=31$ ) qualified between 2000-2007, 21.6% ( $n=24$ ) qualified between 1990-1999, 29.7% ( $n=33$ ) between 1980-1989 and 13.5% ( $n=15$ ) of participants qualified between 1970-1979 (see Table 5). Eight participants had not undergone any formal training, as they were healthcare assistants not qualified nurses.

#### 4.4.2.6 Formal training in pain management

Respondents were asked if they had undergone any formal training in pain management, 64% ( $n=71$ ) said they had. However, a significant proportion of the

community nurses had not attended any form of pain management training (36%,  $n=40$ ) (see Table 5).

Only 26.1% ( $n=28$ ) of nurses had any pain management training in their initial nurse training. A Chi-square test was used to determine if there was a significant relationship between date of qualification and pain education during their initial training. Forty five percent ( $n=23$ ) of the nurses who had qualified between 1990-1999 also had received pain education during their training, compared to nurses who had trained before 1990. Only 10% of nurses who had qualified before 1990 had pain management education included in their initial nurse training (10%,  $n=5$ ). Nurses who had undertaken their initial nurse between 1990-1999 were significantly more likely to have pain management training included ( $\chi^2=11.745$  df3,  $n=101$ ,  $p=0.008$ ).

The majority of the respondents who had formal pain management training had in house training (36%,  $n=40$ ), 27.9% ( $n=31$ ) had attended a pain management study day, 9.9% ( $n=11$ ) had undertaken pain management training as a module for a diploma and 0.9% ( $n=1$ ) had undertaken a pain management degree/diploma.

#### **4.4.3 Community nurses' perceptions of the nature and management of the pain associated with chronic leg ulceration.**

Questions 5-12 focused on investigating the nurses' perceptions of the nature of the pain from chronic leg ulceration. The first part of this section dealt with pharmacological pain management. Participants were asked questions to ascertain their level of understanding of the nature of leg ulceration pain. The first question (Q5) asked the respondent if they thought pain associated with leg ulceration was chronic only, acute only, chronic and acute or unsure. A significant majority of participants answered this question correctly with 90.1% ( $n=100$ ) of them indicating that they thought pain with leg ulceration could be both acute and chronic. No participant indicated that the pain could be only acute.

Question 6 investigated if the respondents were aware that pain associated with leg ulceration could potentially have a neuropathic component as well as a nociceptive component. All participants answered this question and a high percentage indicated that patients with leg ulceration might have neuropathic pain as well as nociceptive pain (77.5%,  $n=86$ ). However, 20% ( $n=22$ ) were unsure and only 1.8% ( $n=2$ ) indicated that leg ulcer pain did not have a neuropathic as well as a nociceptive component. Nurses who had formal training in pain management were more likely to have indicated that leg ulcer pain may have nociceptive pain as well as neuropathic pain component (85%,  $n=59$ ). A significantly smaller number of nurses who had not

had pain management training indicated that they thought leg ulcer pain may be neuropathic as well as nociceptive (67.5%,  $n=27$ ). A Fisher's exact test determined that nurses who had formal pain management training were significantly more likely to indicate that leg ulcer pain may have nociceptive as well as neuropathic properties ( $p<0.05$ ), suggesting they had a better understanding of the nature of this type of pain (Fisher's exact=4.932, df 1,  $n=109$ ,  $p=0.025$ ).

Question 7 asked respondents if pain severity was directly proportional to the amount of tissue involvement. Only 3% ( $n=3$ ), two healthcare assistants and one staff nurse, thought that pain severity was directly proportional to tissue involvement, 9% ( $n=11$ ) were unsure and 88% ( $n=97$ ) indicated that pain severity was not directly proportional to tissue involvement.

Question 8 asked respondents if pain was a good sign for indication of sensation, healing and infection. A significant number thought that pain was a good sign as it indicated sensation (38.7%,  $n=43$ ), a small number indicated that pain was a good sign as it indicated healing (6.3%  $n=7$ ) and 46.8% ( $n=52$ ) of nurses thought that pain was a good sign as it indicated infection.

Respondents more frequently specified that pain in these patients was a good sign as it indicated sensation compared with healing. Fisher's exact test determined that respondents were significantly more likely to indicate that pain was an indication of sensation compared with healing (Fisher's exact=6.181 df 1,  $n=77$ ,  $p=0.018$ ).

Respondents also more frequently specified pain in these patients was a good sign as it indicated infection compared with healing. Fisher's exact test determined that respondents were significantly more likely to indicate that pain was an indication of infection compared with healing (Fisher's exact=7.690 df1,  $n=78$ ,  $p=0.006$ ).

Questions 9 and 10 explored nurses opinions on using report of pain severity and pain triggers, as an indicator of type of leg ulcer; a large number of respondents use pain severity as a tool to identify type of leg ulcer, 44.1% ( $n=49$ ) indicated that patients report of pain intensity helped them in identifying type of leg ulcer.

Eighty seven percent ( $n=97$ ) indicated that patients' pain triggers such as elevating legs, standing and pain at night, helped them in identifying type of leg ulcer. A Fisher's exact test determined that respondents were significantly more likely to indicate that pain triggers were an indication for type of leg ulcer compared with using pain intensity as indication for type of leg ulcer ( $p<0.05$ ) (Fisher's exact=4.909, df 1,  $n=96$ ,  $p=0.029$ ).

Chi-squared testing was undertaken to determine if factors such as age, job title, level of training and pain management training were associated with whether or not the respondents indicated they used pain triggers as a determinant of type of leg ulcer. A Bonferroni correction was applied to each variable due to multiple testing. No statistically significant findings were evident (see Table 7).

**Table 6: Source data percentage (n) nurse characteristics and if they indicated report of pain triggers can help diagnose type of leg ulcer.**

Age	Report of pain triggers can help diagnose type of leg ulcer		
		True	False
20-29		8% (8)	2% (2)
30-39		16% (16)	2% (2)
40-49		41% (41)	-
50-60		29% (29)	2% (2)
Level of training	Report of pain triggers can help diagnose type of leg ulcer		
		True	False
	Certificate	25% (25)	-
	Diploma	29% (29)	3% (3)
Degree or above	37% (37)	4% (4)	
Job Title	Report of pain triggers can help diagnose type of leg ulcer		
		True	False
	Matron	6.3% (6)	1% (1)
	Nurse specialist	4.2% (4)	-
	Case load holder	24% (23)	2.1% (2)
	Senior staff nurse	32% (31)	4.2% (4)
	Staff nurse	27% (26)	-
Healthcare assistant	7.3% (7)	1% (1)	
Have you had formal pain management training?	Report of pain triggers can help diagnose type of leg ulcer		
		True	False
	yes	60% (64)	4.2% (4)
No	34% (33)	4.2% (4)	

**Table 7: Association between nurses' characteristics and their use of pain triggers to identify type of leg ulcer ( $\chi^2$  test).**

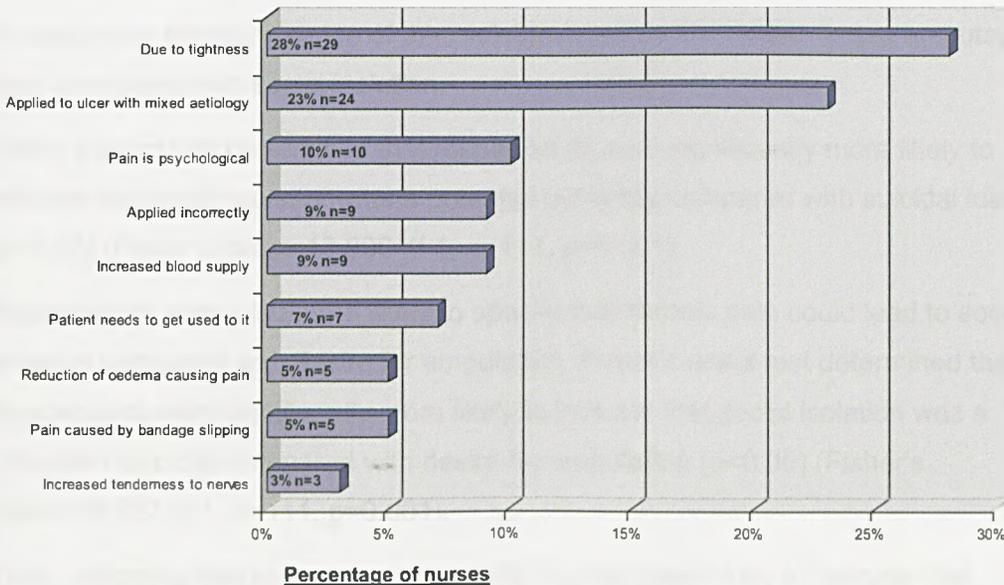
Nurses' characteristic	$\chi^2$ statistics	Required alpha level with Bonferroni correction	P value
Age	$\chi^2 = 6.937$ df 3, n=100	0.005	0.074
Level of training	$\chi^2 = 2.630$ df 2, n=97	0.004	0.157
Job title	$\chi^2 = 4.168$ df 1, n=105	0.005	0.665
Pain management training	$\chi^2 = 0.827$ df 1, n=105	0.004	0.293

Question 11 asked respondents if compression bandaging caused or worsened pain in all patients, some patients or in no patients. A large majority of respondents

indicated that this was the case for “some patients” (94.6%,  $n=105$ ). Participants were also asked what they thought the reason for this was. The reasons given are shown in figure 6.

**Figure 6: Percentage of nurses who cited each potential cause of pain associated with compression bandaging.**

**Potential cause of pain**



The most common reasons given were due to tightness and if the compression had been applied to an ulcer of mixed aetiology. Although no one suggested neuropathic pain might cause pain from compression, 3% ( $n=3$ ) did suggest an increased tenderness to the nerves.

Chronic pain may lead to other negative impacts for some people such as depression, insomnia, and loss of mobility, pain at night, suicidal ideation, social isolation and desire for amputation. Patients from study 1 frequently reported episodes of these negative impacts of chronic pain. Question 12 aimed to find out if the nurses caring for these patients had an awareness of this.

Table 6 represents the data that suggested a large number of nurses were aware of these negative impacts (chronic pain morbidity). However, for suicidal ideation and desire for amputation there was lower awareness.

**Table 8:** Percentage (*n*) nurses who were aware of each potential chronic pain morbidity.

Potential morbidity	%	<i>n</i>
Insomnia	96.4%	(107)
Depression	96.4%	(107)
Loss of mobility	95.5%	(106)
Pain at night	97%	(108)
Social isolation	91%	(101)
Suicidal ideation	55.9%	(62)
Desire for amputation	67.6%	(75)

To determine the significance of this, suicidal ideation and desire for leg amputation were compared with social isolation.

Fisher's exact test determined that respondents were significantly more likely to indicate that social isolation was a potential morbidity compared with suicidal ideation ( $p < 0.05$ ) (Fisher's exact=13.906 df 1,  $n=111$ ,  $p=0.001$ ).

Respondents were also more likely to specify that chronic pain could lead to social isolation compared with desire for amputation. Fisher's exact test determined that respondents were significantly more likely to indicate that social isolation was a potential morbidity compared with desire for amputation ( $p < 0.05$ ) (Fisher's exact=16.620 df 1,  $n=111$ ,  $p=0.001$ ).

Thus, indicating that respondents were significantly least likely to indicate that chronic leg ulceration may lead to suicidal ideation and desire for leg amputation compared to the other morbidities.

Just under half (44.1%,  $n=49$ ) of the respondents did not indicate that suicidal ideation was a risk for this patient group. Furthermore, over a quarter of the respondents did not think that patients might have a desire for amputation of their affected limb (32.4%,  $n=36$ ). A large majority of the respondents acknowledged that depression (96.4%,  $n=107$ ), insomnia (96.4%,  $n=107$ ), pain at night (97.3%,  $n=108$ ), loss of mobility (95.5%,  $n=106$ ) and social isolation (91%,  $n=101$ ) were risk factors for this patient group.

Using Chi-square tests nurses who indicated they thought pain may lead to a desire for leg amputation were compared with variables such as age, job title, level of qualification and pain management training. Due to multiple testing a Bonferroni correction was applied to each test.

There was no association between the nurses' age, job title, level of training or pain management training and if the nurse indicated that patients with leg ulceration may desire leg amputation.

**Table 9: Source data percentage (n) of nurses' characteristics and if they indicated desire for leg amputation.**

	Leg ulcer pain may lead to desire for amputation of affected limb		
		yes	no
Age	20-29	3.6% (4)	7.2% (8)
	30-39	9% (10)	7.2% (8)
	40-49	31% (35)	6.3% (7)
	50-60	20% (22)	10% (11)
Level of training	Leg ulcer pain may lead to desire for amputation of affected limb		
		yes	no
	None	7% (8)	1.8% (2)
	Certificate	13% (15)	9% (10)
	Diploma	16% (18)	14% (16)
	Degree or above	30% (34)	7% (8)
Job Title	Leg ulcer pain may lead to desire for amputation of affected limb		
		yes	no
	Matron	7.2% (8)	0.9% (1)
	Nurse specialist	3.6% (4)	-
	Case load holder	16.2% (18)	12.6% (14)
	Senior staff nurse	18.9% (21)	12.6% (14)
	Staff nurse	16.2% (18)	9.9% (11)
	Healthcare assistant	5.4% (6)	2.7% (3)
Have you had formal pain management training?	Leg ulcer pain may lead to desire for amputation of affected limb		
		yes	no
	yes	45% (50)	22.5% (25)
	No	18.9% (21)	13.5% (15)

**Table 10: Association between nurses' characteristics and if they indicated desire for leg amputation was a risk factor ( $\chi^2$  test and Fisher's exact test).**

Nurses' characteristics	$\chi^2$ or Fisher's exact test (n)	Adjusted significance level with Bonferroni correction	P-value
Age	$\chi^2 = 12.389$ df 3, n=111	0.005	0.006
Level of training	$\chi^2 = 8.305$ df 4, n=111	0.004	0.081
Job title	$\chi^2 = 5.900$ df 6, n=111	0.005	0.435
Pain management training	Fisher's exact= 13.607 df 1, n=111	0.004	0.258

#### 4.4.4 Current strategies used by the community nurses to manage pain in this patient group.

Questions 13-20 aimed to determine how the nurses were managing the pain associated with painful leg ulceration.

The first part of this section dealt with pharmacological pain management. The first question (Q13) asked the respondents to indicate which drugs they routinely

recommended for the pain management of leg ulceration and to indicate if they recommended these drugs always, sometimes or never (see Table 11).

**Table 11: Percentage (*n*) of nurses who indicated that they recommended the following analgesics to their patients.**

Drug	Frequency of recommendation			
	Always	Sometimes	Never	Missing
Paracetamol	46.8% (52)	35.1% (39)	1.8% (2)	16.2% (18)
Ibuprofen	3.6% (4)	45% (50)	15.3% (17)	36% (40)
Diclofenac	-	37.8% (42)	19.8% (22)	42.3% (47)
Codeine	7.2% (8)	55% (61)	8.1% (9)	29.7% (33)
Tramadol	-	52.3% (58)	15.3% (17)	32.4% (36)
Morphine	-	44.1% (49)	21.6% (24)	34.2% (38)
Oxycodone	-	15.3% (17)	36.9% (41)	47.7% (53)
Fentanyl	-	32.4% (36)	24.3% (27)	43.2% (48)
Pethidine	-	4.5% (5)	45.9% (51)	49.5% (55)
Amitriptyline	0.9% (1)	46.8% (52)	16.2% (18)	36% (40)
Galceperidin	-	45% (50)	21.6% (24)	33.3% (37)
Pregabalin	-	8.1% (9)	42.3% (47)	49.5% (55)

The most frequently recommended analgesic was paracetamol, with 46.8% ( $n=52$ ) of respondents indicating that they always recommended paracetamol and 35.1% ( $n=39$ ) recommending it sometimes. The next most frequently recommended drug was codeine. Fisher's exact test determined that paracetamol was significantly more likely to be recommended compared with codeine (Fisher's exact=6.561 df=1,  $n=69$ ,  $p=0.009$ ). Therefore, we can determine that paracetamol was more likely to be recommended to this group of patients.

Under half of the respondents indicated that non-steroidal anti-inflammatory drugs were recommended sometimes, 45% ( $n=50$ ) recommended the use of ibuprofen sometimes and 37.8% ( $n=42$ ) recommended diclofenac sometimes. However, a large proportion of the respondents did not indicate if they recommended non-steroidal drugs and chose to leave this part of the question blank; ibuprofen (36%,  $n=40$  missing) and diclofenac (42.3%,  $n=47$  missing).

Opioids were indicated as being recommended sometimes by the community nurses, with codeine as the most frequently recommended (61%,  $n=55$ ). Fifty-two percent ( $n=58$ ) of respondents indicated they recommended tramadol sometimes and 44.1% ( $n=49$ ) recommended morphine sometimes. Over a quarter of the respondents stated they would recommend a fentanyl patch sometimes (32.4%,  $n=36$ ).

Pethidine was rarely indicated as being recommended. However, 4.5% ( $n=5$ ) of respondents stated they would recommend pethidine for pain management of leg ulceration sometimes. Over half of the respondents (54.1%,  $n=60$ ) did not correctly indicate that they would not recommend pethidine for leg ulcer pain.

Oxycontin a synthetic opioid was stated as being recommended sometimes by only 15.3% ( $n=17$ ) of the respondents.

Drugs used to manage neuropathic pain such as gabapentin; pregabalin and amitriptylene were included to see if these drugs were familiar to the community nurses and also to see if these types of drugs were being recommended. The most frequently recommended drug of this type was amitriptylene, 46.8% ( $n=52$ ) of the community nurses stated they recommended this drug sometimes. Nearly half of the respondents 45% ( $n=50$ ) sometimes recommended gabapentin. A very small number of respondents stated they would recommend pregabalin (8.1%,  $n=9$ ).

**Table 12:** Source data percentage ( $n$ ) of nurses' characteristics and if they recommend amitriptylene for leg ulcer pain.

	Do you recommend amitriptylene for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
Age	20-29	-	4.7% (5)	2.8% (3)	3.8% (4)
	30-39	-	9.5% (10)	2.8% (3)	4.7% (5)
	40-49	0.9% (1)	20% (22)	6.6% (7)	11% (12)
	50-60	-	12% (13)	3.8% (4)	15% (16)
Level of training	Do you recommend amitriptylene for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	Certificate	-	11% (11)	3% (3)	11% (11)
	Diploma	1% (1)	11% (11)	8% (8)	14% (14)
	Degree or above	-	28% (28)	5% (5)	9% (9)
Job title	Do you recommend amitriptylene for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	Matron	-	6.3% (7)	0.9% (1)	0.9% (1)
	Nurse specialist	-	1.8% (2)	-	1.8% (2)
	Case load holder	-	11% (13)	4.5% (5)	6.3% (7)
	Senior staff nurse	0.9% (1)	15% (17)	3.6% (4)	11% (13)
	Staff nurse	-	11% (13)	5.4% (6)	9% (10)
Healthcare assistant	-	-	1.8% (2)	6.3% (7)	
Have you had formal pain management training?	Do you recommend amitriptylene for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	yes	-	30% (34)	9% (10)	24% (27)
	No	0.9% (1)	16% (18)	7.2% (8)	11% (13)

**Table 13: Association between nurses' characteristics and if they indicated they recommended amitriptylene ( $\chi^2$  test).**

Nurses' characteristic	$\chi^2$ statistic	Adjusted odds ratio with 95% confidence interval	P value
Age	$\chi^2 = 5.887$ df 9, n=105	0.005	0.75
Level of training	$\chi^2 = 11.786$ df 6, n=101	0.004	0.067
Job title	$\chi^2 = 17.586$ df 18, n=111	0.005	0.48
Pain management training	$\chi^2 = 2.590$ df 3, n=111	0.004	0.45

**Table 14: Source data percentage (n) nurse characteristics and if they recommend gabapentin for leg ulcer pain.**

	Do you recommend gabapentin for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
Age	20-29	-	3.8% (4)	3.8% (4)	3.8% (4)
	30-39	-	8.5% (9)	4.7% (5)	3.8% (4)
	40-49	-	22% (24)	6.6% (7)	11% (12)
	50-60	-	12% (13)	6% (6)	13% (14)
Level of training	Do you recommend gabapentin for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	Certificate	-	9% (9)	5% (5)	11% (11)
	Diploma	-	10% (10)	10% (10)	14% (14)
Job title	Do you recommend gabapentin for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	Matron	-	4.5% (5)	2.7% (3)	0.9% (1)
	Nurse specialist	-	1.8% (2)	-	1.8% (2)
	Case load holder	-	11.7% (13)	8% (9)	2.7% (3)
	Senior staff nurse	-	12.6% (14)	3.6% (4)	15.3% (17)
	Staff nurse	-	11% (13)	6% (7)	8% (9)
Have you had formal pain management training?	Do you recommend gabapentin for leg ulcer pain?				
		Always	Sometimes	Never	Left blank
	yes	-	34% (38)	11% (12)	20% (23)
No	-	12% (14)	9% (10)	12% (14)	

Using a Fisher's exact test, gabapentin was significantly more likely to be recommended sometimes compared with pregabalin (Fisher's exact=8.043, df1, n=56.p=0.004). Relationships of age, job title, level of training and pain management

training were also compared with recommendation of gabapentin and amitriptylene. Because these variables were tested multiple times a Bonferroni correction was applied to each variable. There were no statistically significant differences found (see Tables 13 and 15).

**Table 15: Association between nurses' characteristics and if they indicated they recommended gabapentin ( $\chi^2$  test).**

Nurses' characteristics	$\chi^2$ statistics	Significant (yes/no) with Bonferroni correction	P-value
Age	$\chi^2 = 5.707$ df 6, n=105	0.005	0.45
Level of training	$\chi^2 = 13.859$ df 8, n=111	0.004	0.086
Job title	$\chi^2 = 18.149$ df 12, n=111	0.005	0.111
Pain management training	$\chi^2 = 3.483$ df 2, n=111	0.004	0.175

Nurse prescribing is a relatively new practice within the nursing profession, 34.2% ( $n=38$ ) of the respondents stated they were nurse prescribers. However, only 12.6% ( $n=14$ ) prescribed analgesics to this group of patients sometimes. Only 37% ( $n=14$ ) of nurses who were nurse prescribers indicated they prescribed analgesics sometimes. Comparisons between nurse prescribing and job title show that 92% ( $n=23$ ) of caseload holders were nurse prescribers but only 28% ( $n=7$ ) of them prescribe analgesics sometimes. Five percent ( $n=2$ ) of senior staff nurses can prescribe and only 3% ( $n=1$ ) of them prescribe analgesics sometimes. Only 6% ( $n=2$ ) of staff nurses were nurse prescribers and none of them stated they prescribed analgesics.

Assessment of pain is vital to ensure adequate management of pain, questions 16 and 17 investigated pain assessment and measurement activity for this patient group. Question 16 asked the respondents how they assess pain.

This was an open question, the responses were grouped into the four responses given, these were; patient verbal report and pain score, pain score, verbal report with no score recorded and left blank. Just under half of the respondents stated they assess pain using verbal report and a pain score (46.8%,  $n=51$ ), with 30.6% ( $n=34$ ) assessing pain using a pain score. Nearly a quarter of the respondents (22.5%,  $n=24$ ) either left the question blank (7.2%,  $n=8$ ) or took a verbal report but did not record a pain score (15.3%,  $n=17$ ).

Using a Chi-square test, age, job title, level of training and pain management training were compared with nurses who assessed patients' pain using pain score and verbal

report, none were found to have a statistical significance (see Table 17). A Bonferroni correction was applied to each variable because of multiple testing.

**Table 16: Source data percentage (n) of nurses' characteristics and how the nurses stated they assess pain.**

	How do you assess pain?				
		Verbal report & pain intensity score	Pain score	Patient verbal report	Left blank
Age	20-29	4% (4)	6% (6)	1% (1)	1% (1)
	30-39	10% (11)	4% (4)	2% (2)	1% (1)
	40-49	19% (20)	10% (11)	7.6% (8)	5% (5)
	50-60	14% (15)	10% (11)	5% (5)	2% (2)
Job title	How do you assess pain?				
		Verbal report & pain intensity score	Pain score	Patient verbal report	Left blank
	Matron	2.7% (3)	5.4% (6)	-	-
	Nurse specialist	1.8% (2)	1.8% (2)	-	-
	Case load holder	11% (12)	4.5% (5)	5.4% (6)	1.8% (2)
	Senior staff nurse	16% (18)	8.1% (9)	5.4% (6)	1.8% (2)
	Staff nurse	13.5% (15)	9% (10)	2.7% (3)	0.9% (1)
Healthcare assistant	1.8% (2)	1.8% (2)	0.9% (1)	2.7% (3)	
Level of training	How do you assess pain?				
		Verbal report & pain intensity score	Pain score	Patient verbal report	Left blank
	Certificate	14% (14)	6% (6)	3% (3)	2% (2)
	Diploma	15% (15)	11% (11)	7% (7)	1% (1)
Degree or Masters degree	20% (20)	14% (14)	6% (6)	2% (2)	
Have you had formal pain management training?	How do you assess pain?				
		Verbal report & pain intensity score	Pain score	Patient verbal report	Left blank
	yes	29% (32)	23% (26)	9% (10)	2.7% (3)
no	18% (20)	7.2% (8)	6.3% (7)	4.5% (5)	

**Table 17 Association between nurses' characteristics and if they undertook pain scoring and verbal report ( $\chi^2$  test).**

Nurses' characteristics	$\chi^2$ statistics	Residual Expected percentage	P value
Age	$\chi^2 = 4.572$ df 9, n=105	0.005	0.87
Job title	$\chi^2 = 28.372$ df 18, n=111	0.005	0.57
Level of training	$\chi^2 = 2.453$ df 6, n=101	0.004	0.874
Pain management/ training	$\chi^2 = 5.065$ df 3, n=111	0.004	0.167

Participants were also asked when and how frequently they measured and documented pain. Just over half measured and documented pain on every visit (55.9%,  $n=62$ ), 9.9% ( $n=11$ ) measured and documented pain on admission to the community nurse team and 17.1% ( $n=19$ ) measured and documented pain only if the patient reported pain. Just 15.3% ( $n=17$ ) stated they never measured and documented pain; only 2 participants left this question blank. Nurses who measured pain score using a verbal report were also more likely to measure pain on every visit. Seventy one percent ( $n=37$ ) who recorded patient verbal report and pain score also did pain measurement on every visit. Compared with 47% ( $n=16$ ) of nurses who only recorded pain score. Using a Fisher's exact test this was however, found to be not statistically significant (Fisher's exact=3.290,  $df_1$ ,  $n=63$ ,  $p=0.076$ ).

Question 18 asked participants what they used for pain at dressing changes. The most frequent technique being used was gentle dressing technique with 73.9% ( $n=82$ ) of respondents indicating this. Provision of analgesics pre-dressing and post-dressing was also a frequently used method to manage pain associated with dressing changes. Thirty nine percent ( $n=43$ ) reported they always gave analgesics before dressing changes and 60.4% ( $n=67$ ) reported they gave them sometimes. Extra analgesics after the dressing changes were stated as being given always by 2.7% ( $n=3$ ) of respondents and 61.3% ( $n=68$ ) reported sometimes giving them.

Fewer respondents indicated that they used non-pharmacological pain management methods sometimes for management of pain associated with dressing changes (38.7%,  $n=43$ ). Numbers were too small to demonstrate any association between job title and the use of pre-emptive analgesia.

Forty three percent ( $n=47$ ) of nurses who had received formal pain management training also recommended pre-emptive analgesia compared with 20% ( $n=22$ ) of nurses who had not had formal pain management training. Using Chi-square analysis it was demonstrated that level of qualification and formal pain management training did not have a significant impact on whether pre-emptive analgesics were indicated as being given, ( $p>0.004$ ). A Bonferroni correction was applied to each variable because of multiple testing (see Table 19).

**Table 18: Source data percentage (n) of nurses' training characteristics and the use of preemptive analgesia.**

Level of training	Do you use analgesia before dressing changes?			
		Always	Sometimes	Never
Certificate		7.9% (8)	16.8% (17)	-
Diploma		11.9% (12)	20.8% (21)	1% (1)
Degree or Masters degree		15.8% (16)	25.7% (26)	-

Have you had formal pain management training?	Do you use analgesia before dressing changes?			
		Always	Sometimes	Never
yes		28% (31)	34% (38)	1.8% (2)
no		7% (8)	24% (27)	2.7% (3)

**Table 19: Association between nurses' training characteristic and the use of preemptive analgesia ( $\chi^2$  test).**

Nurses' training characteristics	$\chi^2$ statistic	Adjusted alpha level with Bonferroni correction	P Value
Level of training	$\chi^2 = 1.017$ df 2, n=101	0.004	0.601
Pain management training	$\chi^2 = 6.850$ df 2, n=111	0.004	0.033

Question 19 asked respondents if they recommended the use of non-pharmacological methods always, sometimes or never. Just over half of the community nurses sometimes recommended them sometimes (53.2%,  $n=59$ ) with only 7.2% ( $n=8$ ) recommending non-pharmacological methods always. Over a quarter of the respondents never recommended the use of non-pharmacological methods (33.3%,  $n=37$ ). Of the respondents who indicated they were recommending sometimes or always, 67% ( $n=48$ ) of them had pain management training. Respondents who had received formal pain management training were also more likely to recommend the use of non-pharmacological pain management. Sixty nine percent of respondents who had formal pain management training also recommended the use of non-pharmacological pain management compared with 48.6% who had not had formal pain management training. Using a Fisher's exact test this was found to not be statistically significant ( $p>0.004$ ) (see Table 21). A Chi-square test was used to determine if there was a significant association between nurses' level of education and whether or not they would use non-pharmacological pain management methods This was not statistically significant ( $p>0.004$ ). A Bonferroni correction was applied to each variable because of multiple testing (see Table 21).

**Table 20:** Source data percentage (*n*) of nurses' training characteristics and the use of non-pharmacological pain management.

Level of training	Do you recommend the use of non-pharmacological pain management?				
		Always	Sometimes	Never	Left blank
	Certificate	-	9.9% (10)	12.9% (13)	2% (2)
	Diploma	1% (1)	18% (19)	12.9% (13)	1% (1)
Degree or Masters degree	6.9% (7)	27.7% (28)	5.9% (6)	1% (1)	

Have you had formal pain management training?	Do you recommend the use of non-pharmacological pain management?				
		Always	Sometimes	Never	Left blank
	yes	6.3% (7)	36.9% (41)	16.2% (18)	4.5% (5)
	no	0.9% (1)	16.2% (18)	17.1% (19)	1.8% (2)

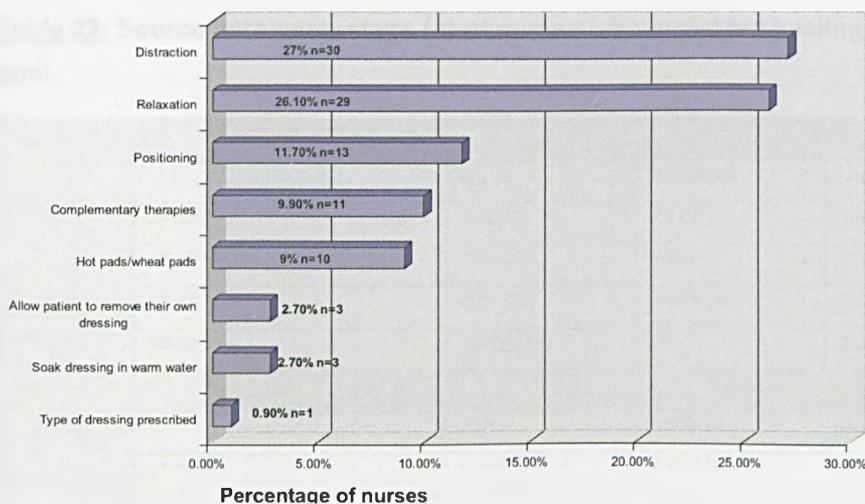
**Table 21:** Association between nurse training characteristic and the use of non-pharmacological pain management ( $\chi^2$  and Fisher's exact test).

Nurses' training characteristic	$\chi^2$ or Fisher's exact statistics	Required alpha level with expected variables	P-value
Level of training	$\chi^2 = 7.267$ df 6, n=101	0.004	0.297
Pain management training	Fisher's exact = 4.170 df 1, n=96	0.004	0.034

Participants were also asked if they did recommend the use of non-pharmacological methods either always or sometimes, and what methods they recommended. This was an open question therefore answers were grouped in the following categories; positioning, complementary techniques, soaking dressing in warm water, allowing patients to remove their own dressing, distraction, relaxation and hot pads/wheat bags. Distraction (27%, *n*=30) and relaxation (26.1%, *n*=29) were the most frequently specified methods (see Figure 7).

**Figure 7: Percentages (*n*) nurses who recommended the following non-pharmacological methods of pain management**

**Methods of non-pharmacological pain management**



**4.4.5 Professional nurses' attitudes in relation to providing pain management for this group.**

Questions 21-31 aimed to survey nurses attitudes in relation to providing pain management for this patient group. Section three of the questionnaire investigated community nurses' professional attitudes with regard to pain management of chronic leg ulceration.

Patients with chronic pain can be referred to a pain consultant; participants were asked if patients on their case list had been referred to a pain consultant. Forty two percent ( $n=47$ ) of the community nurses indicated that they had referred patients to a pain specialist. Suggesting that they viewed patients with pain associated with chronic leg ulceration as patients who may require specialist consult with a pain physician. However, more (44.1%,  $n=49$ ) had not and 13.5% ( $n=15$ ) were unsure.

The literature and results from study 1 suggested that much of the emphasis was on the healing; therefore respondents were asked if healing was the primary goal for this patient group. Half of the respondents indicated that healing was the primary goal (50.5%,  $n=56$ ). Forty five percent disagreed ( $n=50$ ) that healing was the primary goal and 4.5% ( $n=5$ ) were unsure.

A Chi-square test was used to determine if there were significant differences in whether or not the nurses indicated they thought healing was the primary goal

compared with age, job title, level of training and pain management training. A Bonferroni correction was applied to each variable because of multiple testing (see Table 23). There was no statistical significance between these variables and if the nurses indicated they thought healing was the primary goal.

**Table 22: Source data percentage (n) of nurses who indicated healing was the primary goal.**

	Healing is the primary goal			
		Agree	Disagree	Unsure
Age	20-29	1.8% (2)	7% (8)	1.8% (2)
	30-39	12% (13)	8% (9)	0.9% (1)
	40-49	20% (22)	22.5% (25)	6% (7)
	50-60	12.6% (14)	6% (7)	0.9% (1)
Job title	Healing is the primary goal			
		Agree	Disagree	Unsure
	Matron	4.5% (5)	3.6% (4)	-
	Nurse specialist	-	3.6% (4)	-
	Case load holder	9% (10)	10% (11)	3.6% (4)
	Senior staff nurse	20% (22)	10% (11)	1.8% (2)
	Staff nurse	10% (11)	16% (18)	-
Healthcare assistant	6.3% (7)	1.8% (2)	-	
Level of training	Healing is the primary goal			
		Agree	Disagree	Unsure
	Certificate	13.5% (15)	8% (9)	0.9% (1)
	Diploma	12% (13)	17% (19)	17% (19)
Degree or Masters degree	19% (21)	17% (19)	1.8% (2)	
Have you had formal pain management training?	Healing is the primary goal			
		Agree	Disagree	Unsure
	yes	32.1% (34)	31.1% (33)	-
no	20.8% (22)	16% (17)	-	

**Table 23: Association between nurses' characteristics and nurses who indicated that healing was the primary goal ( $\chi^2$  test).**

Nurses' characteristic	$\chi^2$ statistics	Required alpha level with Bonferroni correction	P value
Age	$\chi^2=13.864$ df 6, n=105	0.005	0.031
Job title	$\chi^2=17.340$ df 12, n=111	0.005	0.137
Level of training	$\chi^2=6.344$ df 8, n=111	0.004	0.609
Pain management training	$\chi^2=0.904$ df 2, n=111	0.004	0.63

Attitudes to pain being a normal part of ageing were also investigated by asking the respondents if they thought pain was a normal part of ageing. A large majority

(93.7%,  $n=104$ ) indicated that they disagreed that pain was a normal part of ageing. Only two respondents thought that pain was a normal part of ageing and five respondents were not sure.

Question 24 asked participants if with repeated exposure some nurses might become desensitized to patients expressing pain during dressing changes. A large number of the community nurses agreed with this statement (52.3%,  $n=58$ ). A Chi-square test was used to determine if there were significant differences in whether or not the nurses might become desensitized to patients expressing pain during dressing changes with age, job title, level of training and pain management training. Using a Chi-square test no statistically significant differences were demonstrated (see Table 25).

**Table 24: Source data percentage ( $n$ ) of nurses who agreed they become desensitized to patients pain.**

	With repeated exposure some nurses may become desensitized to patients pain.			
		Agree	Disagree	Unsure
Age	20-29	5.4% (6)	2.7% (3)	2.7% (3)
	30-39	11% (12)	5.4% (6)	-
	40-49	19% (21)	13% (15)	11% (12)
	50-60	14% (16)	12.6% (14)	1.8% (2)
Job title	With repeated exposure some nurses may become desensitized to patients pain.			
		Agree	Disagree	Unsure
	Matron	6.3% (7)	0.9% (1)	0.9% (1)
	Nurse specialist	1.8% (2)	0.9% (1)	0.9% (1)
	Case load holder	11% (13)	9% (10)	1.8% (2)
	Senior staff nurse	12.6% (14)	4.5% (5)	4.5% (5)
	Staff nurse	16% (18)	2.7% (3)	-
Healthcare assistant	3.6% (4)	-	-	
Level of training	With repeated exposure some nurses may become desensitized to patients pain.			
		Agree	Disagree	Unsure
	Certificate	12% (12)	11% (11)	2% (2)
	Diploma	16% (16)	14% (14)	4% (4)
Degree or Masters degree	25% (25)	12% (12)	5% (5)	
Have you had formal pain management training?	With repeated exposure some nurses may become desensitized to patients pain.			
		Agree	Disagree	Unsure
	yes	34% (34)	22.5% (25)	10% (11)
no	19% (21)	13.5% (15)	4.5% (5)	

**Table 25: Association between nurses' characteristics and nurses who agreed they become desensitized to patients' pain ( $\chi^2$  test).**

Nurses' characteristics	$\chi^2$ statistics	Adjusted significance level with Bonferroni correction	P-value
Age	$\chi^2=7.044$ df 6, n=105	0.005	0.67
Job title	$\chi^2=10.201$ df 12, n=111	0.005	0.59
Level of training	$\chi^2=2.246$ df 4, n=101	0.004	0.69
Pain management training	$\chi^2=0.794$ df 2, n=111	0.004	0.67

A large majority of the community nurses agreed that patients with pain from leg ulcers have a right to expect pain relief (95.5%,  $n=106$ ). However, there were five respondents who did not agree that patients with pain from leg ulceration have a right to expect pain relief. Of these five, one was a matron, two were caseload holders and two were senior staff nurses, they were all female.

Very few respondents indicated that they were hesitant in giving opioids to older patients (9.9%). However, 23.4% ( $n=26$ ) were unsure with 61.3% ( $n=68$ ) of respondents indicating they disagreed with the statement "In general, I am hesitant to give opioids to older patients (65 years and over) with leg ulcers". Chi-square testing demonstrated no statistically significant associations between this hesitancy and age, job title, level of training and pain management training were compared to how this question was answered (see Table 26). A Bonferroni correction was applied because of multiple testing.

**Table 26: Association between nurses' characteristics and hesitancy in giving opioids to older adults ( $\chi^2$  test).**

Nurses' characteristics	$\chi^2$ statistics	Adjusted significance level with Bonferroni correction	P-value
Age	$\chi^2=5.143$ df 9, n=111	0.005	0.162
Job title	$\chi^2=23.534$ df 18, n=111	0.005	0.171
Level of training	$\chi^2=8.104$ df 6, n=101	0.004	0.231
Pain management training	$\chi^2=5.143$ df 3, n=111	0.004	0.162

**Table 27: Source data percentage (n) of nurses who were hesitant in giving opioids to older adults.**

	In general, I am hesitant to give opioids to older adults.			
		Agree	Disagree	Unsure
Age	20-29	0.9% (1)	7% (7)	3.8% (4)
	30-39	-	13% (14)	26% (28)
	40-49	4.7% (5)	26% (28)	0.9% (1)
	50-60	4.7% (5)	16% (17)	2% (2)
Job title	In general, I am hesitant to give opioids to older adults.			
		Agree	Disagree	Unsure
	Matron	2.7% (3)	4.5% (5)	0.9% (1)
	Nurse specialist	-	2.7% (3)	0.9% (1)
	Case load holder	4.5% (5)	12.6% (14)	4.5% (5)
	Senior staff nurse	0.9% (1)	0.9% (1)	8.1% (9)
	Staff nurse	1.8% (2)	17% (19)	4.5% (5)
	Healthcare assistant	-	0.9% (1)	4.5% (5)
Level of training	In general, I am hesitant to give opioids to older adults.			
		Agree	Disagree	Unsure
	Certificate	4% (4)	14% (9)	5% (5)
	Diploma	-	23% (23)	10% (10)
	Degree or Masters degree	7% (7)	26% (26)	7% (7)
Have you had formal pain management training?	In general, I am hesitant to give opioids to older adults.			
		Agree	Disagree	Unsure
	yes	9% (10)	39% (44)	12% (14)
	no	0.9% (1)	21% (24)	11% (12)

With regard to confidence in managing pain for this patient group only 35.1% ( $n=39$ ) indicated they were confident managing pain for this patient group. A Chi-square test was used to determine if there was a significant relationship between nurses' characteristics and confidence in pain management. A Bonferroni correction was applied because of multiple testing. Statistical analysis demonstrated that the nurses were similar in their response to this question and nurses with a bachelor's or master's degree were not significantly more likely to state they were confident in managing pain for this patient group (see Table 28).

**Table 28: Association between nurses' characteristics and confidence in managing pain ( $\chi^2$  test).**

Nurses characteristics	$\chi^2$ statistics	Required Bonferroni correction	alpha level with	p value
Age	$\chi^2=2.597$ df 3, n=105	0.005		0.458
Job title	$\chi^2=9.185$ df 1, n=111	0.005		0.133
Level of training	$\chi^2=3.719$ df 2, n=101	0.004		0.156
Pain management training	$\chi^2=0.724$ df 1, n=111	0.004		0.261

**Table 29: Source data percentage (n) of nurses' characteristics and confidence in managing pain.**

	I am confident in managing pain		
		Agree	Disagree or unsure
Age	20-29	6% (6)	6% (6)
	30-39	5% (5)	12% (13)
	40-49	12% (13)	27% (29)
	50-60	13% (14)	18% (19)
Job title	I am confident in managing pain		
		Agree	Disagree or unsure
	Matron	4% (4)	4.5% (5)
	Nurse specialist	2% (2)	2% (2)
	Case load holder	11% (11)	11% (12)
	Senior staff nurse	7% (8)	24% (27)
	Staff nurse	9% (10)	17% (19)
	Healthcare assistant	2% (2)	6% (7)
Level of training	I am confident in managing pain		
		Agree	Disagree or unsure
	Certificate	5% (5)	20% (20)
	Diploma	13% (13)	21% (21)
	Degree or Masters degree	18% (18)	24% (24)
Have you had formal pain management training?	I am confident in managing pain		
		Agree	Disagree or unsure
	yes	24% (27)	40% (44)
	no	11% (12)	25% (28)

Statistical analysis were also undertaken to determine if pain management training and confidence in pain management were related. It was found that pain management training did not have an impact on the nurses' confidence in managing pain ( $p>0.004$ ), (see Table 28). The majority (82%,  $n=91$ ) stated they would like more training in managing pain for this patient group. The numbers of respondents who did not want pain management training were too small to gain statistically significant differences when compared with other variables.

The majority, 56.8% ( $n=63$ ) of the participants indicated they felt well supported by the multi disciplinary team when managing pain for this patient group.

Only 6.3% of the participants indicated they avoided asking patients about their pain because they were not sure how to manage it. The numbers of nurses who suggested they avoided asking patients about their pain were too small to gain statistically significant differences when comparing variables. However, these nurses were all qualified; one was a matron, two were senior staff nurses and three were staff nurses. Three of this group had a degree and two had a diploma and were all between the ages of 40-60 years.

Question 31 involved asking community nurses how much time and energy they would expend to manage the same degree of pain but for different conditions. Twelve conditions were included (see Table 30), 93.7% ( $n=104$ ) of participants indicated that they would use maximum time and energy to manage pain caused by cancer. In contrast to this under half of the respondents (46.8%,  $n=51$ ) would spend maximum time and energy managing pain related to substance abuse. For chronic wound pain it was 70.3% ( $n=78$ ) of respondents, and for chronic pain 69.4% ( $n=77$ ).

The other conditions that showed smaller percentages of nurses that would expend maximum time and energy to manage the related pain were suicide attempt (54.1%,  $n=60$ ) and laparoscopic surgery (56.8%,  $n=63$ ). Conditions that gained the highest number of nurses who would spend maximum time and energy included cancer (93.7%,  $n=104$ ), multiple trauma (80.2%,  $n=89$ ) and the elderly patient (76.6%,  $n=85$ ).

**Table 30: Percentage (*n*) of nurses who would give maximum time and energy to manage the same degree of pain for various conditions (1=little time and energy to 5=maximum time and energy).**

Condition	1	2	3	4	5	Left Blank
Cancer pain	-	-	-	1.8% (2)	93.7% (104)	4.5% (5)
Multiple Trauma	-	-	2.7% (3)	6.3% (7)	80.2% (89)	10.8%(12)
Elderly patients	-	0.9% (1)	2.7% (3)	15.3% (17)	76.6% (85)	4.5% (5)
AIDS	-	-	-	5.4% (6)	73% (81)	12.6% (14)
Diabetes	-	2.7% (3)	6.3% (7)	15.3% (17)	70.3% (78)	5.4% (6)
Chronic wounds	-	-	4.5% (5)	20.7% (23)	70.3% (78)	4.5% (5)
Chronic pain	-	-	1.8% (2)	21.6% (24)	69.4% (77)	7.2% (8)
General surgery	-	0.9% (1)	7.2% (8)	18% (20)	67.6% (75)	6.3% (7)
Renal	-	2.7% (3)	4.5% (5)	19.8% (22)	63.1% (70)	9.9% (11)
Laparoscopic surgery	0.9% (1)	4.5% (5)	10.8% (12)	18.9% (21)	56.8% (63)	8.1% (9)
Suicide attempt	0.9% (1)	3.6% (4)	11.7% (13)	12.6% (14)	54.1% (60)	17.1% (19)
Substance abuse	2.7% (3)	9.9% (11)	12.6% (14)	10.8% (12)	46.8% (52)	17.1% (19)

In the other conditions the percentage of respondents who would expend maximum time and energy to manage the related pain ranged from 46.8% ( $n=52$ ) for substance abuse to 69.4% ( $n=77$ ) for chronic pain. Other conditions were suicide attempt (54.1%,  $n=60$ ), renal patients (63.1%,  $n=70$ ), general surgery (67.6%,  $n=75$ ) and laparoscopic surgery (56.8%,  $n=63$ ).

A Chi-square test was used to determine if there were significant relationships between age, job title, level of training and pain management training with nurses who spend maximum time and energy on all patients regardless of condition. Because of multiple testing a Bonferroni correction was applied to each test. No variable was determined as being statistically significant with regard to nurses who gave maximum time and energy to manage all patients' pain (see Table 32).

**Table 31: Source data percentage (n) of nurses' characteristics and willingness to give maximum time and energy to manage pain regardless of cause.**

Age	Regardless of cause of pain all patients are given maximum time and energy to manage all patients pain.		
		Yes	no
20-29		5% (5)	6% (7)
30-39		4% (4)	13% (13)
40-49		17% (18)	23% (24)
50-60		14% (15)	17% (18)
Job title	Regardless of cause of pain all patients are given maximum time and energy to manage all patients pain.		
		Yes	no
Matron		5.4% (6)	2.7% (3)
Nurse specialist		3.6% (4)	-
Case load holder		6.3% (7)	16.2% (18)
Senior staff nurse		14.4% (16)	17% (19)
Staff nurse		8% (9)	18% (20)
Healthcare assistant		2.7% (3)	5.4% (6)
Level of training	Regardless of cause of pain all patients are given maximum time and energy to manage all patients pain.		
		Yes	no
Certificate		10% (10)	15% (15)
Diploma		10% (10)	24% (24)
Degree or Masters degree		21% (21)	21% (21)
Have you had formal pain management training?	Regardless of cause of pain all patients are given maximum time and energy to manage all patients pain.		
		Yes	no
yes		27% (31)	36% (40)
no		12.6% (14)	23% (26)

**Table 32: Association between nurses' characteristics and willingness to give maximum time and energy to manage pain regardless of cause ( $\chi^2$  test and Fisher's exact).**

Nurses' characteristic	$\chi^2$ or Fisher's exact statistics	Required alpha level with Bonferroni correction	P value
Age	$\chi^2=2.936$ df 3, n=105	0.005	0.402
Job title	$\chi^2=25.269$ df 18, n=111	0.005	0.118
Level of training	$\chi^2=13.559$ df 4, n=111	0.004	0.009
Pain management training	Fisher's exact 0.796 df 1, n=111	0.004	0.246

#### 4.6 Summary

The study group was representative of a community nurse team within the primary care trust studied and representative of characteristics of nurses registered with the NMC (NMC, 2006) (see Appendix 13).

Over a third of the nurses had not attended any form of pain management training, with just 26.1% ( $n=29$ ) having pain management training in their original nurse training. In house training was the most common formal pain management training undertaken.

The study suggested that there was some awareness of the nature of pain associated with chronic leg ulceration. The majority of the respondents correctly indicated that pain from chronic leg ulceration could be acute and chronic. Also a high percentage indicated that this pain might have nociceptive as well as neuropathic components, although, 20% ( $n=22$ ) were unsure.

A significant number of respondents indicated that pain was a good sign as it might indicate infection or sensation. Moreover, a majority of respondents indicated that they used report of pain severity and pain triggers to diagnose type of leg ulcer. The majority of respondents indicated that compression might cause pain although neuropathic mechanisms were not identified as causing this pain. A small number suggested that the pain maybe nerve related and the most common reason specified was compression applied to ulcers of mixed aetiology.

With regard to chronic pain co-morbidities there was a high level of awareness that depression, insomnia, loss of mobility, pain at night and social isolation could be caused by chronic pain. However, fewer respondents acknowledged that suicidal ideation and a desire for limb amputation were a risk for this patient group.

With regard to management of pain of chronic leg ulceration the data suggested that analgesic recommendations were inadequate. The only drug that the nurses indicated they routinely recommended was paracetamol; recommendation of drugs to manage neuropathic pain was indicated as being undertaken by under half of the respondents. There was also an apparent disparity amongst the nurses in their analgesic recommendations.

Assessment of pain was not undertaken by all the respondents, with nearly a quarter not undertaking any form of pain assessment. Under half indicated they assessed pain using a pain score and verbal report. There appeared to be a lack of consistency in the pain assessment activity the nurses stated they were undertaking. Just over half indicated that they measured and documented pain on every visit. However, a

significant number indicated they were not measuring and documenting pain on every visit, with 15.3% ( $n=17$ ) stating they never undertook any form of pain assessment.

The most frequently used non-pharmacological method of pain management during dressing changes was shown to be gentle dressing technique. Distraction and relaxation were reported by a quarter of the respondents.

The professional nurse attitudes section has given some interesting insight, with the majority of the respondents indicating that healing is the primary goal for all patients. There did not appear to be any ageist attitudes to pain, although 23.4% ( $n=26$ ) of respondents were unsure about giving opioids to older people. Furthermore, the majority of the nurses did not indicate they thought pain was a normal part of ageing. The majority indicated that patients with pain from chronic leg ulcers have a right to pain relief. Likewise the majority indicated that nurses become desensitised to pain with repeated exposure.

Only 35% ( $n=39$ ) of respondents indicated they were confident in managing pain in this patient group and 82% ( $n=91$ ) would like more pain management training. Moreover, just under half of the respondents indicated they did not feel supported by the multidisciplinary team when managing pain for this patient group.

There was some difference in the numbers of nurses who would spend maximum time and energy on wound pain and chronic pain compared with cancer pain. The data suggested that community nurses were more likely to expend maximum time and energy on cancer pain and fewer respondents indicated that they would spend maximum time and energy on managing pain for wound pain or chronic pain.

The data have provided some insight into the awareness that community nurses have on the nature of chronic leg ulcer pain. Data investigating pain management strategies showed disparities in practice especially with regard to pain assessment. Attitudes to pain management have indicated that the focus was on the healing. The data suggested that pain management was a consideration but there appeared to be inconsistencies in pain management methods amongst this group. There did not appear to be any routine practice in managing pain for this patient group.

#### **4.7 Discussion of study 2**

This section discusses the findings of the study within the context of the available literature. An overall combined theoretical discussion and conclusion of study 1 and study 2 is then presented with recommendations for practice, further research, National guidelines and educational requirements in chapter 5.

#### **4.7.1 Study 2 aim**

Findings from study 1 suggested that patients with chronic leg ulceration were not having their pain managed effectively. Findings also suggested that the healthcare professionals caring for the patients were not measuring or documenting their patients' pain. Moreover, they appeared not to be addressing the pain that their patients reported. Therefore, the findings of study 2 are presented according to the three aims of the study, namely:

- i. To explore community nurses' perceptions of the nature of the pain associated with chronic leg ulceration.
- ii. To describe current strategies used by community nurses to manage pain in this patient group.
- iii. To survey nurses' attitudes in relation to providing pain management for this group.

#### **4.7.2 Community nurses' perceptions of the nature of the pain associated with chronic leg ulceration**

The first part of the questionnaire investigated the community nurses understanding with regard to the nature of the pain of the leg ulcer. The literature (refer to Chapter 2, section 2.4) and findings from study 1 indicated that pain associated with chronic leg ulceration could be acute or chronic with a possible neuropathic component.

Nurses from the survey predominantly indicated that pain from leg ulceration could be acute and chronic, 90.1% ( $n=100$ ) indicated the pain could be acute and chronic with only 25% ( $n=28$ ) of them being unsure.

The majority of respondents correctly identified that pain associated with chronic leg ulceration may have a neuropathic component. Although a large majority indicated that pain associated with chronic leg ulceration might have a neuropathic element as well as nociceptive pain a significant number were unsure. As expected nurses who had received formal pain management training were significantly more likely to indicate that leg ulcer pain may have nociceptive pain as well as neuropathic pain component. Insufficient knowledge/training in pain management has been reported as causing a barrier to providing effective pain management (Elliott & Elliot, 1992; Fife, Irick & Painter, 1993; Elliott *et al.* 1995; Oneschuk *et al.* 1997; Jastrab *et al.* 2003). Numerous studies have found that nurses who have received formal education in pain management demonstrate being more knowledgeable with regards to pain. These

studies investigating nurses' knowledge relating to pain all highlight clear deficits in nurses' knowledge, which are often attributable to inadequate education (McCaffery *et al.* 1990; Ferrell *et al.* 1991; Ferrell, McGuire & Donovan, 1993; Clarke *et al.* 1996; Comley & Banks, 2000; Coulling, 2005).

Although a large majority (77.5%,  $n=86$ ) of nurses indicated that pain associated with chronic leg ulceration may have a neuropathic component it is not clear if these nurses understood the mechanisms associated with neuropathic pain. This is especially apparent because not one of the respondents indicated that compression bandaging could cause further pain because of the neuropathic component. However, 3% ( $n=3$ ) did indicate it could be due to an increased tenderness to the nerves. The most common reason given for compression causing further pain was if the compression was applied to an ulcer of mixed or arterial aetiology. This may be correct; however it could be that the pain caused by compression is possibly because of the neuropathic component. Allodynia is a likely characteristic of neuropathic pain (Wall, 1991). It can be described as pains that are provoked by normal innocuous stimuli; therefore applying a tight heavily layered bandage can be expected to cause further pain. Moreover, hyperalgesia is also a common feature of neuropathic pain. The definition of hyperalgesia is a heightened painful response to a painful stimulus (Wall, 1991). Both hyperalgesia and allodynia if present would cause a significant amount of pain if a heavy bandage were being applied to the area. The respondents answering the study did not mention neuropathic symptoms or neuropathic pain as a reason that may cause pain with compression. This perhaps puts into question their true understanding of what neuropathic pain is and how it manifests. They may know that these patients are at risk of neuropathic pain but they did not appear to have a clear understanding of what it was. It is possible if they understood neuropathic pain mechanisms they would have identified neuropathic pain as a cause of the compression causing further pain. Moreover, the nurses from this survey did not suggest they were using any procedures to assess for neuropathic pain such as the LANSS. For clinicians to successfully diagnose neuropathic pain Bennett developed a pain scale to assess for neuropathic signs and symptoms (Bennett, 2001), known as the Leeds assessment of neuropathic symptoms and signs (LANSS). The LANSS pain scale has been shown to distinguish patients with neuropathic pain from those with nociceptive pain (Bennett, 2001), allowing quick and effective screening. Thus promoting and enabling adequate treatment in patients with neuropathic pain. The scale has since been tested and validated in several settings (Potter *et al.* 2003; Yucel *et al.* 2004; Kaki, El-Yaski &

Youseif, 2005). It can be suggested that without adequate assessment patients may not get their neuropathic pain diagnosed.

The majority of participants correctly indicated that pain severity was not directly proportional to tissue involvement. A neuropathic component can impact on the pain severity as neuropathic pain can cause a chronic pain state that remains with the patient even after healing. Briggs *et al.* (2007) and Park, Ferreira and Santos (2008) demonstrated that pain intensity did not correlate with ulcer size, ulcer duration and frequency of wounds. Furthermore, Flaherty (2005) in a qualitative study investigating the lives of patients with healed ulcers reported that participants experienced pain following healing. The gate control theory and the neuromatrix theory suggest that the brain is the authority of the multiple dimensions of pain (Melzack & Wall, 1965; Melzack, 1999). Melzack (1999) suggests that the spatial distribution and synaptic links are initially determined genetically and are later sculpted by sensory inputs. The cyclical processing and synthesis of nerve impulses results in a characteristic "neurosignature" for a particular individual that is determined by a combination of genetic and sensory influences. The neuromatrix theory of pain recognizes the simultaneous convergence of a myriad of influences such as past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems as well as immediate sensory input. Thus, to only consider the painful stimulus as the main factor determining the pain severity would be largely inaccurate.

Question 8 asked the nurses if they thought pain was a good sign, as it indicated healing, infection and sensation. A significant number of the respondents indicated that they thought pain could be a good sign as it may indicate infection or sensation (46.8%  $n=52$ , 38.7%  $n=43$  respectively). The fact that a significant number of the nurses believed that pain was a good sign to indicate infection and/or sensation may not be conducive to effective pain management. Previous studies have identified professionals incorrect attitude to pain (Lebovits, Florence & Bathina, 1997; Levin, Berry & Leiter, 1998; Ponte & Johnson-Tribino, 2005) and have shown that this impacts negatively on the pain management ability of the clinician. However, the leg ulcer literature encourages the use of pain as an indicator of infection and sensation or arterial involvement. The RCN clinical guidelines (1998; 2006) and the Scottish intercollegiate guidelines (SIGN, 1998) suggest that infection can be detected by an increase in pain severity. It can be suggested that if the National guidelines on management of leg ulceration promote use of pain as an indicator of sensation or infection it is to be expected that the community nurses use pain as an indicator of

sensation or infection. Whilst using an increase of pain as an indicator for infection is not necessarily inappropriate it needs to be interpreted in context of patient familiarity (Cutting & White, 2005). Gardner, Frantz, and Doebbeling (2001) concluded that signs specific to secondary wounds appeared to be more valid indicators of chronic wound infection such as serous fluid, inflammation, delayed healing, discoloration, friable granulation, foul odour and wound breakdown. There is evidence of pain being under managed in other conditions because the clinicians fear losing the pain as an indicator to worsening of condition or change of condition (masking the pain). This survey did not ask the nurses directly if they maintained the patients' pain because they did not want to mask changes, but the nurses did indicate they were using pain as an indicator for infection and sensation. It has been demonstrated that when clinicians use pain as an indicator for changes in the condition of a patient they are less likely to manage the pain for fear of masking. In a study undertaken by Tait, Ionescu and Cuschieri (1999) it was shown that 38% of clinicians stated that analgesia might mask physical signs. Others support appropriate management of pain and have demonstrated that managing pain does not lead to an inability to detect or diagnose further problems (Thomas & Silen, 2003a; Thomas *et al.* 2003b; Karagianis & Hardern, 2005). A culture of using pain as an indicator to detect changes in severity or to detect worsening of condition is apparent in the world of surgery and trauma. We cannot state that this culture exists in the world of community health care, as there is no evidence of this in the literature. However, the majority of the nurses working as community nurses would have undertaken training within an acute trust. Thus, they would gain some of their pain management expertise and attitude from that experience. Wallace *et al.* (1995) state that nurse's primary source of information about pain and pain management includes their basic training, previous employee hospital orientation and previous peers in practice.

With regard to pain severity being used to help in diagnosing type of leg ulcer, this study has identified that a significant number of the community nurses use pain severity to aid diagnosis in type of leg ulcer (44.1%,  $n=49$ ). A larger number of community nurses (87.4%,  $n=97$ ) indicated they use report of pain triggers in aiding diagnosis of type of leg ulcer. The leg ulcer literature (Phillips, 2004; Dowsett, 2005; Reichenberg & Davis, 2005) and more pertinently the current leg ulcer management guidelines encourage clinicians to use pain report as a tool for diagnosis of type of leg ulcer. The RCN (1998; 2006) clinical practice guidelines suggest that rest pain is associated with arterial ulcers. The Scottish guidelines (SIGN, 1998) correctly comment that leg ulcers are painful. However, they then go onto say, "particularly if

they have an arterial component". Reichenberg and Davis (2005), in a review of management of venous leg ulceration state that venous ulcers are associated with a minimum of pain. They go on to suggest recent work has highlighted that although the pain is minimal these patients can still suffer from emotional discomfort. The recent work they refer to in fact suggested that patients with leg ulceration suffer severe pain regardless of the aetiology (Phillips *et al.* 1994; Charles, 1995; Krasner, 1998). Report of trigger of pain as an aid to diagnosis was again endorsed by the guidelines and within the leg ulcer literature. It was reported that patients with arterial ulcers are more likely to have an increase in pain when their legs are elevated or after exertion (RCN, 1998; SIGN, 1998; Phillips, 2004; RCN, 2006). Moreover, it was suggested that only severe arterial disease will cause pain at rest (Phillips, 2004). The literature and current practice guidelines suggested that patients with venous ulcers are more likely to have pain with exercise and relief of pain can be gained by elevating their legs (SIGN, 1998; Phillips, 2004; RCN, 2006). This perhaps offers an explanation as to why the nurses use severity of pain and pain triggers as a tool to diagnose aetiology of leg ulcer. This is unfortunate as there was evidence in the literature which suggested that severity of pain was not directly linked to aetiology of leg ulcer (refer to Chapter 2, section 2.4). Further, results from study 1 advocated that severity of pain was not dependent on aetiology as patients with venous, arterial or mixed aetiology described pain at rest (refer to Chapter 3, section 3.10.3.1.6) and also described intensity of pain that did not suggest it was related to aetiology (refer to Chapter 3, section 3.10.3.1).

With regard to report of pain triggers, there was evidence within the literature which suggested that pain triggers were not necessarily indicative of leg ulcer aetiology. Closs, Nelson and Briggs (2008) in their prospective interview based survey, investigating differences between venous and arterial pain characteristics report that the pain-rating index was not different between groups. The pain-rating index (PRI) was derived from the rank values of the words chosen. The number of words chosen (NWC) was recorded; the NWC was reported as having no significant difference between groups. However, arterial ulcers were associated with having higher pain scores when legs were elevated.

This survey identified that the majority of the community nurses thought that compression therapy caused or exacerbated pain (94.6%,  $n=105$ ). Reasons for the compression causing further pain were identified as predominantly being caused by compression being applied to an ulcer of mixed aetiology. Again the leg ulcer guidelines and literature recommend that an increase in pain may be a sign of arterial

involvement (SIGN, 1998; RCN, 1998; Phillips, 2004; Dowsett, 2005; RCN, 2006). There appears to be a focus on severe pain being associated with arterial ulceration. Other suggestions included reduction of oedema, increased blood supply; bandage applied incorrectly and bandage slipping. All these reasons cited are involving either the incorrect application or use of compression bandaging and the impact of certain physiological processes that occur as a result of the compression. There was evidence to suggest that oedema causes pain and once that has been reduced with the aid of compression, then the pain decreases (Krasner, 1998). There was no discussion in the leg ulcer literature regarding an increased blood supply causing pain. It was understandable that the nurses cited that the pain caused by compression could be caused by the bandage being applied incorrectly and by the bandage slipping. There was a strong emphasis in the leg ulcer literature that suitably trained nurses must undertake application of compression to ensure that it is applied correctly (Moffatt, 2004; RCN, 2006). Heinen *et al.* (2007) found that patients could not tolerate compression because it was too tight. This finding was also reported by Briggs and Closs (2006). It was not possible to ascertain if these patients could not tolerate the compression because of the tightness required to create the compression, or the bandaging had in fact been applied incorrectly.

Franks, Moffatt and Connolly (1994) reported that patients felt compression was painful initially but could improve over time, perhaps once the swelling had reduced. This may explain why the nurses said that patients need to get used to their compression. A relatively significant number indicated that the pain was psychological. This is a concern, but perhaps reflects the current leg ulceration literature. The leg ulcer literature and the leg ulceration guidelines suggest that compression is associated with a reduction of pain (Franks, Moffatt & Connolly; 1994; RCN, 2006; Fogh *et al.* 2008). Fogh *et al.* (2008) developed a wound pain management model, within the model it was suggested that compression should be used to reduce pain. Therefore, this may create confusion in the nurses applying the compression. This may also offer an explanation as to why they may think the pain is not actually caused by the compression but psychological.

The reasons cited appeared to suggest that the nurses did not expect compression bandaging to be painful, if it was applied correctly and appropriately. If it was painful even though it was applied correctly and appropriately, the results suggest the nurses thought it must be because the patient was either imagining the pain, or needed to get used to the compression bandaging. The quantitative and qualitative leg ulceration literature (refer to Chapter 2, section 2.5.3) and results from study 1

suggest that compression is in fact painful for some patients, regardless of correct and appropriate application. It was not possible to determine exactly how many patients experience pain associated with compression. However, Briggs and Closs (2006) and Heinen *et al.* (2007) provided quantitative evidence that patients experience pain associated with compression. Qualitative studies undertaken by Ebbeskog and Emami (2005) and Mudge *et al.* (2006) reported pain associated with compression. Furthermore, the majority of participants in study 1 reported that compression was a cause for exacerbation of their pain (refer to Chapter 3 section, 3.10.3.1.7). As discussed within study 1, pain was to be expected if these patients were also reporting neuropathic symptoms (refer to Chapter 3, section 3.12.2).

The finding that nurses in this survey did not correctly cite neuropathic symptoms, as a reason for compression causing further pain is a concern. A few nurses did cite that the pain could be caused by an increased tenderness to the nerves. However, this was indicated by a very small number (3%,  $n=3$ ). As previously discussed allodynia is a likely characteristic of neuropathic pain (Wall, 1991), therefore applying a tight heavily layered bandage can be expected to elicit this pain. Hyperalgesia is also a common feature of neuropathic pain (Wall, 1991). Both hyperalgesia and allodynia if present would cause a significant amount of pain if a heavy bandage were being applied to the area regardless of correct or appropriate application. It can be surmised that if an individual had some understanding of neuropathic pain and its components they would understand this concept. Therefore, the nurses in this survey may have indicated that leg ulceration can have nociceptive as well as a neuropathic pain component; but they have not demonstrated an understanding of the impact the neuropathic pain component may have on compression. They did not demonstrate that they understood the link between neuropathic symptoms and pain associated with compression. This is unfortunate as there was evidence from the literature (Briggs & Closs, 2006; Parks, Ferreira & Santos, 2008) and also from study 1 (refer to Chapter 3, 3.10.3.3.2) that patients with leg ulceration are at risk of associated neuropathic pain. If the nurses were cognizant of the impact neuropathic pain may have on the pain experience associated with application of compression, this may have improved the patients' pain management. By managing the neuropathic aspect of the pain, the patient may not only have a reduction in pain but their ability to tolerate the compression could be improved. Participants from study 1 described at times, non-compliance with compression because of associated pain. In a systematic review carried out by Van Hecke, Grypdonck, and Defloor (2009) pain and discomfort was reported as being a main cause for non-adherence to compression. Others have

also reported that patients take off their bandages to reduce discomfort (Herber, Schnepf & Rieger, 2007). The nurses in study 2 acknowledged that compression might cause pain. However, they also reported that this was because the compression had been either inappropriately applied or had been applied to a patient with ulcers caused by arterial aetiology.

#### **4.7.2.1 Chronic pain sequelae**

Patients from study 1 frequently reported episodes of chronic pain morbidities such as depression, insomnia, and pain at night, loss of mobility, social isolation, suicidal ideation and a desire for amputation of the affected limb. Nurses from the survey correctly identified that these co-morbidities were a potential risk to patients with chronic pain from leg ulceration. The literature supports this (refer to Chapter 3, table 4) and it is reassuring that the results from the survey demonstrated that these co morbidities were acknowledged by the nurses caring for this group of patients. However, a significantly fewer number of nurses identified suicidal ideation ( $p < 0.05$ ) and desire for amputation of affected limb ( $p < 0.05$ ) as a co-morbidity.

The chronic pain literature demonstrated that suicidal ideation is a risk factor associated with chronic pain (refer to Chapter 3, section 3.12.2.3). The literature demonstrated that suicidal ideation is a risk factor associated with chronic pain, but is also a risk factor associated with older people (Kelly & Bunting, 1998). Studies investigating depression in patients living with chronic leg ulceration have demonstrated that depression is a risk, but these studies do not discuss suicidal ideation (Hareendran *et al.* 2005; Jones *et al.* 2006). In the qualitative literature there was one example of suicidal ideation (Krasner, 1998) and one example of desire for amputation of affected limb (Rich & McLachlan, 2003). Thus, the results from this study are a reflection of the lack of awareness of the risk of suicidal ideation and desire for amputation of affected limb in the current leg ulceration literature.

#### **Key Findings for question I**

- i. The majority of respondents indicated pain associated with chronic leg ulceration was chronic and may have a neuropathic component.
- ii. The majority of respondents indicated that pain severity was not directly proportional to tissue involvement.
- iii. The majority of respondents did not indicate that pain from compression might be caused by a neuropathic component.

- iv. A statistically significant number indicated that pain was a good sign as it indicated infection and/or sensation.
- v. A statistically significant number reported using severity of pain and pain triggers as an aid to diagnose type of leg ulcer.
- vi. A statistically significant number identified the potential risk of chronic pain co-morbidities such as depression, insomnia, pain at night, loss of mobility and social isolation for this group of patients. Fewer indicated the risk of suicidal ideation and desire for limb amputation.

#### **4.7.3 Current strategies used by community nurses to manage pain in this patient group.**

Findings from study 1 and the current leg ulceration literature suggest that pharmacological pain management is inadequate for this patient group and mild analgesics such as paracetamol and codeine are most commonly utilised (refer to Chapter 2, section 2.7.2.1 and Chapter 3, section 3.10.4.1).

##### **4.7.3.1 Recommendation of paracetamol**

This survey adds to findings from the literature (refer to Chapter 2, section 2.7.2.1). Findings from this study suggest that the most frequently recommended analgesic for pain associated with chronic leg ulceration was paracetamol. Just under half of the nurses indicated that they always recommended the use of paracetamol (46.8%,  $n=52$ ). Paracetamol was significantly ( $p<0.05$ ) more likely than any other analgesic drug to be recommended. This finding was also evident in the literature (Ebbeskog, Lindholm & Ohman, 1996; Husband, 2001a, 2001b; Guarnera, *et al.* 2007) and from results from study 1 (refer to Chapter 3, section 3.10.4.1.1). Paracetamol is an analgesic and antipyretic drug that acts via a central site of action (Muth-Selbach *et al.* 1999; Courade, Chassaing & Bardin, 2001). Paracetamol can be used alone or as an adjunct to other analgesics. However, its use is limited by an analgesic ceiling (Maxwell, 2000). Paracetamol is the first drug of choice for many chronic painful conditions (WHO, 2008); it is also the National Kidney Foundations drug choice for patients with renal disease (Ruoff, 1998). Paracetamol is effective for mild to moderate pain, but a stronger analgesic is required for pain that is described as moderate to severe (WHO, 2008).

#### 4.7.3.2 Non-steroidal anti-inflammatory drugs

Under half of the respondents indicated that non-steroidal anti-inflammatory drugs were recommended sometimes. The respondents were asked if they recommended ibuprofen and/or diclofenac. A very small number of participants indicated they were recommending either of these drugs always (3.6%,  $n=4$ ). A larger number indicated they were recommending ibuprofen and diclofenac sometimes (45%  $n=44$ , 37.8%  $n=42$ ) respectively. However, a significant number of respondents left the answer to this blank.

A possible explanation for this could be the well documented potential risks associated with the use of NSAIDs especially in older people (Bandolier, 2008a). NSAIDs are associated with a number of adverse effects. These include effects on the kidney, and exacerbating asthma in some people, but the most important adverse effect of NSAIDs is that on the gastrointestinal tract. NSAIDs cause gastric erosions that can become ulcers. The burden of NSAIDs adverse effects in the UK is significant, the annual NSAIDs prescription in the UK is 25 million, NSAIDs related admissions are 12,000 and the NSAIDs related deaths are 2,6000 (Bandolier, 2008a). Despite these statistics it must be acknowledged that NSAIDs are very effective analgesics, and bring a huge benefit to many people who use them. The recommendation from Bandolier (2008a) is that the risks are highly age related, with high risk associated with people 75 years and over (Blower, Brooks & Fenn, 1997). The leg ulceration literature had only one qualitative study where the use of diclofenac was mentioned (Guarnera *et al.* 2007), there was no quantitative study investigating the use of oral NSAIDs to manage the pain associated with chronic leg ulceration.

The pharmacological/pharmacokinetic literature suggests that the use of ibuprofen has the better safety profile (Garcia, 1998; Hersh, 2000; Manning & Richer, 2003; Bandolier, 2008b). The use of oral NSAIDs as a method of controlling and managing pain of leg ulceration has not been investigated. This may be because people with leg ulceration are likely to be 65 years or over (refer to Chapter 2, section 2.3). Furthermore, older people are at greater risk of drug related adverse events (refer to Chapter 2, section 2.6.3). However, it is an area that requires more research to establish effectiveness and to establish if the risk is greater than the benefit. With regard to the impact of NSAIDs on healing "the jury is still out" the evidence does not conclusively demonstrate that NSAIDs negatively impact healing (refer to Chapter 2, section 2.7.3.2). Despite this a recent NHS guideline advises against the use of

NSAIDs in patients with chronic leg ulceration because of the apparent negative impact on healing (NHS, 2010).

Use of local ibuprofen is a relatively new development and its use for managing pain of leg ulcers has been investigated (refer to Chapter 2, section 2.7.3.2). However, for the purpose of this survey its use was not investigated, as it was such a newly developed technique. Therefore, it was assumed that it would not have been a pain management technique being used at the time of data collection. At the time of study design there was limited evidence of its use and efficacy (refer to Chapter 2, section 2.7.3.2).

#### **4.7.3.3 Weak opioids**

The survey included questions to determine if the nurses were recommending opioids weak and strong. An opioid is any compound, which has pharmacological activity at an opioid receptor, and a compound that can be reversed by an opioid antagonist (naloxone).

Codeine is a weak opioid and was the second most frequently recommended drug. Codeine is a low potency opioid and is the drug recommended as stage two of the analgesic ladder (WHO, 2008) for mild to moderate pain. If pain relief is insufficient with paracetamol alone, codeine may be added as a combination. Combining two different analgesics avoids increasing the dose of either drug, and reduces the likelihood of side-effects from either medication (Helme & Katz, 2003).

The nurses from the survey indicated that they were recommending them sometimes. Although only 7.5% ( $n=8$ ) stated they were recommending codeine always, 55% ( $n=61$ ) of the respondents stated they were recommending codeine sometimes. There was evidence of the use of codeine in the literature but it was limited. The only study that provided evidence with regard to the use of codeine for leg ulceration pain was a study undertaken by Guarnera *et al.* (2007). They undertook a multicentre cross sectional study ( $n=381$ ) in Italy, they found 66% ( $n=251$ ) of participants received some form of analgesia including codeine. However, they did not collect data to determine effectiveness of the codeine. Evidence of the use of codeine in the qualitative literature is apparent (Husband, 2001b). Husband's (2001b) study also suggested that patients using codeine with paracetamol found it insufficient. It was also apparent from the literature that the amount of codeine being administered was usually as a combined preparation of paracetamol 500mg and codeine 8mg (Husband, 2001b). There is some question to the efficacy of this combination to manage pain. There are no controlled trials of the use of paracetamol

500mg/codeine 8mg (Helme & Katz, 2003). Although, it is thought that this combination will cause less adverse events it is likely to be less efficacious than doses of 30-60mg codeine that have been shown to have good effect (Helme & Katz, 2003). A systematic review investigating the use of paracetamol with or without codeine confirmed that codeine 60mg produced worthwhile additional pain relief (Moore *et al.* 1997). Moreover, the literature regarding nurse prescribing suggests that nurse prescribers are most likely to advise patients to purchase over the counter analgesics rather than prescribe analgesics (Luker *et al.* 1998). When codeine is purchased over the counter it can only be purchased as a combined preparation of codeine 8mg/ paracetamol 500mg (BNF, 2008).

Tramadol was also frequently recommended with 52% ( $n=57$ ) of the respondents suggesting they were recommending it sometimes. However, the use of tramadol has not been reported in the leg ulcer literature. A significant proportion (15.3%,  $n=17$ ) of the respondents indicated that they were never recommending tramadol or left this section blank (32.4%,  $n=36$ ). This may reflect the caution associated with use of tramadol because of the risk of seizures. The risk of seizures can be increased in patients taking selective serotonin reuptake inhibitors, tricyclic antidepressants, opioids, monoamine oxidase inhibitors and neuroleptics (Mullican & Lacy, 2001). An Australian study found that of 97 confirmed new onset seizures, eight were associated with tramadol, and that in the authors "First seizure clinic", tramadol was the most frequently suspected cause of provoked seizures (Labate, 2005). Moreover, the risk is increased in older people, as the elimination half-life can be prolonged.

#### 4.7.3.4 Strong opioids

Nurses were also asked if they recommended the use of pethidine. Only a very small number indicated that they were recommending the use of pethidine for leg ulcer pain sometimes (4.5%,  $n=5$ ). The recommendation of pethidine compared with morphine was significantly less. This is encouraging and suggests a level of understanding of the pharmacology of analgesics. Pethidine is not recommended for the use of chronic pain as repeated administration can lead to neurotoxic effect (Kaiko *et al.* 1983). However, a significant proportion of the nurses left the answer to the pethidine question blank (49.5%,  $n=55$ ). This was unfortunate as it suggested a degree of uncertainty. There was evidence in the literature to suggest that nurses have an inadequate knowledge base in pharmacology which impacts on their level of certainty in pharmacological issues (Latter & Courtney, 2004).

Out of all the strong opioids recommended for severe pain morphine was the drug that was indicated as being most frequently recommended. This is perhaps not

surprising as it is the “gold standard” opioid. It is the most commonly used opioid and is the standard against which all other opioids are tested (Heffernan & Rowbotham, 2003). The leg ulcer literature has some evidence that opioids were being used. However, the actual use of morphine was not mentioned (refer to Chapter 2, section 2.7.2.2). The recommendations for the management of leg ulcer pain suggested that opioids may be required for severe pain associated with arterial leg ulceration (SIGN, 1998). There was no recommendation for the use of morphine to manage pain associated with venous leg ulceration in the current guidelines (RCN, 2006). Despite this the nurses from this survey indicated that they were recommending morphine (44.10%) over the other strong opioids.

Other opioids that the nurses indicated they were recommending were fentanyl patch (32.4%,  $n=36$ ) and oxycontin (15.3%,  $n=17$ ). However, far more of them indicated that they were never recommending these drugs or left the answer blank (fentanyl, left blank 43.2%,  $n=48$ /Never 24.3%,  $n=27$  and oxycontin, left blank 47.7%,  $n=53$ /Never 36.9%,  $n=41$ ). The leg ulcer literature did not mention the use of these drugs for patients with leg ulcer pain (refer to Chapter 2, section 2.7.2.2). Moreover, the recommendations on leg ulcer management do not recommend use of either of these drugs (Phillips, 2004; RCN, 1998; RCN, 2006). The use of oxycontin is indicated if a patient has adverse effects with morphine. The fact that morphine does not appear to be used that frequently; to manage leg ulcer pain perhaps gives a reason as to why oxycontin was not being recommended. Morphine is the gold standard as previously suggested. Therefore, if people were not on morphine they would not be requiring a second line opioid. With regard to the use of a fentanyl patch, as previously mentioned there was no evidence in the literature to suggest it was being used to manage leg ulcer pain. There may be several reasons for this; one of them could be that fentanyl is not always recommended for older patients. Due to absorption rates being unpredictable in older people because of differences in body temperature and subcutaneous fat and water (Gloth, 2001). Transdermal fentanyl has a definite, but limited role and is recommended in use for:

- i. Patients already stabilized on other opioids that have a persistent swallowing problem and cannot tolerate other parenteral routes such as subcutaneous administration.
- ii. Patients with moderate to severe renal failure
- iii. Patients who experience troublesome adverse effects on morphine.

Therefore, the fact that fentanyl does not appear to be recommended by the nurses from this survey was of no surprise. It could be surmised that if morphine is the gold

standard and if that is not being used frequently, the other opioids used to replace morphine if there are problems, will not be in use.

For chronic pain conditions fentanyl and oxycontin are considered second line opioids to morphine. There is no evidence that any opioids are superior to morphine in relieving pain (Calam, Doyle & Hanks, 2004).

#### **4.7.3.5 Drugs used for neuropathic pain**

The literature (refer to Chapter 2, section 2.4) and results from study 1 (refer to Chapter 3, section 3.10.3.1.3) have demonstrated that neuropathic pain can be a possible component of chronic leg ulceration pain. Therefore, nurses in this survey were asked if they recommended drugs to manage neuropathic pain. Gabapentin and pregabalin are anticonvulsants that have been shown to have neuropathic pain management properties (Wiffen *et al.* 2004). Amitriptylene is also used as a drug to manage neuropathic pain (Maxwell, 2000). The leg ulcer literature and the results from study 1 suggested that patients were not prescribed drugs to manage neuropathic pain (refer to Chapter 2, section 2.7.2.1; Chapter 3, section 3.10.4.1.5). Interestingly the nurses in the survey indicated that they were recommending the use of amitriptylene and gabapentin, 46.8% ( $n=52$ ) indicated they were recommending amitriptylene sometimes and 45% ( $n=50$ ) indicated that they were recommending gabapentin sometimes. Pregabalin was the least likely to be recommended with only 8.10% ( $n=9$ ) indicating they were recommending this drug sometimes. Amitriptylene was more likely to be recommended despite not being licensed for the use of neuropathic pain (BNF, 2008). A large percentage indicated they would recommend amitriptylene sometimes (46.80%,  $n=52$ ). This practice is repeated throughout the medical profession. Amitriptylene appears to be the most commonly prescribed antidepressant by pain experts for the management of neuropathic pain (Maxwell, 2000). Moreover, in pain treatment amitriptylene is the most extensively studied drug out of the balanced tricyclic's (Sindrup, 2003). However, tricyclic analgesics are not recommended for older adults because of adverse effects (Dworkin *et al.* 2007).

Gabapentin was also stated as being frequently recommended, with 45% ( $n=50$ ) of respondents indicating they were recommending it sometimes. Gabapentin has been demonstrated as a useful drug to manage neuropathic pain. In a systematic review undertaken by Wiffen *et al.* (2004) 23 trials of 6 anticonvulsants were investigated; number of individuals included in this trial was 1,074. The type of pain that responded well to anticonvulsants was neuropathic pain. Approximately two thirds of the patients

who took gabapentin achieved good pain relief. Although gabapentin is effective its inter-subject variability and non-linear pharmacokinetics make it difficult to predict the appropriate dose or which patients are likely to achieve a meaningful clinical response (Rice & Maton, 2001). Pregabalin is a relatively new antiepileptic drug; it is similar to gabapentin but has fewer side effects and does not require titration to individual patients (Rice & Maton, 2001). It is better tolerated than gabapentin and does not have inter-subject variability (Rosenstock *et al.* 2004). The fact that pregabalin was a relatively newly available drug at time of data collection, may provide an explanation as to why the nurses indicated they were not recommending this drug.

The evidence in the literature and results from study 1 suggested that drugs to manage neuropathic pain were not used. There may be a number of reasons for this, firstly the nurses suggested they recommend amitriptylene, however this is not recommended for use with older adults and this may explain why there was limited evidence of its use, as patients with leg ulceration are likely to be older. Furthermore, older adults are at risk of receiving poor pharmacological pain management because of fear of side effects and poor pain assessments (refer to Chapter 2, section 2.6.3 and section 2.7.1). Therefore, whilst the nurses indicated they were recommending drugs for neuropathic pain they may not be doing this for older adults. Another reason that may prevent patients with neuropathic pain from getting drugs to manage the pain, could be the inability of the nurses to diagnose and acknowledge the neuropathic pain in their patients. As previously indicated the nurses from this survey suggested they recognise that pain associated with leg ulceration may have a nociceptive as well as a neuropathic pain element. However, there is some question of the level of understanding with regard to neuropathic pain. Only 3% ( $n=3$ ) of the respondents stated that there might be a nerve involvement that causes pain from compression. Thus, they may be aware of drugs that manage neuropathic pain. However, if they do not identify neuropathic pain in all the patients that have it they will not be recommending the drugs to those patients. Furthermore, the nurses did not indicate they were using any form of neuropathic pain assessment for patients with leg ulceration. There appear to be gaps in their knowledge that may impact on the ability of the nurses to acknowledge neuropathic pain in all patients that have it. This may be preventing patients from getting access to appropriate treatment. There was evidence in the literature that suggested patients with leg ulceration were not taking drugs for neuropathic pain (refer to Chapter 2, section 2.7.2.2). Moreover, evidence from study 1 suggests a lack of appropriate neuropathic pain assessment and management. However, it is acknowledged that evidence of lack of appropriate drug use for

neuropathic pain from study 1 came from 11 patients. Study 1 was a qualitative study therefore; numbers were small and may not have been able to capture data to determine if patients with leg ulceration take drugs for neuropathic pain.

#### **4.7.3.6 Nurse prescribing**

Nurse prescribing is a relatively new practice within the nursing profession in the UK. Many of the initial prescribers (who prescribed from a limited formulary) were health visitors or district nurses and their ability to prescribe was envisaged to be of benefit in reducing GPs workload (Ryan-Woolley, McHugh & Luker, 2007). The introduction of extended nurse prescribing roles has in policy terms been rapid, but it has also had a mixed reception in the medical and nursing profession (Luker *et al.* 1997; Luker *et al.* 1998; Baird, 2001; Avery & Pringle, 2005). The nurse prescribers extended formulary (NPEF) was introduced in 2002 and was expanded in 2003 and 2005 (DoH, 2002). Following this the range of drugs which extended the formulary independent nurse prescribers could prescribe was further extended to include controlled drugs such as diamorphine, morphine and fentanyl (DoH, 2006b). From May 2006 DoH regulations extended formulary independent nurse prescribers (now called independent prescribers) to prescribe any licensed medicine for any medical condition within their competency. This came into force and the NPEF (nurse prescribing extended formulary) was discontinued (DoH, 2006a).

This study included a question regarding nurse prescribing to allow for investigation of this activity amongst community nurses caring for patients with chronic leg ulceration. The data showed that 34.2% ( $n=38$ ) of the nurses indicated they were nurse prescribers. However, only 12.6% ( $n=14$ ) stated they were prescribing analgesics sometimes. There could be various reasons for this. It might be that the nurses who consider themselves nurse prescribers in fact have supplementary prescribing rights not extended formulary-prescribing rights. Therefore, the nurses with supplementary prescribing rights were unable to prescribe analgesics. To have full prescribing rights the practitioner needs to have undergone the combined EFINP/SP (extended formulary independent nurse prescriber/supplementary prescribing) course. However, the literature identified certain issues preventing nurses from using their prescribing rights. Luker *et al.* (1998) found that nurses appeared to feel more comfortable when prescribing in areas where they were perceived as the "expert", for example district nurses and practice nurses had no concerns about prescribing items for wound care, but were more anxious about prescribing laxatives and analgesics. This is unfortunate as the findings from literature and study 1 (refer to Chapter 2, section 2.7.2.1 and 2.7.2.2; Chapter 3,

section 3.10.4) suggested that patients with chronic leg ulceration require adequate analgesics and possibly laxatives. Others have suggested that nurses do not prescribe because they do not have the confidence to do so, even following their EFINP/SP training (Luker *et al.* 1998; Baird, 2001). It has been suggested that this may be because they do not get the opportunity to consolidate their training. In a study undertaken by Ryan-Woolley, Hugh and Luker (2007) it was found that nurses trained as extended formulary independent prescribers did not prescribe. It was suggested by the authors that this was because they had not consolidated their acquired skills obtained from training. Previous research has also found that infrastructures and mentoring mechanisms need to be strengthened to support nurse prescribing (Luker *et al.* 1997; Humphries & Green, 2000; Sodha *et al.* 2002). Moreover, community nurses work predominantly in isolation. Otway (2002) found that nurses' experience a negative influence from working in isolation in practice, this impacted on nurses' confidence to prescribe. Another factor discussed in the literature was pharmacological knowledge amongst nurse prescribers. Sodha *et al.* (2002) found that prescribers actual medication knowledge was found to be inadequate using case scenarios. The authors concluded that nurse prescribers lacked a necessary degree of pharmacological knowledge. Others identified the inadequacy of nurses' knowledge base in pharmacology as a concern (Latter & Courtney, 2004). Furthermore, inadequate pain management for older people was evident in the literature; particularly in relation to inappropriate pharmacological treatment and lack of pain assessment (refer to Chapter 2, section 2.6). These reasons perhaps offer an explanation to the apparent lack of nurse prescribing amongst the nurses questioned for this survey.

#### **4.7.3.7 Non-pharmacological methods of pain management**

Non-pharmacological pain management methods have been shown to be effective. Research supports the effectiveness of behavioural strategies in the treatment of pain. For example, distraction (Cohen *et al.* 1999; Petrovic *et al.* 2000; Dahlquist *et al.* 2002) relaxation and imagery (Syrjala *et al.* 1995; Ball *et al.* 2003) and hypnosis (Hawkins, 2001). In addition, behavioural techniques used in conjunction with non-behavioural techniques have been found to be more effective than non-behavioural techniques alone for both acute (Kazak *et al.* 1996) or chronic pain (Morley, Eccleston & Williams, 1999). Moreover, non-pharmacological measures are easy to use and do not usually have any side effects. They can also be used in conjunction with drug therapies to maximise the patients pain relief (Matthews & Malcolm, 2007). The results of the

survey suggested that non-pharmacological methods were indicated as being utilised. Just over half of the nurses indicated they were recommending the use of non-pharmacological methods sometimes (53.2%,  $n=59$ ). Varied selections of methods indicated as being used by the nurses were given. Positioning was indicated as being used by 11.7% ( $n=13$ ) of the nurses, this is surprising as the literature suggests it was the only form of non-pharmacological management technique being utilized (Hyde *et al.* 1999; Ebbeskog & Ekman, 2001; Hareendran *et al.* 2005). However, the literature and results from study 1 (refer to Chapter 2, section 2.7.2.3 and Chapter 3, section 3.10.4.2) suggested that it was the patient who was initiating the positioning to reduce pain. This may offer an explanation to the results from this survey that demonstrated the nurses were not recommending the use of positioning frequently as a form of non-pharmacological pain management. The two most frequently mentioned forms of non-pharmacological techniques were distraction and relaxation (27%  $n=30$ , 26.1%  $n=29$  respectively). The leg ulcer literature did not suggest that distraction and relaxation were used as a form of non-pharmacological pain management in patients with chronic leg ulceration (refer to Chapter 2, section 2.7.2.3 and Chapter 3, section 3.10.4.2). There were some suggestions that distraction was used by participants from study 1 (refer to Chapter 3, section 3.10.4.2.2).

The nurses who indicated that they were recommending non-pharmacological pain management techniques were significantly more likely to have had formal pain management training. There was evidence in the literature that suggested nurses with a higher level of training have more knowledge and a better ability to manage pain using pharmacological and non-pharmacological techniques (Vortherms, Ryan & Ward, 1992; Clarke *et al.* 1996; McCaffery & Robinson, 2002).

A small number of nurses in this survey indicated they were using CAM as a non-pharmacological technique (9.9%,  $n=11$ ). The results from this survey suggested that a relatively small number of community nurses were using non-pharmacological pain management techniques. This was represented in the literature. The literature and the results from study 1 suggested that the patients initiate the non-pharmacological pain management activity. There was no report of patients receiving advice or training from their nurses to carry out non-pharmacological pain management techniques in the leg ulcer literature or in the results from study 1 (refer to Chapter 2, section 2.7.2.3 and Chapter 3, section 3.10.4.2).

#### 4.7.3.8 Management of pain for dressing changes

The most frequent technique to manage pain for dressing changes as indicated by the community nurses was gentle dressing technique. There was no discussion with regard to "gentle dressing technique" in the literature. Nor was there any discussion within the current leg ulcer management guidelines. This is curious, as it was the technique that a large majority of nurses' indicated they were using. Moreover, what is the alternative to "gentle dressing technique"? Surely this should be an expected strategy.

Provision of analgesics post-dressing was indicated as being given always by just 3% ( $n=3$ ) and 61.3% ( $n=68$ ) indicated they were giving analgesics post-dressing sometimes. Evidence of the use of analgesics post-dressing change was not evident in the literature, the majority of studies suggested use of analgesics but did not provide information on when and how these analgesics were used (refer to Chapter 2, section 2.7.2.1). The results from study 1 suggested that the nurses were advising patients to take analgesics once they had finished the dressing change (refer to Chapter 3, section 3.10.5.2.5). Interestingly the evidence of the recommendation of the use of pre-emptive analgesics was not evident either from the leg ulceration literature or from the results from study 1 (refer to Chapter 2, section 2.7.2.1 and Chapter 3, section 3.10.5.2). However, this study suggests that the use of pre-emptive analgesics was apparent. A significant number of the respondents indicated that they were using pre-emptive analgesia always (39%,  $n=43$ ) or sometimes (60.4%,  $n=67$ ). The use of pre-emptive analgesics would be appropriate and if used could be very beneficial to this patient group.

The concept of pre-emptive analgesia originates from experiences within surgery. The use of pre-emptive analgesia to reduce postoperative pain was founded on a series of successful animal studies that demonstrated central nervous system plasticity and sensitisation after nociception (Page, Blakely & Ben-Eliyahu, 2001; Ong *et al.* 2005). By decreasing the altered central sensory processing, pre-emptive analgesia is thought to consequently decrease the incidence of hyperalgesia and allodynia (Kissin, 2000). The administration of pre-emptive analgesia is good practice. In a review of the use of pre-emptive analgesia carried out by Ong *et al.* (2005) numerous studies were identified that demonstrate its efficacy.

The fact that the nurses from this survey indicated that they used pre-emptive analgesia was positive. However, the findings from this survey are in conflict with what the patients from study 1 reported. Participants in study 1 suggested they were

initiating pre-emptive analgesia and it was not something that they were advised to do by the nurses (refer to Chapter 3, section 3.10.4.1.5). There was also no evidence of the use of pre-emptive analgesia in the leg ulceration literature (refer to Chapter 2, section 2.7.2.1).

The literature has focused on the use of local anaesthetic for dressing changes (refer to Chapter 2, section 2.7.3.1). The results from this survey suggest that the use of local anaesthetic for procedural pain was not being used. It is not possible to determine if this was because nurses were not doing sharp or mechanical debridement or because they were not using pre-emptive pain management pre-debridement. Findings from study 1 suggest sharp or mechanical debridement was not a frequent occurrence as only two patients from study 1 suggested they may have had sharp or mechanical debridement (refer to Chapter 3, section 3.10.3.1.8). The clinical guidelines do suggest that the use of EMLA cream (a mix of 2.5% lidocaine and 2.5% prilocaine in an oil base) may be beneficial (RCN, 2006). However, a Cochrane review investigating the use of local anaesthetics for procedural pain carried out by Briggs and Nelson (2010), stated the main concern with using local anaesthetics appears to be the unknown potential effect on healing. Furthermore, if sharp or mechanical debridement's are not commonly carried out, studies investigating the use of LA for constant pain would be more appropriate. Particularly as studies using LA for the management of constant pain, associated with burns have demonstrated pain relief of long duration (Pal, Cortiella & Herndon, 1997).

#### **4.7.3.9 Measurement and assessment**

The key to effective pain management is a thorough and appropriate assessment (DoH, 2001). The nurses accurate assessment, prompt intervention, and evaluation of pain relief measures are necessary for positive patient outcomes (Ersek *et al.* 2003). The literature supports the recommendation that pain can only be assessed on an individual basis using self-report, careful pain histories and external indicators (McCaffery & Pasero, 1999; Brown, 2004).

Just under one half of the respondents stated they were assessing pain using verbal report and a pain score (46.8%,  $n=51$ ). Therefore, over one half of the respondents stated they were not measuring and assessing pain appropriately. The frequency of pain assessment was also inadequate for a significant number of respondents, 44.1% ( $n=49$ ) of respondents were not assessing pain on every visit. Interestingly nurses who measured pain using a verbal report and a pain score were more likely to also assess pain on every visit. However, on statistical analysis it was shown not to be significant.

Assessment of neuropathic pain using an appropriate scale such as the LANSS to identify neuropathic pain was not mentioned by any of the respondents. Therefore, it can be assumed that the nurses surveyed were not carrying out appropriate assessment to identify neuropathic pain as previously mentioned.

It is unfortunate that under half of the respondents indicated they were not carrying out appropriate pain assessment. Others have reported similar findings to suggest that pain assessment and documentation was not routinely carried out by community nurses (Walker *et al.* 1990; Roe *et al.* 1993; Hollinworth, 1995; Kammerlander & Eberlain, 2002; Moffatt, Franks & Hollinworth, 2002; Lorimer, Harrison & Graham, 2003; Breivik *et al.* 2006). The results of this survey suggest there was a disparity amongst the nurses working for the trust with regard to how and if they assess pain.

According to the literature there were varied reasons for inappropriate pain management and assessment. These included lack of knowledge (Lebovits, Florence & Bathina, 1997; Levin, Berry & Leiter, 1998; Ponte & Johnson-Tribino, 2005) and lack of any formal information and policies on pain control (Tornkvist, Gardulf & Strender, 1998; Pargeon & Hailey, 1999). It would have been advantageous to have included a question regarding the use of local pain management procedures and policy, absence of which has been shown to impact on nurses' assessment of pain activity. Inadequate pain management can be related to a number of factors, one of which is an absence of any formal pain management procedures (Pargeon & Hailey, 1999). Pargeon and Hailey (1999) in their systematic review suggested that local guidelines have improved appropriate pain management for cancer patients.

Furthermore, leg ulceration affects predominantly older people and this may provide some explanation to why the majority of the nurses indicated they were not assessing pain appropriately. Pain assessment in older people presents with a specific set of problems as discussed in the literature review (refer to Chapter 2, section 2.6). These factors are not entirely nurse led but rather are manifested by the older person. Older people are more stoical and may not report their pain (Yong, 2006) and older people demonstrate differences in how they report their pain (refer to Chapter 2, section 2.7.1). However, older people with pain associated with leg ulceration do report pain, there was evidence of this in the literature (refer to Chapter 2, section 2.4.1) and also from study 1 (refer to Chapter 3, section 3.10.5.2.1). Furthermore, the literature has demonstrated that use of pain assessment tools to assess for nociceptive pain and neuropathic pain have been validated for older people (Weiner, Peterson & Keefe, 1999a; Scherder & Bouma, 2000; Chibnall & Tait, 2001; Closs *et al.* 2004; Yucel,

2004). Nurses from this study indicated they wanted more pain management education. Pain management education specific to older adults should form part of that training. This is especially pertinent because the wound pain management guidelines focus on pain management of the wound but not on pain management for older people (EWMA, 2002; World Union of Wound Healing Society, 2004; Woo *et al.* 2008; Fogh *et al.* 2008).

#### **4.7.4 Nurses' attitudes in relation to providing pain management for this group.**

Healthcare professional attitudes have been shown to influence clinical practice (McCaffery & Ferrell, 1992; Clarke *et al.* 1996; Cohen *et al.* 1999). Therefore this section of the survey aimed to investigate the respondents' attitudes regarding pain management of chronic leg ulceration.

Nurses from this survey predominantly indicated that they thought healing was the primary goal for all patients regardless of recurrence rates and history (58.5%,  $n=65$ ). This is in line with the leg ulceration literature where the emphasis appeared to be on the healing and not on symptom management (refer to Chapter 2, section 2.5). Despite the majority of the nurses indicating that healing was the primary goal, a significant number disagreed (45%,  $n=50$ ). The older the nurse the more likely they were to indicate they thought healing was the primary goal. Sixty three percent of the nurses aged between 50-60 years indicated that healing was the primary goal compared with 16% ( $n=17$ ) of nurses aged between 20-29 years. However, because of multiple testing a Bonferroni correction was applied which determined that this difference was not statistically significant ( $p>0.005$ ). For older patients healing may not be possible (Phillips, 1999a) and recurrence is likely (refer to Chapter 2, section 2.3.3), therefore focus on healing may not always be appropriate for this group of patients.

Participants were also asked if they had referred patients with painful leg ulcers to a pain specialist, interestingly 42% ( $n=46$ ) said they had. There was no evidence in the leg ulcer literature with regard to patients being referred to a pain specialist. Moreover, findings from study 1 did not suggest that patients were referred to pain specialists. However, study 1 used qualitative methodology, therefore small numbers were recruited which may not have allowed for capture of this.

Participants were asked questions which investigated attitudes toward older people, pain and pain management. It is not just the attitudes and beliefs held by older people that create a barrier to adequate pain management, healthcare professionals have

been shown to hold attitudinal beliefs that impede effective pain management. Common misconceptions include pain is a normal part of ageing, perception of pain decreases with age and opiates are dangerous in older people (McCaffery & Pasero, 1996; AGS, 2002; Gagliese & Melzack, 2003; Macintyre, Upton & Ludbrook, 2003). The majority of respondents in this study did not agree that pain was a normal part of ageing (93.7%,  $n=104$ ). Moreover, a large majority indicated that patients with pain from leg ulceration had a right to expect pain relief (95.5%,  $n=106$ ). However, the finding that a small number of the nurses did not think that patients with leg ulceration pain have a right to expect pain relief is worrying. It is especially so, as the five respondents who indicated this were senior nurses. Despite the number being insignificant it could be proposed, that for the patient who is being cared for by a nurse who does not believe they have the right to expect adequate pain relief, it is possibly very significant.

With regard to being hesitant in giving opioids to older patients a significant majority stated they disagreed that they were hesitant to give opioids to older people, although 32.4% ( $n=26$ ) were unsure and 9.9% ( $n=11$ ) agreed that they were hesitant in giving opioids to older people. This is a common reason for inappropriate pain management for the older person (McCaffery & Pasero, 1996; Macintyre, Upton & Ludbrook, 2003). It was reassuring that this attitude did not exist amongst the majority of the nurses questioned (61.3%,  $n=68$ ).

A significant number of participants indicated that with repeated exposure to patients in pain they may become desensitised to the patients' pain (52.3%,  $n=58$ ). Others have reported that a consequence to constant exposure to pain nurses become less sensitive to pain (Grootenhuis *et al.* 1996). This maybe a coping mechanism as others have found that exposure to people in pain is likely to arouse emotional distress that may interfere with their ability to manage pain effectively (Brough, 1991). Davidson and Jackson (1985) concluded that for susceptible nurses, the long-term effects of exposure to pain might be similar to the delayed post-traumatic reaction found in war veterans. The authors concluded that these nurses might develop an increased fear of death and feelings of powerlessness. Nagy (1999) described a coping mechanism that some nurses develop when performing painful debridement and dressing changes with burns patients. The most common strategy that these nurses were found to be adopting was a strategy termed "distancing", in an attempt for the nurse to lessen the emotional impact. Nagy (1999) suggested that distancing provided a certain self-protective advantage as it enabled the nurses to ignore the pain that threatened to

overwhelm them emotionally. Therefore, the patient is not the only person to suffer from their pain; the impact on the nurses managing these patients and being exposed to their pain has a negative impact on them. Further, it has been shown that if nurses are instrumental in relieving pain, positive emotions such as feelings of competence and of being in control may result (Davidson & Jackson, 1985). Thus, effective pain management not only benefits the patient but may also have a positive benefit to the nurse caring for that patient.

#### **4.7.4.1 Educational needs and current level of confidence in providing pain management for this patient group.**

This survey found that only 35.1% ( $n=39$ ) of the nurses felt confident in managing pain for this patient group. Moreover, a large majority stated they would like more training (82%,  $n=91$ ). Interestingly nurses who had undergone some form of pain management training were not statistically more likely to be confident. This is in conflict with the literature that suggested nurses who had undergone some form of pain management training demonstrated improvement and increased confidence (Ferrell *et al.* 1993; Francke, Garssen & Abu-Saad, 1996; Lasch *et al.* 2000; Arber, 2001). It is difficult to surmise why this was the case. It could be that the nurses had attended pain management training but pain management of leg ulceration was not included. Furthermore, the fact that the nurses surveyed appeared to have limited understanding with regard to neuropathic pain suggests that the training they had received may have been less than adequate. It could be suggested that they were aware of neuropathic pain but did not have a clear understanding of how it manifests. This may create confusion and a lack of confidence when managing the patients' pain. Also there are particular issues regarding managing pain of older adults and these issues may not have been addressed within the pain management training. Particularly as the majority of the respondents who had attended pain management training had only attended an in house training day. Pain management is a complex and varied subject; perhaps one day of training does not adequately prepare the nurse for appropriate pain management practice. Furthermore, the guidelines regarding pain management of wounds do not include particular pain management advice relevant to older people (EWMA, 2002; World Union of Wound Healing, 2004; Woo *et al.* 2008; Fogh *et al.* 2008), this may be problematic considering the majority of patients with leg ulceration will be older.

#### 4.7.4.2 Nurses who used preconceived notions to decide pain management practices

This survey incorporated, with permission, the Clinical Decision Making Questionnaire (Brockopp *et al.* 2004). The aim of this questionnaire was to investigate if the nurses use factors (such as preconceived notions) other than reported pain to decide pain management practices. The literature has suggested that when individuals have preconceived ideas about particular patient groups, their decision making process is influenced by those ideas. Bodenhausen (2005) described stereotyping as a potentially important factor impacting on the decision making process. Under one half of the community nurses who responded to the questionnaire stated they would spend maximum time and energy on all conditions (40.5%,  $n=45$ ). Thus, suggesting that the majority of the community nurses were using factors other than perceived, reported pain to base their pain management decisions. Nurses with a higher level of training (degree or master's degree) were significantly more likely to manage pain with maximum time and energy on all the conditions ( $p<0.05$ ). However, when the Bonferroni correction was applied the finding was not significant ( $p>0.004$ ). It is not possible to determine if this was due to a type II error (Feise, 2002). Other studies have reported that nurses who have higher degrees are more able and competent at managing pain (Vorthern, Ryan & Ward, 1992; Clarke *et al.* 1996; McCaffery & Robinson, 2002).

Cancer pain attracted the highest number of nurses who would spend maximum time and energy to manage the related pain (93.7%,  $n=104$ ). Brockopp Ryan, and Warden's (2003), also demonstrated this finding. This may be explained by the fact that cancer pain has been given a high profile with organisations such as the World Health Organisation. The seriousness and indiscriminate nature of cancer may also explain why this is the case. Whereas, the two conditions (suicide attempt and substance abuse) that attracted the least number of nurses who would give maximum time and energy, could be described as self-inflicted. In Brockopp, Ryan and Warden's (2003) study using the Clinical Decision Making Questionnaire qualitative data was also obtained. The most intense responses were related to patients who had attempted suicide.

Comments included; *"It is difficult to provide good care for people who want to die when there are so many who are dying but want to live"* (Brockopp, Ryan & Warden, 2003, p.415).

The qualitative data suggested that if patients were seen as contributing to their condition, nurses may not respond to their pain as aggressively as when patients were perceived as not contributing to their pain and health state.

In conflict with the findings from Brockopp, Ryan and Warden's (2003) study, this survey had a higher number of nurses that would expend maximum time and energy on elderly patients. Seventy six percent ( $n=84$ ) of participants from this study would spend maximum time and energy on elderly people's pain compared to 47% of nurses from Brockopp, Ryan and Warden's (2003) study. This is encouraging, as it suggests the nurses surveyed are less likely to allow preconceived conceptions, to impact on their ability to manage older people's pain. The differences could be explained by the differences in the groups studied. This survey examined community nurses within the UK and Brockopp study examined nurses working in acute hospital settings in America. There are no other studies available using this questionnaire investigating nurses within the UK or nurses working in the community.

Chronic pain (25%,  $n=26$ ) and chronic wound pain (26%,  $n=28$ ) were found to have a significant number of nurses who use factors (such as preconceived notions) other than reported pain to decide pain management practices.

#### **4.7.5 Limitations of the study**

The response rate was low. However, the sample who formed the group studied, were a good representation of a community nurse team within the PCT (Appendix 12). As previously discussed response rates from healthcare professionals particularly community nurses is historically low. Response rates between 15%-37% have been demonstrated when the target audiences are community nurses (Hollinworth, 1995; Moffatt, Franks & Hollinworth, 2000; Kammerlander & Eberlain, 2002). Furthermore, a low response rate does not necessarily create bias as previously discussed (refer to Chapter 4, section 4.4). It is not possible to determine if the response rate from this survey created a bias. It is possible that nurses who were more interested in the topic of research and who were better educated were most likely to complete the questionnaire (Dillman & Frey, 1974; Cartwright, 1978; Clark & Rees, 1989). Therefore the study sample represented a self selection of community nurses.

However, the age and gender of nurses registered with the NMC at the time of data collection was compared with the respondents' age and gender, minimal differences were apparent (Appendix 13). Furthermore, job title distribution amongst the

respondents represented a typical community nurse team working in the PCT studied (Appendix 12).

Another study limitation was that this survey asked the nurses to provide a report of their activity. It did not measure their activity using observational or audit of activity methods, to collect data. Therefore, there may be a difference in what the respondents stated they were doing compared with what they were actually doing. Hollinworth (1995) demonstrated this in her study; nurses who had been interviewed stated they supported the use of pain assessment and measurement. However, when they were observed in practice they were not using appropriate pain assessment. Therefore, this survey demonstrated what the nurses either; thought they should be doing or what they would have liked to be doing rather than actual activity.

#### **4.7.6 Summary**

In summary the nurses demonstrated that they acknowledged the pain that patients with leg ulceration may have. However, there apparent lack of understanding with regard to the nature and the symptoms associated with neuropathic pain were confirmed. The data suggested that the nurses were aware of the possibility that compression may cause pain. However, they did not acknowledge that this maybe because of the neuropathic component. Rather, they suggested that pain caused by compression is caused by failure of the compression technique, either because it has been put on incorrectly or inappropriately. Whilst this may not be inaccurate, it is pertinent that the nurse is aware that neuropathic pain maybe associated with pain and compression. Without this knowledge and understanding their ability to manage this very distinct pain will be compromised. The data suggests that the nurses were using severity of pain and pain triggers, as a tool for diagnosis of further complications or deterioration of condition. The nurses were also using patient report of pain triggers and severity of pain, as an aid to diagnose aetiology of leg ulceration. Unfortunately the current practice guidelines support this. The community nurses are in a difficult situation as they are practising according to the guidelines and the leg ulcer literature, which appear to focus greatly on the healing. Thus, instead of encouraging effective pain management, the literature and the guidelines appear to encourage the use of patient pain report as an aid to diagnosis or to detect further complications.

Current pain management practices identified by this study suggest inadequate pain management practices. The nurses from the survey indicated they were recommending inadequate analgesics for this patient group. Management of pain

appeared to be lacking. Moreover, the nurses suggested pain was often used as an indicator to complications and aetiology of the ulcer. The most frequently identified methods of non-pharmacological pain management were distraction and relaxation. A large number of participants suggested they were using pre-emptive analgesia for procedural related pain, but this was in conflict with evidence from study one and evidence in the leg ulcer literature. The most frequently investigated method for procedural pain management in the literature was the use of local anaesthetic. However, this was not mentioned as a method of pain management being used by the nurses. This might be because the use of local anaesthetic is used for sharp or mechanical debridement pain and, it could be that the nurses were not carrying out these procedures.

Pain assessment for patients with pain associated with leg ulceration was reported as being inconsistent amongst the nurses surveyed. Assessment of neuropathic pain was not reported as something these nurses were implementing.

Attitudes of the nurses surveyed suggested that the focus remained on the healing and that patients were managed using an acute care model. Whereas, the literature and evidence from study 1 suggest that a more symptom management focus may be more appropriate in some cases. Common misconceptions associated with opioid use in older people are evident. However, it is encouraging that the study suggests that this group of nurses were not ageist, when it comes to attitudes with regard to older people's pain.

The nurses appeared to have an insight concerning their coping mechanisms, in that they acknowledged that they might become desensitised to patients' pain over time. Moreover, a significant number of the respondents use preconceived ideas, when managing pain of particular patient groups, including chronic wound and chronic pain.

The respondents indicated that they were aware they required more education in pain management and also appeared to have insight with regard to lacking in confidence when managing pain for this patient group.

## **Chapter 5**

### **Theoretical Discussion of Study 1 and Study 2, Combined with Conclusions and Recommendations.**

#### **5.1 Introduction**

Study 1 and study 2 were undertaken to improve our understanding of the nature of the pain associated with chronic leg ulceration and how the patients and the nurses were managing that pain. Study 1 aimed to answer the following questions;

- i. What is the nature of pain associated with chronic leg ulceration?
- ii. What are the outcomes for patients with pain associated with their chronic leg ulcers?
- iii. What are people with pain associated with leg ulcers doing to manage their pain?
- iv. What reasons are there for inappropriate pain management?

The findings from study 1 suggested that pain associated with leg ulceration could be chronic, with associated chronic pain sequelae. The most troublesome pain was the constant chronic pain. It is proposed that patients described being in constant chronic pain because they had not received adequate acute pain management on initial development of their leg ulcer and had not subsequently had their chronic nociceptive or neuropathic pain identified or managed appropriately. Patients from study 1 described chronic pain with associated negative consequences. Chronic pain became threatening and aversive; it impacted on the individuals' quality of life by reducing mobility and shrank the individuals' personal worlds. Pain as a system that protects, aids healing and acts to preserve life became pathological and developed a "life of its own" (Daudet, 2002).

Study 2 aimed to answer the following questions;

- iv. What reasons are there for inappropriate pain management?
- v. What do nurses looking after these patients understand about the pain?
- vi. What strategies do nurses use to manage their patients' pain?

vii. Do nurses have confidence in managing pain for this group of patients?

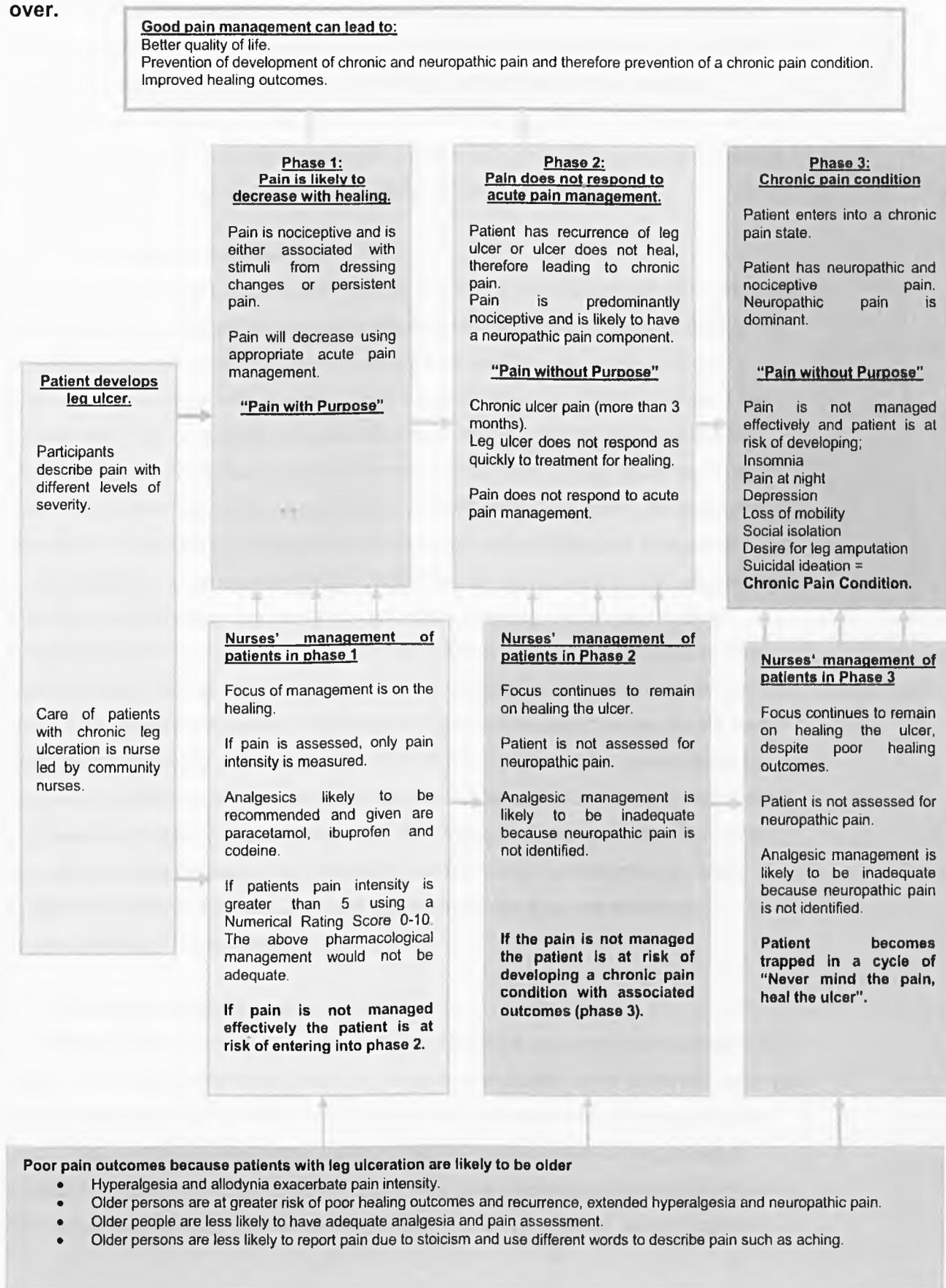
There was a lack of pain assessment and nurses from study 2 reported inappropriate pain assessment and did not report they assessed patients for neuropathic pain. Furthermore, the nurses from study 2 had limited understanding regarding neuropathic pain symptoms. Nurses from study 2 reported management that may have managed acute mild to moderate pain but did not report practices that would have managed chronic pain with neuropathic symptoms. The nurses also reported a focus on healing which participants from study 1 reported exacerbated their pain. The nurses from study 2 understood and acknowledged that patients with chronic leg ulcers may have pain. The nurses also reported that patients were at risk of chronic pain sequelae such as insomnia, depression and social isolation. The findings from study 2 suggested that the nurses looking after the patients did not understand the nature of the pain associated with chronic leg ulceration. The pain management the nurses described would have been suitable for patients who had acute nociceptive pain. However, the pain management requirements for patients with chronic neuropathic pain would not have been met because acute pain management would not address the neuropathic aspect of the pain. Furthermore, the majority of the nurses reported that they were not confident in managing pain for this patient group and would like pain management training.

The findings have been used to generate an integrated theory of how pain associated with leg ulceration is experienced and managed. Figure 8 presents a theoretical model developed from the research. It is proposed that patients entered the leg ulcer healing trajectory with acute nociceptive pain (phase 1). This pain subsided with healing and had predominantly nociceptive properties, in keeping with the acute pain model. However, if this acute pain was not managed effectively and they did not heal or had recurrence, the patient began to develop chronic pain with both nociceptive and neuropathic properties (phase 2). If this chronic pain was not managed patients went on to develop a chronic pain condition with associated negative outcomes (phase 3).

The nurses from study 2 described pain management practices that would be suitable for patients with acute pain. They did not describe suitable pain management for patients with chronic pain with associated neuropathic properties. Furthermore, participants from study 1 reported that the focus on healing the ulcer and the treatment used to promote healing exacerbated their pain.

This chapter will provide an overall theoretical discussion and conclusion of the two studies comprising this thesis, following the three phases presented in the model shown in figure 8. Recommendations for practice, further research, national guidelines and educational requirements are presented following the discussion.

**Figure 8: Theoretical model of the causes and outcomes of inadequate pain management associated with chronic leg ulceration in people 65 years and over.**



## **5.2 Phase 1**

It is proposed that on initial development of the leg ulcer patients enter into phase 1 (see Figure 8). The pain initially is nociceptive induced and can be described as pain with purpose. The purpose here is to alert the patient to their wound and skin injury and encourage the patient to attend to their injury which may include seeking healthcare assistance. It is possible that some patients may have neuropathic pain on development of their leg ulcer because of previous leg ulceration and development of neuropathic pain, in which case these patients would fit in phase 2.

### **5.2.1 Acute nociceptive pain**

Acute nociceptive pain has a function in that it serves to aid tissue repair by alerting the individual to the injury and encouraging attendance to the injury (Johnson, 2006). The associated inflammation also serves to protect the painful area. Acute pain has a trajectory that ensures with healing comes a reduction in pain. Whilst in phase 1 the patient may respond well to an acute care model where the focus is on healing the ulcer, with their healing the patient experiences a reduction in pain. Acute nociceptive pain management would be appropriate for patients whilst in phase 1. Acute pain will respond to an acute pain management model which would consist of analgesics such as paracetamol, codeine and NSAIDs. Depending on the intensity of the pain patients may also benefit from morphine. Some patients from study 1 described seeking healthcare assistance because of the pain sensations they were experiencing. They also described varying degrees of pain intensity at the point of the development of the ulcer. This was to be expected, since pain is a personal experience that results from both the invasiveness of the painful stimulus and how that stimulus is modulated by factors both external and internal to the individual (Stevens *et al.* 2003). If we consider the neuromatrix theory of pain (Melzack, 1999) it was likely that patients from study 1 described varying degrees of pain intensity. Furthermore, the existence of control systems in the brain that modulate pain experience have been confirmed by neuroscientists (Tracey & Mantyh, 2007).

### **5.2.2 Inadequate pain assessment**

To effectively manage pain, accurate pain assessment is required. The patients from study 1 did not describe having their pain assessed and there were disparities amongst the nurses from study 2, not all of them were routinely measuring and documenting pain. This is unfortunate as without appropriate pain assessment management is unlikely (Donaldson, 2009). Results from study 2 also suggested that the majority of the nurses were using preconceived thoughts and ideas to assess patients' pain and

did not use patient report of pain as the only indicator. Older people are at risk of poorly managed pain irrelevant of the cause of the pain for several reasons. This is partly because clinicians and many older people assume that ageing is associated with a reduction in the older person's ability to perceive pain (Harkins, Price & Martelli, 1986; Yong, 2006), despite evidence in the literature suggesting otherwise (refer to Chapter 2, section 2.6.1). Other factors that impact on poor pain management of older people are cognitive factors (refer to Chapter 2, 2.6.2). Older people may display attitudes and behaviours that are not conducive to effective pain management; these include stoical behaviour and older person's differences in describing their pain (refer to Chapter 2, section 2.6.2). Furthermore, older adults are perceived as not being able to provide pain report by healthcare professionals (Closs *et al.* 2002), despite evidence to the contrary (Weiner, Peterson & Keefe, 1999a; Scherder & Bouma, 2000; Chibnall & Tait, 2001; Closs *et al.* 2004).

### **5.2.3 Pain management**

The nurses in study 2 described using an acute pain model and participants from study 1 described being managed using an acute pain model. Patients in study 1 described being prescribed paracetamol and codeine. The literature regarding pharmacological management of pain associated with chronic leg ulceration reflects the findings from study 1 (refer to Chapter 2, section 2.7.2). The use of paracetamol and codeine for this patient group was reportedly recommended by the nurses from study 2. Furthermore, while National venous leg ulcer management guidelines recommend the use of paracetamol and codeine, they do not recommend the use of any other analgesics or adjuncts (NHS, 2010). This approach may be suitable initially for patients that have mild to moderate pain and as the patient's ulcer heals the pain decreases. However, patients that do not heal or who have a recurrence of their leg ulcer are at risk of developing chronic pain and this approach would not be adequate. Furthermore, patients that experience severe pain intensity are not likely to have their pain managed effectively with paracetamol and codeine alone.

Nurses from study 2 reported using non-pharmacological management to manage procedural related pain. This suggests that the nurses were using non-pharmacological methods as a way to manage the acute pain associated with dressing changes. It is understandable that the nurses reported using non-pharmacological techniques for procedural pain. Their focus was on the healing; therefore when they were performing tasks to encourage healing, they also used techniques to promote comfort. This was undertaken to encourage patient compliance and comfort during the procedure. The

nurses managed the pain that they witnessed, using pre-conceived ideas and patient behaviour to assess the individuals' pain. This would fit with normal pain physiology; stimulus to an already inflamed area is likely to cause an increase to the nociceptive pain experience. However, once that stimulus is removed the pain is likely to decrease. Therefore, the focus of pain management during dressing changes would be appropriate when managing a wound that has nociceptive acute pain.

Patients that have nociceptive pain of mild to moderate severity may respond well to the management described by the nurses from study 2. However, if the patients' pain is more severe or they experience an exacerbation of pain associated with leg ulcer treatments, they are at risk of developing chronic pain. Patients who have severe pain and patients, who experience exacerbation of pain because of treatments to heal their leg ulcer, require appropriate pain assessment and management. This would not only reduce their suffering but may also reduce their risk of developing neuropathic pain. There was evidence to suggest that appropriately managed acute pain can prevent central sensitisation, preventing development of neuropathic pain (Wu, Marsh & Dworkin, 2000). Bonezzi and Demartini (1999) suggested that there is a possible window of opportunity for preventing central sensitisation early in the course of shingles. Thus, it may be possible to prevent patients with pain associated with chronic leg ulceration from developing neuropathic pain. It is proposed that if the participants of the study whilst in phase 1 had received adequate pain assessment and therefore management, central sensitisation may have been prevented. This may have prevented them from developing neuropathic pain. Unfortunately participants from study 1 described receiving inadequate pain management which may have caused them to develop chronic neuropathic pain.

#### **5.2.4 Focus on healing**

The focus on healing for patients whilst in phase 1 is not inappropriate because with healing may come a reduction in pain. Unfortunately leg ulcer treatments have been shown to cause further pain, either pain associated with compression dressings or procedural pain. The focus of care in both studies appeared to be on healing the ulcer. This may have been appropriate if the occurrence of healing was likely. With healing of an acute wound with associated acute pain, pain will decrease. The wound and pain follow a normal trajectory, whereby the pain decreases and that decrease also alerts the patient to healing and "getting better". However, for some patients healing can take weeks or months and recurrence is likely. Whilst in phase 1 (see Figure 8) the patient may be at risk of entering into phase 2 and then 3 if they do not receive

appropriate pain assessment and management. Furthermore, the focus on the healing in some cases exacerbates their pain, because the treatments used to promote healing can cause pain.

Patients with pain associated with leg ulceration may fit into phase 1 initially, with healing also comes a reduction in pain. However, some patients do not heal and are at risk of developing chronic pain. Without a more focused approach to the assessment of pain associated with chronic leg ulceration, nurses may not understand the true nature of the individuals' pain. Some patients will have their pain managed using paracetamol and codeine if they have mild to moderate nociceptive pain. Moreover, if some patients responded to the acute care model the nurses may continue to use an acute pain management model for all patients.

### **5.3 Phase 2**

Phase 2 is characterized by patients who start to develop chronic pain, either because they do not have their acute nociceptive pain managed or because they do not heal or have recurrence (see Figure 8). Patients in phase 2 are at risk of developing neuropathic pain because of the associated central sensitization associated with prolonged inflammation (Treede *et al.* 2004).

#### **5.3.1 Poor healing outcomes and recurrence.**

Older patients with leg ulceration are at greater risk of chronic pain. The older the patient the greater the likelihood of failed healing and recurrence of the ulcer (refer to Chapter 2, section 2.3.3). Recurrence and poor healing outcomes associated with older people heighten the risk of the individual developing chronic pain. This puts the older patient at greater risk of entering into phase 2 where they develop chronic pain with associated neuropathic signs and symptoms (see Figure 8). Older patients are likely to receive inadequate pain management, and are at risk of complications such as infection, or the presence of extended peripheral activity associated with inflammatory processes, and the length of time the ulcer can take to heal or the ulcer not healing. These processes put the patient at risk of central sensitisation; this may be triggered by primary nociceptive stimulation or by on going peripheral activity or both (Treede *et al.* 2004).

#### **5.3.2 Development of chronic pain**

If a state of peripheral activity associated with inflammatory processes persists patients are at greater risk of developing neuropathic pain. It is becoming clearer that unrelieved acute post-traumatic pain or postoperative pain are risk factors in the

development of chronic pain (Shipton & Tait, 2005). It has been demonstrated that patients who do not receive adequate analgesics post operatively are at risk of developing a chronic pain syndrome (Hayes & Molloy, 1997; Brown, 2004). This is also the case with medical conditions such as shingles, where significant percentages (20%) go onto develop post herpetic neuralgia (Bowsher, 1991). Treede *et al.* (2004) state that central sensitisation may be triggered by primary nociceptive stimulation or by on going peripheral ectopic activity or both. Study 1 participants reported having inadequate pain management, which made it more likely that they developed chronic pain with neuropathic signs and symptoms. The emphasis for leg ulcer management appeared to be on healing the ulcer, as described by the participants in study 1. This is particularly relevant to the pain experience that these patients had because the treatments to heal the ulcer were reported as causing further pain. The focus on the healing exacerbated the pain because of the treatments but also because the nurses focused on what they knew. They appeared to focus on the healing because this is what they were expected to do; the leg ulcer management guidelines promote a focus on healing (RCN, 2006; NHS, 2010). The community nurses are rightly perceived as being experts on wound management but the focus on the healing in some cases caused further pain.

For patients who have a chronic leg ulcer and who do not heal or have recurrence it is possible that they may develop chronic pain with associated neuropathic properties. The term "pain without purpose" provides a good description of chronic neuropathic pain because chronic neuropathic pain often serves no purpose and the nociceptive system itself has become dysfunctional (Johnson, 2006).

This treatment related pain and focus on healing puts the patient at greater risk of developing chronic pain. This is unique for patients with chronic leg ulceration because other conditions that have a risk of becoming a chronic pain condition, emphasis of management is on managing the pain to prevent this occurrence. This is especially apparent with shingles and the prevention of post herpetic neuralgia (Bonezzi & Demartini, 1999) and with the management of pain associated with rheumatoid arthritis (O'Dell, 2004).

### **5.3.3 Inadequate pain assessment**

Once patients enter into phase 2 (see Figure 8) they require assessment of neuropathic pain, but patients from study 1 and the nurses from study 2 did not indicate that any assessment for neuropathic pain was being carried out. The nurses suggested they were aware of neuropathic pain but they did not mention they were using any form of neuropathic pain assessment, despite the availability of simple and

easy to use diagnostic tools such as the S-LANSS (Bennett, 2005). There was a disparity regarding pain assessment activity amongst the group of nurses and this could be due to a lack of any formal information or policies on pain control (Tonkvisr, Gardulf & Strender, 1998; Pargeon & Hailey, 1999). Pargeon and Hailey (1999) carried out a systematic review to determine what the barriers to effective pain management were. A lack of pain management guidelines and policies was shown to be a barrier to healthcare professionals in providing effective chronic pain management. Moreover, the National guidelines for leg ulcer management do not promote the management of neuropathic pain and the focus of treatment remains on the healing of the leg ulcer (RCN, 2006; NHS, 2010). Furthermore, the guidelines that promote pain management of wounds focus on pain management of the wound and do not discuss the specific pain management requirements of older adults (EWMA, 2002; World Union of Wound Healing, 2004; Woo *et al.* 2008; Fogh *et al.* 2008). Results from study 2 suggested that the nurses were using an acute care model without appropriate assessment for neuropathic pain. Therefore, without assessment of neuropathic pain patients are not likely to have their neuropathic pain diagnosed. If the neuropathic nature of the pain is not identified the patient will not receive appropriate management for neuropathic pain. Therefore, patients who develop chronic pain and enter into phase 2 do not get their pain successfully managed.

If the nurses of patients in phase 2 diagnosed the true nature of the pain it could be proposed that these patients would then not develop chronic pain sequelae. Participants in study 1 did not mention they had neuropathic pain despite describing symptoms associated with neuropathic pain. The description of pain and its outcomes from patients in study 1 suggested that their pain had not been managed effectively.

#### **5.3.4 Pharmacological pain management**

As discussed previously paracetamol and codeine are appropriate for nociceptive pain that is either mild or moderate. However, for more severe pain a stronger opioid and multi modal approach may be required. This may be problematic because of the associated inadequacies regarding pharmacological management of pain in older people which were evident in the literature (refer to Chapter 2, section 2.6.3). These include problems and fears about opioid use in older adults which were evident from patients in study one (refer to Chapter 3, section 3.10.4.1.6). This is further compounded because older people have attitudes and fears associated with analgesic use which were evident in the literature (refer to Chapter 2, section 2.7.2.1) and also from participants from study 1 (refer to Chapter 3, section 3.10.4.1.2). Problems with pharmacological pain management are relevant, particularly with regard to

polypharmacy and associated adverse reactions (refer to Chapter 2, section 2.6.3). Participants from study 1 described concerns they had with polypharmacy and this may have further added to their poor pain management (refer to Chapter 3, section 3.10.4.1.2). Additionally, some nurses from study 2 indicated they were either unsure or hesitant in giving opioids to older people.

Thirty-four percent of the respondents from study 2 stated they were qualified nurse prescribers, but only 12.6% stated they were actually prescribing analgesics. As discussed in Chapter 4, section 4.6.3.6 there may be several reasons for this, particularly regarding the literature which suggests that nurses do not have the confidence to prescribe analgesics. Furthermore, Luker *et al.* (1998) found that nurses were more likely to prescribe pharmacology in their area of expertise. Nurses working in the community are rightly perceived as wound experts but they are not necessarily pain experts. The lack of pain management training and the desire for further training was apparent from nurses in study 2.

Participants from study 1 did not discuss the use of drugs to manage neuropathic pain. The nurses from study 2 suggested they were recommending these drugs to their patients. However, the drug they indicated they were most frequently recommending was amitriptylene. Tricyclic analgesics are not recommended for older adults because of adverse events (Dworkin *et al.* 2007). There appeared to be a gap in the nurses' knowledge with regard to appropriate pain management, especially with regard to neuropathic pain. Nurses from study 2 also reported that they did not generally prescribe analgesics even if they were qualified to do so. Luker *et al.* (1998) reported that community nurses were anxious about prescribing analgesics, this is further compounded because community nurses work in isolation (Otway, 2002). Ryan-Woolley *et al.* (2007) suggested that community nurses are given guidance and mentorship during their nurse prescribing course by GPs, but they do not consolidate this training, possibly because mentoring mechanisms are not in place (Sodha *et al.* 2002). The majority of the care the patient receives for their leg ulcer management is undertaken by the community nurse in isolation. Community nurses do not appear to possess the expertise or confidence in managing complex pain.

The findings from study 1 and study 2 demonstrated that pharmacological pain management being received or offered to this patient group was inadequate. The nurses from study 2 suggested they were recommending medication for neuropathic pain. However, without appropriate assessment of neuropathic pain these drugs may not be administered.

### 5.3.5 Focus on healing

Whilst the focus of treatment remains on the healing of the ulcer the pain aspect may not be given enough attention. The management of leg ulceration appears to be entrenched within a culture that focuses predominantly on healing the ulcer. The guidelines promote that culture which results in a ritual of caring for the leg and preserving the leg at any cost. With other chronic pain conditions such as back pain and post herpetic neuralgia there is not a visible component; improvement is indicated by patient report. The results from study 2 suggested that the nurses used pain as an aid for diagnosing aetiology of leg ulcer or deterioration of the leg ulcer, providing further evidence of a focus on healing. Participants in study 1 suggested that the nurses viewed their pain as a good sign as it indicated healing and sensation. A significant number of community nurses from study 2 used report of pain triggers as an aid in diagnosing type of leg ulcer. The current leg ulcer management guidelines encourage clinicians to use pain report as a tool for diagnosis of type of leg ulcer. The RCN (1998, 2006) clinical practice guidelines suggest that rest pain is associated with arterial ulcers. The Scottish guidelines (SIGN, 1998) correctly comment that leg ulcers are painful. However, they then go on to say, "particularly if they have an arterial component". They continue to suggest that venous leg ulceration may have pain, but pain is a particular feature of arterial ulceration. It is reported that patients with arterial ulcers are more likely to have an increase in pain when their legs are elevated or after exertion (RCN, 1998; SIGN, 1998; Phillips, 2004; RCN, 2006). Moreover, it is suggested that only severe arterial disease will cause pain at rest (Phillips, 2004). The literature and current practice guidelines suggest that patients with venous ulcers are more likely to have pain with exercise and relief of pain can be gained by elevating their legs (NHS, 2010; SIGN, 1998; Phillips, 2004; RCN, 2006). This perhaps offers an explanation as to why the nurses use severity of pain and pain triggers as a tool to diagnose aetiology of leg ulcer. This is unfortunate as there was evidence in the literature to suggest that severity of pain is not directly linked to aetiology of leg ulcer (refer to Chapter 2, section 2.4). However, the leg ulcer literature encourages the use of pain as an indicator to infection and sensation or arterial involvement. The RCN Clinical guidelines (1998, 2006) and the Scottish intercollegiate guidelines network (1998) suggest that infection can be detected by an increase in pain severity. If the National guidelines on management of leg ulceration promote use of pain as an indicator to sensation or infection, it is to be expected that the community nurses will use pain as an indicator to sensation or infection. Instead of the nurses responding to pain report with appropriate pain management they reported that they used pain type and report to further diagnose problems with the ulcer. Nurses from study 2 suggested

they were using report of increases in pain or a change in pain as a diagnostic tool to establish leg ulcer aetiology or a change in the ulcer. If the guidelines suggest that type of pain and pain intensity can be used as an aid to diagnose aetiology or deterioration in the leg ulcer this may deter the nurses from managing the patients' pain. The majority acknowledged that pain from compression was not caused by a neuropathic element but was a consequence of the compression being applied incorrectly or inappropriately. The guidelines understandably promote the use of compression to heal ulcers with venous aetiology. Patients in study 1 reported that the compression used to heal their ulcers caused a significant amount of pain. Participants from study 1 described at times, non-compliance with compression because of associated pain. In a systematic review carried out by Van Hecke, Grypdonck, and Defloor (2009) pain and discomfort was reported as being a main cause for non-adherence to compression. Others have also reported that patients take off their bandages to reduce discomfort (Herber, Shnepp & Rieger, 2007). The nurses in study 2 acknowledged that compression might cause pain. However, they also reported that this was because the compression had been either inappropriately applied or had been applied to a patient with ulcers caused by arterial aetiology. The nurses did not demonstrate that they understood the link between neuropathic symptoms and pain associated with compression. Only 3% ( $n=3$ ) indicated that compression pain may be caused by an increased tenderness to the nerves. This is particularly relevant with the older age group; older people are more likely to have extended hyperalgesia (Gibson & Farrell, 2004). This may lead to increases in sensitivity which would not be compatible with recovery and the reduction of inflammation. Allodynia and hyperalgesia are consequences of neuropathic pain the presence of which are used to diagnose neuropathic pain (refer to Chapter 2, section 2.4.3). Therefore, applying a heavy tight bandage to that area is likely to cause a significant amount of pain. If patients in phase 2 were diagnosed with neuropathic pain and had their pain managed using a chronic pain management model they may be able to tolerate compression. As previously discussed, pain and discomfort has been identified as a main factor associated with non-compliance to treatment (Van Hecke, Grypdonck & Defloor, 2009). The guidelines suggest that pain caused by compression maybe due to inappropriate application. Moreover, the guidelines suggest that pain may reduce with compression. There appears to be a conflict with what the patients report and what the guidelines promote. The guidelines focus predominantly on the healing; promoting an acute care model that does not consider chronic pain and its management. The focus on the healing is understandable as a significant number of patients do heal. However, there are a significant number of patients who do not heal or after healing have a recurrence of

their leg ulcer. All the participants of study 1 had suffered with chronic leg ulceration for months and sometimes years.

As previously mentioned, the focus on healing may be appropriate for patients who are in phase 1. However, patients that do not heal or have recurrence may develop chronic pain and this would require a chronic pain management model (phase 2). Patients with chronic pain require chronic pain management that includes a more thorough assessment including assessment of neuropathic pain. The nurses focus on an acute pain management model which includes a simple assessment of pain intensity but does not consider more complex pain which requires the use of assessment instruments such as the MPQ, or the S-LANSS, which assess the quality of the pain. Patients who develop chronic pain and enter into phase 2 do not get their pain managed. They are then at risk of developing insomnia, depression, loss of mobility, pain at night, social isolation, suicidal ideation and desire for amputation (phase 3) (See Figure 8). Perhaps if the nurses of patients in phase 2 assessed the nociceptive and neuropathic components of the pain it may be that these could be treated and patients would then not develop chronic pain sequelae.

#### **5.4 Phase 3**

Participants from study 1 described chronic pain with associated chronic pain sequelae (see Figure 8). Their pain was not only dysfunctional and served no purpose; it had also led to unfortunate chronic pain outcomes.

##### **5.4.1 The chronic pain condition**

Older patients with leg ulceration are at greater risk of chronic pain, the older the patient the greater the likelihood of failed healing and recurrence (refer to Chapter 2, section 2.3.3). Participants from study 1 described pain that was chronic and used word descriptors that suggested they had neuropathic pain; they also described episodes of chronic pain sequelae such as depression, insomnia and suicidal ideation. The patients from study 1 desired to be pain-free. Freedom from pain would give them a better quality of life and would free them from their suffering, which, they described as endless and persistent. The nurses in study 2 did acknowledge that patients might be at risk of depression, insomnia, loss of mobility, pain at night, and social isolation. However, they did not report they were undertaking neuropathic pain assessment, which may suggest that the nurses were not associating these sequelae with chronic neuropathic pain. Furthermore, the number of nurses who thought suicidal ideation and desire for leg amputation may be a risk for patients with chronic leg ulceration was

significantly less. This may be in part due to the lack of discussion of suicidal ideation and desire for leg amputation in the available literature. Much of leg ulcer management focuses on preserving the limb (Phillips, 2004; RCN, 2006; NHS, 2010). Thus, the patients' desire for a leg amputation was in contrast to the leg ulcer management that the nurses focused on. There was a disparity with what the patients desired compared with what the nurses aims of management were. The nurses' focus remained on the healing of the ulcer; their management focused on healing the leg with the intention of reducing suffering for the patient.

The leg ulcer guidelines appear to underestimate the severity of the pain especially with regard to pain caused by compression and venous leg ulcer pain. Thus, adding further to the confusion that nurses and patients appear to have with regard to the pain associated with chronic leg ulceration. The patients from study 1 accepted that their leg ulcer might not heal. They reported a desire to be free from the leg ulcer pain and some desired leg amputation to give them that release.

Some patients in study 1 also described suicidal ideation and at times when their pain was so severe and unrelenting they desired death. Suicidal ideation is a risk associated with other chronic pain conditions. Therefore it was to be expected that some patients reported suicidal ideation.

Unfortunately it is not acknowledged or recognised in the leg ulcer management guidelines that patients with leg ulceration are at risk of developing chronic neuropathic pain (Phillips, 2004; RCN, 2006; NHS, 2010). Nor is it mentioned that patients with newly diagnosed leg ulcers are likely to have acute nociceptive pain and if that pain is not managed the patient is at risk of developing a chronic pain condition. Furthermore, the pain management guidelines for wound pain (EWMA, 2002; World Union of Wound Healing Society, 2004; Woo *et al.* 2008; Fogh *et al.* 2008) do not include recommendations regarding specific management for older adults, despite older adults being most at risk of chronic wounds. The problem of pain associated with older people and leg ulceration does not appear to be apparent within the pain management world. The majority of papers discussing the problem of pain associated with leg ulceration are published within wound journals and nursing journals, as demonstrated in the referencing of this thesis. Furthermore, as discussed in Chapter 2, section 2.7.3.4 there appears to be little or no discussion around pain associated with leg ulceration in the pain management journals.

#### **5.4.2 How this pain compares to other chronic pain conditions; similarities and differences.**

The chronic pain associated with leg ulceration does not appear to have the same focus and drive as other chronic pain syndromes, such as postherpetic neuralgia, RA and back pain (Bonezzi & Demartini, 1999; Samanta & Beardsley, 1999; Wu, Marsh & Dworkin, 2000). The focus of clinical studies investigating pain management has been on procedural pain (refer to Chapter 2, section 2.7.3) rather than managing the chronic pain condition that patients from study 1 and other studies have described. Perhaps this can be explained because leg ulceration has a visible component, namely the ulcer, which may change with treatment and display visible evidence of healing. Participants in study 1 described at times, visible evidence that the ulcer was "getting better". It was difficult perhaps for the nurses to focus on the pain as a separate entity with its own unfortunate outcomes, when they could see an improvement in the ulcer. Other conditions such as back pain and post herpetic neuralgia do not have a visible component. RA does have a visible component associated with changes in joints and inflammation. However, the treatment associated with RA which influences the visible aspect also reduces the pain, as the treatments aim is to reduce the inflammatory processes. These conditions also have much more focus on pain management with the aim of preventing chronic pain syndromes (Wu, Marsh & Dworkin, 2000; Samanta & Beardsley, 1999). For these chronic pain conditions it is acknowledged and accepted that there is no cure and therefore management focuses on symptom management. For patients with leg ulceration treatment is around curing the ulcer and this creates a focus on treatment to enable the healing which creates an illusion of cure. This is because many of these patients, particularly older patients, either do not heal or have frequent recurrence.

Problems associated with inadequate pain management apply to management of pain for older people irrelevant of the cause of the pain. However, this may be even more so for patients with pain associated with leg ulceration, because of the focus on healing and, because the pain does not appear to be acknowledged as a chronic pain problem with associated sequelae. Although the patients from study 1 reported severe pain caused by compression they were encouraged to persevere. This finding is also evident in other qualitative studies investigating the experience of living with leg ulceration (refer to Chapter 2, section 2.5.3). Furthermore, the nurses from study 2 reported that the majority of them perceived healing as the most important outcome. The management of leg ulceration appears to be entrenched within a culture that focuses entirely on healing the ulcer. The guidelines promote that culture which results

in a ritual of caring for the leg and preserving the leg at any cost. With other chronic pain conditions such as back pain and post herpetic neuralgia there is not a visible component; improvement is indicated by patient report. The visible nature of the leg ulcer is perhaps promoting the focus on the observable healing of the leg ulcer. It may also be ensuring that patients remain within an acute care model that ensures all the focus remains on healing, regardless of patient outcome.

Once in phase 3 ulcer type or size may not necessarily impact on pain experience. This was reported by participants in study one who described pain intensity that was not necessarily related to the state of their leg ulcer. The nurses promoted the use of compression to the patients and encouraged the patients to tolerate it, despite the pain, in the belief that it would cure the ulcer. Patients from study 1 described being encouraged to focus on the healing despite continuing pain. Some patients described tolerating painful procedures in the belief that these procedures would encourage healing. However, their pain continued and so did their leg ulceration, which caused them chronic pain with dismal outcomes. From the participant report the picture that was given was of some patients being trapped in a cycle of healing and pain. There are clear similarities with the outcomes for these patients compared with outcomes for patients who have other chronic pain conditions (refer to Chapter 2, section 3.10.3). The focus remains on the healing and the patient remains in a cycle of "Never mind the pain, heal the ulcer".

This study did not aim to compare the pain management of chronic pain associated with leg ulceration compared with the success of managing pain in older people with other chronic pain conditions. Therefore, it is not possible to state that the pain management of other chronic pain conditions is better than management of pain associated with leg ulceration in older people. However it can be surmised that the pain associated with leg ulceration is least likely to be managed because of the treatment which has been shown to exacerbate the pain, the focus on healing rather than symptom management, and because the pain associated with leg ulceration is not managed using a chronic pain management approach. For other chronic pain conditions the management and focus is on symptom management and, treatments to manage the conditions do not cause further pain.

#### **5.4.3 Nurses moral distress**

The nurses worked according to the leg ulcer management guidelines and appeared to be entrenched in a culture that has always promoted the ideal outcome as being "a

healed ulcer". To change this culture can be considered as an extremely complex task, especially when the guidelines continue to drive that culture. Therefore, we can hypothesize that the nurses are also trapped in a cycle of healing the ulcer despite the pain. They are unable to remove their patients from the acute care model, as they work according to the current guidelines and are not given permission to work outside of the guidelines. This is relevant to the wellbeing of the nurses who may experience negative emotions if they are caring for patients with unresolved pain.

Evidence suggests that continually witnessing the suffering of others results in nurses distancing themselves from patients and contributes to a feeling of moral distress (Nagy, 1999). The concept of moral distress was developed by Jameton (1984). It is a term which defines the painful feelings and the psychological disequilibrium that occurs when nurses are prevented from doing the morally right thing, or required to do the morally wrong thing. Berlinger and Borneman (2007) in their discussion of moral distress within the context of pain management suggested that moral distress of a professional was triggered by observing situations in which there appeared to be a barrier that prevented patients from receiving adequate pain management. Davidson and Jackson (1985) concluded that nurses who were frequently exposed to patients displaying pain behaviour developed an increased fear of death and feelings of powerlessness. Nagy (1999) described a coping mechanism that some nurses develop when performing painful procedures. Nagy reported that the most common strategy that nurses were found to be adopting was a strategy termed "distancing", in an attempt for the nurse to lessen the emotional impact. Others have also reported that nurses distance themselves from a patients' pain and become less sensitive to the patients' pain behaviour over time (Grootenhuis *et al.* 1996). A significant number of nurses from study 2 reported they became desensitized to the patients' pain and this perhaps was a way of them protecting themselves from the emotional impact. Effective pain management would not only benefit the patient but may also have a positive benefit to the nurse caring for the patient. It has been shown that if nurses are instrumental in relieving pain, positive emotions such as feelings of competence and of being in control may result (Davidson & Jackson, 1985).

For those patients who are at risk of poor healing outcomes and recurrence it may be appropriate to care for them using a chronic disease management model that would allow focus on symptom management, rather than cure. Therefore, allowing the nurses to achieve realistic outcomes of care and giving these patients a better quality of life.

### **5.5 Limitations of the Research**

There are certain factors that may have affected the credibility of the theory developed from the studies and further research is required to confirm the findings from both studies.

All the participants from study 1 described chronic pain; this was probably because the community nurses were asked to invite participants who had painful leg ulcers.

Therefore, it may be possible that patients who had well controlled pain were not invited to participate. Furthermore, all the participants had their leg ulcers for many months and sometimes years. This may have created a misrepresentation of leg ulcer pain, pain management and its outcomes. However, it has been acknowledged that a large number of patients with leg ulcers may heal and may not develop a chronic pain complaint. The nurses were responsible for identifying and inviting patients to participate in the study, it is not possible to determine if all patients that may have been suitable for the study were invited. However, due to ethics constraints patients had to be invited by the nurses and the researcher was not able to access patients with leg ulceration without the assistance of the nurses. Furthermore, all patients were Caucasian likely due to inclusion criteria requiring participants to speak English. Therefore, the theory developed within this thesis provides an explanation to how and why some patients with chronic leg ulceration develop a chronic pain complaint.

Both studies used methodology that collected data regarding what the participants and nurses reported, and did not collect data from observation of practice or data from documentation of patient care. Study 1 findings were based on the account of painful leg ulceration according to the patients. The information and description of the pain and its experience from development of the ulcer to where the patient was at time of interview, relied on the memory of the experience as described by the patient. Therefore what the participants described may not have been an accurate reflection of events. However, this was a qualitative study which aimed to develop theory grounded in the persons' description of their experiences. Study 2 findings were based on the nurses' account of what they reported they did or perhaps what they thought they should do, or would like to do. The study did not use methods that allowed for capture of actual practice.

Therefore, both studies were a reflection of the patients and nurses' perceptions regarding pain and leg ulceration. This is acknowledged by the researcher and further testing of actual practice and pain experience would be required to further confirm the theory developed from this research.

Study 2 had a low response rate as discussed in the results section of study 2 (section 4.4). It is not possible to determine if this created a response bias, however it is possible that nurses who were more interested in the topic of research and who were better educated were most likely to complete the questionnaire (Dillman & Frey, 1974; Cartwright, 1978; Clark & Rees, 1989). Therefore the study cohort represented a self-selection of community nurses. This is acknowledged by the researcher however, the response rate this study achieved was greater or similar compared with other published studies that used postal questionnaires with community nurses (see section 4.4).

The theoretical model developed from the research is related to older people with chronic leg ulceration. It is possible that the focus on healing may also cause younger adults with chronic leg ulceration to develop a chronic pain condition. To determine this further research with a younger cohort would be required. However, it is likely that older adults are at greater risk because of the known poor pain management practices associated with older people and the problems associated with poor healing outcomes for older people. Whilst the theoretical model developed may be applicable to older adults with other chronic wounds and associated pain such as pressure ulcers and post-surgical wounds, further testing would be required to determine this.

## **5.6 Conclusion**

Both studies were undertaken to understand the nature of the pain associated with chronic leg ulceration and how the patients and the nurses were managing that pain. The findings suggested that for some patients the pain associated with chronic leg ulceration had similar sequelae to other chronic pain conditions, such as depression, insomnia and suicidal ideation. From the participant report the picture that was given was one of some patients being trapped in a cycle of healing and pain. There are clear similarities with the outcomes for these participants compared with outcomes for patients who have chronic pain.

The neuropathic pain element did not appear to be understood by the patients, and only superficially by the nurses looking after them. Nurses from the survey indicated that they had a poor understanding of the effects of neuropathic pain. Pain was reported as not being assessed and measured appropriately by the majority of the nurses. There was no mention of the use of any neuropathic pain measurement tool such as the S-LANSS. Moreover, the nurses appeared to be using type and severity of

pain as an indicator for leg ulcer type and deterioration. The treatment patients were receiving to heal the ulcer in some cases was exacerbating their pain situation. The pain for patients in phase 2 and 3 may have nociceptive properties as well as neuropathic properties. These patients probably do not have good pain management in part because of the lack of recognition of the neuropathic pain and because they are older. Without appropriate pain management for chronic pain, patients are likely to develop chronic pain sequelae and become fixed in phase 3.

The leg ulcer guidelines appear to underestimate the severity of the pain especially with regard to pain caused by compression and venous leg ulcer pain. Thus, adding further to the confusion that nurses and patients appear to have with regard to the pain associated with chronic leg ulceration. Moreover the wound pain guidelines do not factor in problems associated with pain management associated with older adults.

Patients reported they were not having adequate pain management. Moreover, pharmacological and non-pharmacological pain management was reported as not being effective. This could be due to the lack of assessment, particularly of neuropathic pain. The focus of nursing intervention continues to remain on the healing despite poor healing outcomes and poor quality of life outcomes for some patients, particularly older patients.

The nurses work according to the leg ulcer management guidelines and appear to be entrenched in a culture that has always promoted the ideal outcome as being "a healed ulcer". To change this culture can be considered as an extremely complex task, especially when the guidelines continue to remain within that culture. Therefore, we can hypothesize that the nurses are also trapped in a cycle of healing the ulcer despite the pain. They are unable to remove their patients from the acute care model as they work according to the current guidelines and are not given permission to work outside of these guidelines.

It is postulated that patients who do not have their pain managed and who have had their leg ulcers for several months or years enter a cycle of poor healing and constant chronic pain. They develop chronic pain sequelae. These patients may benefit from a palliative care model that shifts the focus onto symptom management. The nurses who care for these patients may also benefit from being given permission to use a palliative care model to manage some of their patients who warrant it. The model may also be applicable to older adults with other chronic wounds and associated pain such as pressure ulcers and post-surgical wounds. It is apparent from this research that the

focus on healing and the apparent lack of focus on pain in older people causes some older people to develop a chronic pain condition. This may also be the case with other chronic wounds where the focus is on the healing and the treatment to promote healing also causes further pain.

The following section details the implications of the thesis for future research, practice, policy and education.

### **5.7 Recommendations of the thesis for future research, practice, policy and education.**

The following section details the implications of the thesis for future practice, policy, education and research.

#### **5.7.1 Key messages identified by this thesis are;**

- i. Pain management was reported as not effective.
- ii. Healing is the main driver of a patient's management, regardless of patient history of healing outcomes.
- iii. Patients reported poor quality of life associated with poor pain management.
- iv. Pain associated with chronic leg ulceration led to negative chronic pain sequelae such as depression, insomnia and suicidal ideation.
- v. A significant number of the nurses reported they did not assess patients' pain appropriately.
- vi. The level of understanding of neuropathic pain was poor.
- vii. Nurses used pain triggers and severity as a tool to diagnose type of leg ulceration.
- viii. Patients who may have benefitted from a palliative care model rather than an acute healing model of care did not have that option.

#### **5.7.2 Recommendations for further research**

These findings together with the wider literature suggest some clear recommendations which have the potential to improve the care of older people with leg ulceration.

- i. Research is required to test the theory developed from this thesis, to answer the question; if patients on initial development of a leg ulcer had their pain adequately managed would this prevent them from developing a chronic pain condition?

- ii. Further research is required to determine the impact neuropathic pain has on healing amongst patients with leg ulceration.
- iii. Research is required that would determine the prevalence of neuropathic pain in patients with healed ulcers and if this is a determinant in recurrence and lack of compliance with measures to prevent recurrence.
- iv. Further research is required to validate the questionnaire.
- v. Further research is required to investigate why nurse prescribers are reluctant to prescribe analgesics.
- vi. Research is required to explore referral patterns for pain specialists for people with chronic painful leg ulceration.
- vii. There is a scarcity of research investigating the use of analgesics to manage leg ulcer pain. Patients with chronic leg ulceration represent a large cohort; this group requires randomised controlled trials of drugs to manage chronic pain. Of particular use would be a study to determine the use of local anaesthetic to manage persistent pain. Patient outcome and patient quality of life need to be measured as part of these trials. Healing outcomes need to be considered but should not become the main focus of these trials.
- viii. Research investigating the patient outcomes using a palliative care model compared to patients remaining on the acute care model. Quality of life, pain and incidents of chronic pain sequelae need to be measured to provide a comprehensive observation of the differences between the two approaches.
- ix. An appropriate tool needs to be developed and validated, with the aim to allow for accurate and easy identification of patients who have chronic pain sequelae associated with leg ulceration and who are not likely to heal. Therefore, allowing the nurses to access a tool to allow them to easily and accurately identify patients that would benefit from a palliative care model that focuses on symptom management rather than healing.
- x. Further research is required to test the theoretical model in other cohorts such as younger people with leg ulceration and also older people with other

chronic wounds. This would determine if this model is predominantly applicable to older age groups and also would determine if the same situation is apparent in older people with other chronic wounds, such as pressure ulcers.

### **5.7.3 Recommendations for practice**

#### **i. Pain relief should be available for all patients**

All patients should have their pain assessed and documented using a standard proforma and standard pain scoring and assessment tools. It is not appropriate to have a situation where only some patients have their pain assessed and therefore managed. Procedures need to be introduced to ensure all the nurses assess pain of all their patients under their care with a particular emphasis on older people's pain assessment. Without appropriate assessment pain will not be managed effectively. This assessment needs to include assessment of neuropathic pain for all patients.

#### **ii. Nurse prescribers require support and education**

Nurse prescribers require support and education to encourage nurse prescribing of analgesics for older people. This education needs to consider management of adverse events such as constipation and appropriate use of drugs to manage neuropathic pain in older people. This is especially pertinent considering that community nurses will manage patients once they have been diagnosed with a leg ulcer and the majority of these patients will be 65 years and over.

#### **iii. The leg ulceration guidelines need to acknowledge that for some patients, particularly older patients, palliative care may be needed.**

There needs to be recognition of the group of patients that won't heal or have frequent recurrence. Furthermore, the guidelines need to discuss the specific problems associated with healing and recurrence for older people. Nurses caring for these patients need to be given permission to shift their care from the healing focus to symptom management. This will only be achieved if the guidelines give clear messages that palliative management for some patients is acceptable and appropriate.

iv. **General practitioners should be more involved in the care of these patients.**

Presently patients are handed over to the community nurse teams as the care is focused on the healing. GPs rightly believe that nurses specialise in wound management. Their activity reflects the culture of leg ulcer management that is driven by healing outcomes rather than patients' quality of life outcomes. It would be pertinent to have collaboration between the doctors and the nurses to promote best practice for the individual patient.

v. **Healthcare professionals need to be accountable for the pain management of their patients.**

There need to be effective pain management guidelines within the primary care trusts to ensure that accountability of managing pain is acknowledged and adhered to. Multi-disciplinary teams as well as individual health professionals need to ensure that all patients being cared for in the community receive and benefit from effective pain management regardless of their condition.

vi. **Pain management specialists should be accessible in primary care areas across the UK.**

The focus of pain management is more apparent in the acute care trusts, where it is likely a pain management team will be driving forward effective pain management practices. Education and training and access to advice for pain management are more apparent within the acute trusts and should be extended into community settings.

#### **5.7.4 Recommendations for policy**

i. **Appropriate pain management strategies need to be incorporated within national leg ulcer guidelines and wound management guidelines.**

This should be done using a collaboration of pain specialists and tissue viability nurse specialists to ensure best practice. Rather than having separate wound pain guidelines the pain guidelines should form part of the leg ulcer guidelines with a particular focus on management of older people's pain.

- ii. **Appropriate pain management for all patients being cared for within the PCTs should be available.**

Pain management needs to become a priority and a national focus is required to ensure that appropriate pain provision is available. The focus on pain management within the acute trusts ensured more cohesive provision nationally; this focus is required within the PCTs.

- iii. **Pain management within the Primary Care area requires the same level of focus as pain management within the acute trusts.**

National guidelines advising on pain management provision within the primary care need to be considered. The British Pain Society has already produced guidelines for provision of chronic pain services within the PCT (British Pain Society, 2004).

### **5.7.5 Recommendations for education**

- i. **Education about pain management must form part of any community nurses' training or induction to a primary care trust.**

Pain management of patients within the community is vital if we are to promote best practice. New employees of a trust are expected to attend mandatory training; pain management education should form part of that mandatory training.

- ii. **Pain management training should be provided by pain specialists**

Employment of pain specialist within a primary care trust would ensure that appropriate and relevant training is available and undertaken.

- iii. **Management guidelines need to incorporate pain management**

Current guidelines that form part of the education and training given to community nurses do not consider pain management appropriately. These guidelines need to be revised with input from pain specialists to ensure that appropriate training and education is provided.

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## Appendix 1 Pain terms and physiology

### **Acute Pain**

Acute pain may be defined as an expected consequence of tissue injury; it is usually self-limiting and is relatively easy to treat. Acute pain is defined by the British Pain Society as a short-term pain of less than twelve weeks duration (BPS, 2008). Acute pain is sharp, immediate pain usually from an injury to the tissue although it can also be caused by physiological malfunction or illness. Acute pain has an obvious cause and its purpose is to warn of injury and/or damage (Nagy & Rice 2003).

### **Allodynia**

Allodynia is pain due to a stimulus that does not normally cause pain and can be either static or mechanical. Patients with lesions of the nervous system have allodynia and describe pain associated with touch, light pressure or moderate cold or warmth application. Allodynia is taken to apply to conditions which may give rise to sensitizations of the skin, e.g. sunburn, inflammation and trauma. The original modality is normally non-painful, but the response is painful. In allodynia the stimulus mode and the response mode differ, unlike the situation with hyperalgesia (IASP 2007). Allodynia is a feature associated with painful conditions such as neuropathies, postherpetic neuralgia, fibromyalgia, migraine and other chronic pain conditions.

### **Chronic Pain**

Chronic pain is continuous, long term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery (BPS, 2008). Chronic pain is defined by the international association of the study of pain (IASP, 1986) and the American Geriatric Society (AGS, 2002) as a pain that has a multidimensional phenomenon characterized by unpleasant sensory and emotional experiences. Chronic pain is a state in which pain persists beyond the usual course of an injury or acute disease, and is associated with actual or potential tissue damage that continues for a prolonged period and that may or may not be associated with a recognizable disease process (AGS, 2002; Gordon *et al.* 2005; IASP, 1986).

### **Central sensitization**

Central sensitization describes the increased synaptic efficacy established in somatosensory neurons in the dorsal horn of the spinal cord following intense peripheral noxious stimuli, tissue injury or nerve damage. Sensitisation is an example

of learning in which the progressive amplification of a response follows administration of a stimulus (Bell *et al.* 1995). For example if an individual rubs their arm continuously for a length of time, the arm will become warm and eventually painful. Pain is caused by the amplified synaptic response of the peripheral nerves, with the purpose of informing the individual that the repeated stimulus is damaging. This heightened synaptic transmission leads to a reduction in pain threshold, an amplification of pain responses and a spread of pain sensitivity to non-injured areas (Kohno, Moore & Woolf, 2003).

### **Hyperalgesia**

Hyperalgesia is an increased response to a normally painful stimulus and allodynia, pain perceived in response to a normally innocuous stimulus. It is caused by platelet activating factor (PAF) which comes about in an inflammatory or an allergic response. It occurs via immune cells interacting with the peripheral nervous system and releasing pain producing chemicals (cytokines and chemokines) (Marchand, Perretti & McMahon, 2005). There is a biological role associated with this, in that it encourages the individual to immobilize and protect the injured tissue from further trauma, allowing the process of repair to occur (Nagy & Rice 2003). However, if the inflammation becomes chronic, neurogenic changes can cause the hyperalgesia to become neuropathic with associated central mechanisms (Treede *et al.* 2004).

### **Integrated pain mechanisms**

The pain experience has various components: affective, defensive and perceptive. To explain why even with nociceptive activity there is not always pain and in some cases without nociceptive activity there is pain, the system must be capable of interfering with the "pathway", thus there must be some form of modulation. The Gate Control Theory proposes that activity in A-beta afferents inhibits dorsal horn neurons from responding to A-delta and C-fibre inputs. Therefore, allowing pain to be relieved by stimulation of the myelinated afferent fibres (Melzack & Wall 1965). Melzack and Wall (1965) proposed that within the spinal cord, a physiological "gate" existed and, depending on the degree of opening of this gate, nociceptive information was permitted or prevented from ascending to the brain. The principle mediators of modulation are endogenous opioid compounds.

The patient's psychological state contributes significantly to complaints of pain and suffering and is fundamental to the subjective nature of pain and how well it is accepted (Gamsa, 1994). Until the development of the Gate Control Theory (Melzack

& Wall, 1965) there was no theory that took into account the impact of psychological effects on pain. Following on from the Gate control theory Melzack (1999) developed a further theory known as the neuromatrix. Melzack proposed that a genetically built in matrix of neurons for the whole body produces characteristic nerve-impulse patterns for the body and the myriad somatosensory qualities felt by an individual. This matrix has been termed the "neuromatrix". Melzack suggests that the spatial distribution and synaptic links are initially determined genetically and are later sculpted by sensory inputs. The cyclical processing and synthesis of nerve impulses results in a characteristic "neurosignature" for a particular individual that is determined by a combination of genetic and sensory influences. The neuromatrix theory incorporates many of the same elements of the gate control theory. The neuromatrix theory of pain recognizes the simultaneous convergence of a myriad of influences such as past experiences, cultural factors, emotional state, cognitive input, stress regulation and immune systems as well as immediate sensory input.

The Neuromatrix and Gate Control Theory have the ability to integrate psychological, behavioural and physiological elements. They allow for an explanation of pain phenomena, which has both psychological and physical components. Pain is a highly personal experience that results from both the invasiveness of the painful stimulus and how that stimulus is modulated by factors both external and internal to the individual (Stevens, Watt-Watson & Gibbins, 2003). Melzack and Dennis (1978) state that painful stimuli enter an already active nervous system that is a substrate of past experience, culture, anticipation, and emotions. As a result there is no one standard response to any painful stimulus and the same pain relieving intervention may not be effective for all patients or even for the same patient over time. Furthermore, with this theory in mind it would not be possible to determine pain intensity using leg ulcer size and type.

### **Neuropathic pain**

Neuropathic pain is initiated or caused by a primary lesion or dysfunction in the peripheral or central nervous system. An example of neuropathic pain would be pain caused by shingles, or an amputation or spinal cord trauma. Neuropathic pain can be associated with acute nociceptive pain. However, neuropathic pain is also likely to last longer than acute nociceptive pain because it is more difficult to treat and is associated with conditions that have a longer time scale and/or that are chronic (Attal *et al.* 2006; Dworkin, Backonja & Rowbotham, 2003; Finnerup, Otto & McQuay, 2005). Examples of these conditions include shingles, diabetes, and central pain associated with stroke and multiple sclerosis'. Therefore, neuropathic pain is most likely to be associated with chronic conditions and chronic pain (McDermott, 2006).

Neuropathic pain is the label given to pain syndromes thought to be a secondary response from pathophysiologic changes in the peripheral or central nervous system. It is now widely accepted that central mechanisms contribute to the painful consequences of disease that are clearly initially limited to the periphery. The pain associated with neuropathic mechanisms is often described as a continuous burning pain, or spontaneous lancinating or electrical pain (Gracely & Kwilosz, 1988; Rasmussen *et al.* 2004; Bennett, 2006).

### **Nociceptive pain**

It is proposed that cutaneous receptors responding selectively to tissue-damaging (*noxious*) stimuli should be described as nociceptors (Beaulieu & Rice 2003). A chain of events is started once a noxious stimulus has been applied to the skin; this chain of events usually results in pain. Before an individual feels the noxious stimulation as pain, a series of complex electrical and chemical actions will take place. There are two types of primary afferent fibres involved in nociception: A-delta and C-fibres. The principle functions of the primary afferent neurons are stimulus transduction and transmission of encoded stimulus information to the central nervous system (CNS). These processes explain the consequences of noxious stimuli, associated with tissue damage. However, they do not offer an explanation in the mechanisms associated with chronic pain e.g. associated with chronic illness or post surgery. Chronic wounds become chronic because the wound does not follow the normal wound healing trajectory associated with acute wounds. Chronic wounds remain in the inflammatory phase for too long (Snyder 2005). The inflammation stage is the second stage of wound healing which presents with erythema, swelling, warmth and often pain. Chronic wounds may never heal or may take years to do so (Augustin & Maier 2003). The two components associated with chronic pain are inflammation and peripheral nerve damage. The tissue injury is generally followed by an inflammatory response; this will result from the action of both inflammatory cells and C polymodal nociceptors. It is the nociceptors that are responsible for the release of substance P, as well as serotonin, histamine, acetylcholine, and bradykinin ("inflammatory soup"). Their job is to activate and sensitise other nociceptors. Thus, this generation of complex chemical signals alters the transduction properties of nociceptors to enable them to be activated by low intensity stimuli. This pain is still nociceptor mediated but can be generated by low intensity or innocuous stimuli thus, creating hyperalgesia.

As part of the inflammation process the spinal cord neurons display an increase in excitability, particularly those in the dorsal horn (Doubell, Mannion & Woo 1999). With

this process there are three main changes in the physiological features of the dorsal horn neurons, a reduction in activation threshold, an increased responsiveness and an expansion of receptive field (a larger receptive area). As a consequence of cellular post-translational and transcriptional changes the spinal cord neurones have an increased probability of action potential. This creates an enhanced input to higher centres. Chronic inflammation with nociceptive pain may be the source of constant pain. Secondary neural changes that lead to chronic nociceptive pain may also be caused by tissue injury.

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## Appendix 2 Ethics approval Study 1

**NHS**  
Research Ethics Committee

18 February 2008

Ms Tania Taverner  
PhD Research Student  
School of Healthcare  
Sains Wing  
University of Leeds

Dear Ms Taverner

**Full title of study:** An exploratory study of self-management of leg ulcer pain in older people  
**REC reference number:** 06/Q1206/3

Thank you for your letter of 09 February 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The Committee has designated this study as having "no local investigators". There is no requirement for other Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

**Conditions of approval**

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

An advisory committee to West Yorkshire Strategic Health Authority

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document Type:	Version	Dated:	Date Received:
Application		14/12/2004	16/12/2004
Investigator CV			16/12/2004
Protocol	1	13/12/2004	16/12/2004
Peer Review		24/01/2006	27/01/2006
Consent form		06/10/2004	16/12/2004
Participant Information Sheet	2	06/02/2006	11/02/2006
Participant Consent Form	1	13/12/2004	16/12/2004
Response to Request for Further Information		06/02/2006	11/02/2006
Agreement to contact form	1	06/02/2006	11/02/2006
Flow chart for data collection	1	13/12/2004	16/12/2004
Supervisor's CV-Prof B J Chas			16/12/2004
Letter from Bradford South & West PCT confirming research governance approval		17/01/2006	01/02/2006
Supervisor's CV-Dr Michelle Briggs		17/01/2006	16/12/2004

**Management approval**

You should arrange for all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

**Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

**Notification of other bodies**

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedure for Research Ethics Committees in the LPH.

An advisory committee to West Yorkshire Strategic Health Authority

66013003 Quote this number on all correspondence

With the Committee's best wishes for the success of this project,

Yours sincerely,

*Am Potho*  
Dr P R F Dear  
Chair

Cc: Claire Skinner, University of Leeds

Enclosures  Standard approval conditions

Appendix 3 Research and development approval Study 1



Our Ref: 725/Approval  
Date: 27 January 2005

Mr I Turner  
PhD Student University of Leeds  
Office Number 4.03  
Heslam Wing  
University of Leeds  
LS2 9JT

Dear Iain

Re: An exploratory study investigating management of leg ulcer pain.

Thank you for sending your project to the Research and Development Unit, (R&D Unit) Bradford South and West PCT for Research Governance Approval. As you will be aware the R&D Unit provides Research Governance Approval for all Primary Care Research across Bradford, Leeds and Wakefield.

After considering your project I am pleased to inform you that your project has been approved by the R&D Unit, subject to Ethics Committee Approval and I would be grateful if you could ensure the research complies with the following requirements throughout:

- Consent for us to audit your project on a regular basis and where necessary until its completion.
- The research activity should comply with requirements of the Research Governance Framework for Health & Social Care (2001).
- The principle investigator should ensure that health and safety and data protection policies are adhered to where appropriate.
- The R&D Unit will also need to see a copy of your Local Research Ethics Committee (LREC) approved letter.
- A final report should be sent to the R&D Unit on completion of your project and a copy to the appropriate Primary Care Trust.
- Should any adverse events occur throughout the course of the research this should be reported immediately to the R&D Unit.

In addition to the above, you will need to send to the R&D Unit a sponsorship letter, (see enclosed for guidance) confirming that the project has a nominated sponsor.

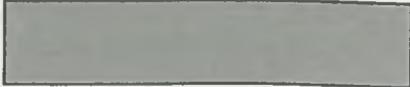
Director of Studies

If you require any clarification regarding any of the points raised above, or have any further queries in relation to the approvals process then please do not hesitate to give me a call.

Finally, may I take this opportunity to wish you well with your study and look forward to hearing about your progress in due course.

Kind regards  
Yours sincerely

Dr Shuhid Ali  
Director R&D

CC: Mr M Mahomed  
Mrs J Mawson  
Dr S G...  
Dr J...  
Dr M Turner  
Mr P...  


## Appendix 4 Study 1 Information leaflet



### STUDY INFORMATION LEAFLET

TITLE: An exploratory study of self-management of leg ulcer pain in older people

#### **Introduction**

You have been asked if you would like to volunteer to take part in a study. Before you decide it is important that you understand why the research is being undertaken and what it will involve. Please take time to read the following information before you decide whether or not you wish to take part. If you have any queries regarding the study you may contact Ms Tarnia Taverner who is the researcher, she will be happy to answer your questions.

Contact details are as follows:

Ms Tarnia Taverner MSc.RGN. (PhD student) University of Leeds

Mobile number: 07984908946

Office Number: 0113 3431373

E-mail address: [hestt@leeds.ac.uk](mailto:hestt@leeds.ac.uk) Address: School of Healthcare, Baines Wing 4<sup>th</sup> Floor, University of Leeds, PO BOX 214, LEEDS. LS2 9UT.

#### **Why the Research is being done?**

- The research is investigating patients who have chronic leg ulcers and how they manage the associated pain.
- The aim of the study is to identify pain killers used and if they work and also if participants are using other forms of pain management.
- Investigation on where information and assistance regarding pain management is sought.
- There has been a very limited amount of research undertaken investigating the pain associated with leg ulcers and it is hoped that this study will give us insight that may in the future assist in helping the management of pain associated with chronic leg ulcers.

#### **Why have you been asked?**

The study wishes to investigate patients with chronic leg ulcers who are 65years and over.

### **What happens to you if you decide to take part in this study?**

- Your community nurse will take your contact details these will be sent to the researcher, who will then contact you.
- If you wish to volunteer to take part in this study you will be required to sign an informed consent form, the researcher will carry out consent before undertaking the interview. Three copies will be signed, one kept by you, one copy kept in patient notes and the researcher will keep one copy.
- A time and date suitable to you will be arranged with the researcher for an interview to be carried out in your home.
- The interview will involve the researcher asking you questions about your pain and how you deal with it.
- The interview will last between 30-60 minutes and no more than an hour, this will depend on how much you would like to tell us.
- Your input is extremely valuable, however at any point you are free to withdraw from the study with no explanation necessary if you wish.

### **What happens if you decide not to take part?**

It is entirely your choice whether or not you wish to take part in this study; your on-going treatment for your leg ulcer will not be affected in any way by your decision.

### **What will happen to the information gained about you?**

- You will be issued with a patient identification number for the study; this is to protect your confidentiality.
- The interview will be audio-recorded. The recordings will then be typed up as transcripts and used to identify themes and theories important to this topic. The transcripts will not have any names attached to them, to retain confidentiality.
- All information will be stored securely at The University of Leeds and only the Chief researcher and the supervisors Professor Jose Closs and Dr Michelle Briggs will have access to it.



## Appendix 5 Study 1 Consent form

Participant ID number
--------------------------

### Consent Form

Title of project: An exploratory study of self-management of leg ulcer pain in older people  
**please initial box**

1. I confirm that I have read and understand the information sheet for the above study & have had the opportunity to ask questions.
2. I understand that participation in this study is entirely voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected.
3. I understand that sections of my medical notes may be looked at by responsible individuals from the University of Leeds, I give permission for these individuals to have access to my records.
4. I agree to take part in the above study

Name of Participant	Date	Signature
-----	-----	-----

Name of Researcher	Date	Signature
-----	-----	-----

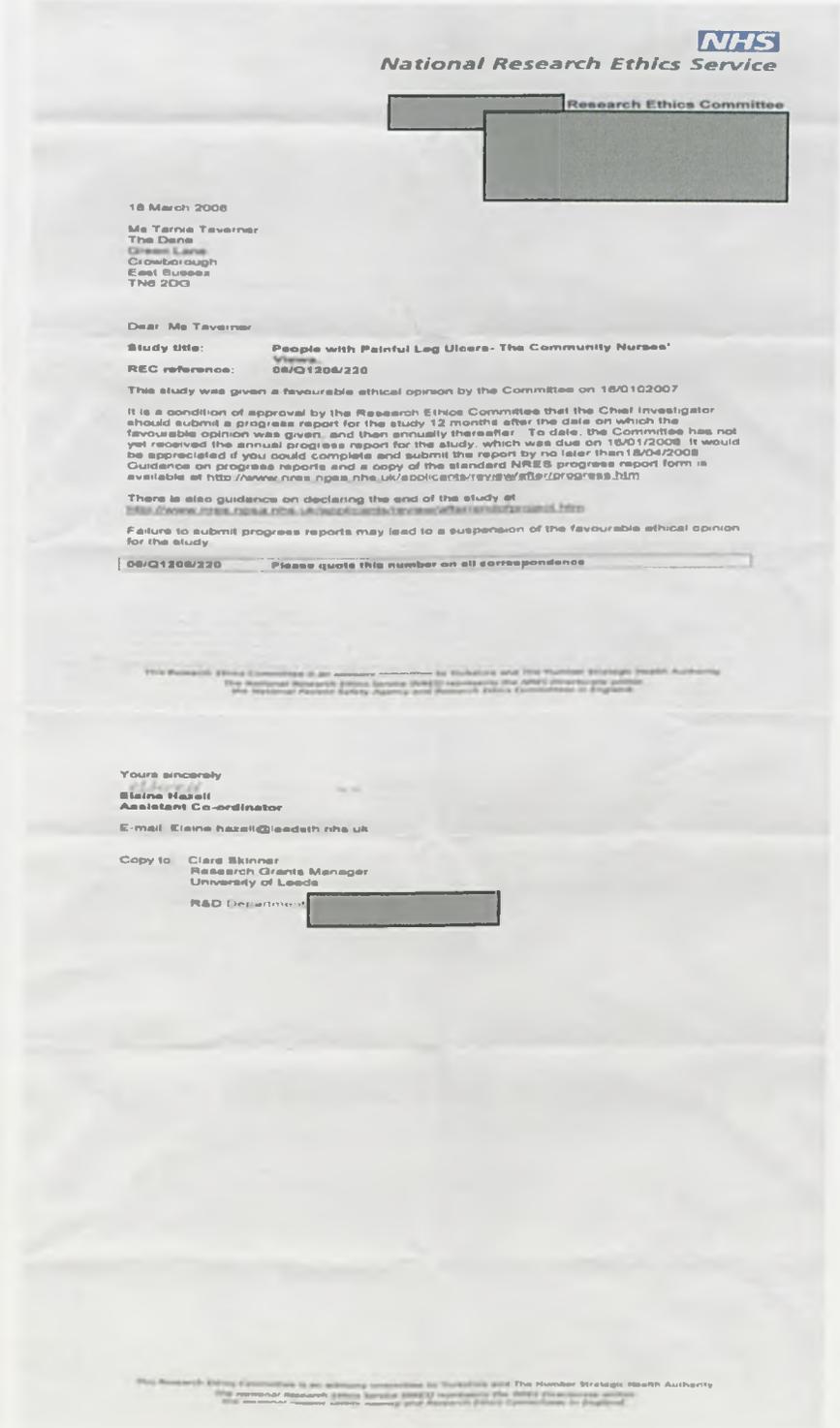
Researcher Ms Tarnia Taverner MSc. RGN. (PhD) Student University of Leeds.

Contact details: mobile number:0797685740 Office Number: 0113 3431373

e-mail: [hcstt@leeds.ac.uk](mailto:hcstt@leeds.ac.uk)

*1 for participant      1 for researcher      1 to be kept in patient community records*

Appendix 6  
Study 2 Ethics approval



## Appendix 7

## Study 2 Research and development approval

[Redacted] **NHS**  
teaching Primary Care Trust

Our Ref: 946/Approval  
Date: 23<sup>rd</sup> February 2007

Ms T Tevermer  
Doctoral Student  
The Dene  
Green Lane  
Crowborough  
East Sussex, TN6 2DG

Dear Ms Tevermer

**Re: People with painful leg ulcers – community nurse's views.**

Thank you for sending your project to the Research and Development Unit, (R&D Unit), Bradford and Airedale IPCT for Research Governance Approval. As you will be aware the R&D Unit provides Research Governance Approval for all Primary Care Research across Bradford, Leeds and Wakefield.

After considering your project I am pleased to inform you that your project has been approved by the R&D Unit, and I would be grateful if you could ensure the research complies with the following requirements throughout:

- Consent for us to audit your project on a regular basis and where necessary until its completion.
- The research activity should comply with requirements of the Research Governance Framework for Health & Social Care (DoH, 2005).
- The principle investigator should ensure that health and safety and data protection policies are adhered to where appropriate.
- A final report should be sent to the R&D Unit on completion of your project and a copy to the appropriate Primary Care Trust.
- Should any adverse event(s) occur throughout the course of the research this should be reported immediately to the R&D Unit.

[Redacted]

Also, as you are employed by the University of Leeds as opposed to an NHS employee, you will also need an NHS Honorary contract for research purposes and the R&D Unit will need to see a copy of this prior to commencement of the research. Please contact Mrs Petra Newbound on 0113 305 9632.

If you require any clarification regarding any of the points raised above, or have any further queries in relation to the approvals process then please do not hesitate to give me a call.

Finally, may I take this opportunity to wish you well with your study and look forward to hearing about your progress in due course.

Kind regards, [Redacted]

Yours sincerely,

  
Dr Shahid Ak  
Director R&D

CC  
Dr I Cameron  
Mrs P Newbound [Redacted]

**Appendix 8****Study 2 Introduction letter**

Baines Wing

Leeds

Dear:

**RE: STUDY TITLE: PEOPLE WITH PAINFUL LEG ULCERS – THE  
COMMUNITY NURSES' VIEWS.**

I am writing to ask you if you would like to take part in the above study. The questionnaire should take you only approximately 10 minutes to complete. It is entirely voluntary and all information collected will remain confidential.

My first study involved investigating pain of chronic leg ulcers and its management in people 65 years and over. This study is a follow on from the first study to gain a nursing perspective of the problem.

A chocolate has been included as an incentive; however, you are not obliged to participate.

I would really appreciate your assistance in this study.

If you would like to discuss any aspect of this with me please do contact me.

Sincerely,

Ms Tarnia Taverner. MSc. RGN.  
(PhD Student The University of Leeds).

Phone:

**Appendix 9****Study 2 Information leaflet****UNIVERSITY OF LEEDS****STUDY INFORMATION LEAFLET****TITLE: PAINFUL LEG ULCERS – THE COMMUNITY NURSES' VIEWS.****Introduction**

You have been asked if you would like to volunteer to take part in a study. Before you decide it is important that you understand why the research is being undertaken and what it will involve.

Please take time to read the following information before you decide whether or not you wish to take part. If you have any queries regarding the study you may contact Ms Tarnia Taverner who is the researcher. She will be happy to answer your questions.

Contact details are as follows:

Ms Tarnia Taverner MSc. RGN. (PhD student) University of Leeds

Mobile number:

E-mail address:

Address: School of Healthcare Studies,

**Why the Research is being done?**

- There has been a very limited amount of research undertaken investigating the pain associated with leg ulcers. As a follow on from the first study that investigated patients with chronic leg ulcers and how they manage their pain. This study will investigate the healthcare professionals who care for them in the community.
- The research is investigating community nurses' perceptions of the nature of the pain associated with chronic leg ulceration.

- The aim of the study is to describe current strategies used by community nurses to manage pain in this patient group.
- To identify additional support for pain education and management.
- To survey nurses' attitudes in relation to providing pain management for this group.

#### **Why have you been asked?**

The study wishes to investigate nurses and healthcare assistants working for the Leeds primary care trust, who look after patients with leg ulcers.

#### **What happens to you if you decide to take part in this study?**

- You will be asked to complete the questionnaire anonymously, to be sent back to the researcher in the stamped addressed envelope provided.
- It will take approximately 10 minutes to complete the questionnaire.
- Your consent to take part in this study is implied if you complete the questionnaire and return it to the researcher.
- The study is entirely voluntary.
- Your input is extremely valuable. however you are not obliged to take part and you are not required to provide an explanation.

#### **What happens if you decide not to take part?**

Nothing, it is entirely your choice whether or not you wish to take part in this study.

#### **What will happen to the information gained?**

- All information will be stored securely at The University of Leeds and only the researcher and the supervisors Professor Jose Closs and Dr Michelle Briggs will have access to the data.
- No individual employed by the I [redacted] PCT will have access to the data.
- A report will be produced at the end of the research and a summary of this will be sent to you at your place of work.
- You will be invited to attend a presentation of the results from study one and study two once the PhD has been completed.

#### **Incentive**

The chocolate has been included as an incentive to encourage you to complete the questionnaire however; you are not obliged to do so.

Appendix 10 Study 2 questionnaire

**Painful Leg Ulcers: Community Nurses' Views**

**Do you care for patients with leg ulcers?**

- YES (If yes please continue with questionnaire)
- NO (If no do not complete questionnaire but please return it with the no box ticked).

Study No:

**YOUR BACKGROUND**

Please tick the most appropriate box

Year of Birth 19\_\_ \_\_  Female  Male

1. Highest Level of Training:  Certificate  Diploma  Bachelor's Degree
- Master's Degree

2. Are you:  Community Matron  Nurse Specialist  Case load holders band 6/7
- Senior Staff Nurse band 5/6  Staff Nurse band 5  Enrolled Nurse  Healthcare Assistant

Other  .....

3. Please write the year you qualified .....

4. Have you attended formal training on pain management?  Yes  No

*If yes, please tick in which form that took place (you can tick more than one).*

- Included in Nurse Training  Module for Degree  Module for Diploma
- Pain Management Study Day  In House Training  Pain Management
- Diploma/Degree

Confidential questionnaire

Please tick which box you think is the correct answer to the following statements

**5. Pain associated with leg ulcers can be described as**

Chronic  Acute  Chronic & Acute  Unsure

Other(please specify).....

**6. Leg ulcer pain may be neuropathic as well as nociceptive.**  True  False  Unsure

**7. Pain severity is directly proportional to the amount of tissue involvement.**

True  False  Unsure

**8. Pain in these patients is a good sign as it indicates:**

**Sensation**  True  False  Unsure

**Healing**  True  False  Unsure

**Infection**  True  False  Unsure

**9. Patients report of pain intensity (e.g. mild, moderate, severe) can help in diagnosing type of leg ulcer.**  True  False  Unsure

**10. Patients report of pain triggers e.g. elevating legs, standing and pain at night can help in diagnosing type of leg ulcer.**

True  False  Unsure

**11. Compression bandaging may cause or worsen pain.**

In all patients  In some patients  In no patients

If you have ticked in all or some patients why do you think it causes or worsens pain?

.....

.....

.....

**12. Leg ulcer pain may lead to (you may tick more than one)**

Insomnia  Depression  Loss of mobility  Pain at night

Suicidal ideation  Social isolation  Desire for amputation of affected limb

Confidential questionnaire

**MANAGEMENT OF PAIN ASSOCIATED WITH CHRONIC LEG ULCERS**

*Please tick the most appropriate box*

**13. Which analgesics do you routinely recommend for leg ulcer pain?**

	Always	Sometimes	Never
Paracetamol			
Codeine			
Ibuprofen			
Diclofenac			
Tramadol			
Pethidine			
Morphine			
Amitriptylene			
Gabapentin			
Pregabalin			
Oxycontin			
Fentanyl patch			

Other (Please Specify).....

**14. I am a nurse prescriber**  Yes  No

**15. I routinely prescribe analgesics for patients with chronic leg ulcer pain.**

Always  Sometimes  Never

**16. How do you assess pain?****17. Do you measure and document pain:** On every visit Never On admission to community nurse team Only if the patient reports pain**18. For pain at dressing changes do you use:** Always Sometimes Never

Analgesia before dressing change

Extra analgesics post dressing change

Non-pharmacological techniques  
(E.g. TENS, relaxation, distraction etc.)

Gentle dressing technique

Other-please specify  
.....**19. Do you recommend the use of non-pharmacological methods of pain management to patients in this group?** Always  Sometimes  Never**20. If always or sometimes, what non-pharmacological pain management methods do you recommend for use in this patient group?**

.....

.....

.....

.....

Confidential questionnaire

## PROFESSIONAL ATTITUDES

Please tick the box that most closely fits your response to the statements

**21. Patients on my case list with pain from leg ulcers have been**  Agree  Disagree  Unsure

referred to a pain specialist?

**22. Healing is the primary goal for all patients with leg ulcers regardless of recurrence rates and history.**  Agree  Disagree  Unsure

**23. Pain is a normal part of ageing.**  Agree  Disagree  Unsure

**24. With repeated exposure some nurses may become desensitised to patients expressing pain during dressing changes?**  Agree  Disagree  Unsure

**25. Patients with pain from leg ulcers have a right to expect pain relief.**  Agree  Disagree  Unsure

**26. In general, I am hesitant to give opioids to older patients (65 years and over) with leg ulcers.**  Agree  Disagree  Unsure

**27. I am confident in managing pain for this patient group.**  Agree  Disagree  Unsure

**28. I would like more training in managing pain for this patient group.**  Agree  Disagree  Unsure

**29. I feel well supported by the multi-disciplinary team when managing pain for this patient group.**  Agree  Disagree  Unsure

**30. I sometimes avoid asking the patients about their pain when I am not sure how to manage it.**  Agree  Disagree  Unsure

31. Given that all the patients have the same degree of pain using the following scale (1-5) rate the time and energy you would choose to spend managing the pain of the following patients. (1=little time and energy, 5=maximum time and energy) circle one number for each condition.

<u>Patients Condition</u>	1	2	3	4	5
Cancer					
Substance Abuse					
AIDS					
Multiple Trauma					
Suicide Attempt					
Elderly Patients					
Renal Patients					
Diabetes					
General Surgery					
Chronic Pain					
Laparoscopic Surgery					
Chronic Wound					

Confidential questionnaire

## **Appendix 11 Job descriptions**

A brief job description for each job is as follows;

**Community matron** – is affiliated to a GPs surgery and will be responsible for policy, best practice and management at a strategic level. They do not have their own caseload of patients. They cover several community nurse teams.

**Nurse specialist** – is a nurse specialist who has patients' referred to them that require specialist treatment. They will have their own caseload of patients. They provide education and training in their speciality and will be involved in protocol development. They cover several community nurse teams.

**Case load holder** – is a district nurse with a district nurse qualification. They are responsible for their community nurse team and allocate patients from their caseload to members of their team.

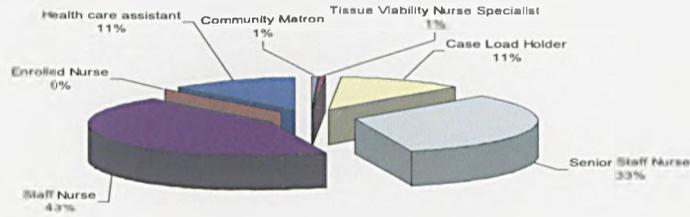
**Senior staff nurse** – does not necessarily have a district nurse qualification. They work at higher level than the staff nurses and are allocated the more complex patients. They do not have their own caseload.

**Staff nurse** – does not necessarily have a district nurse qualification. They will work within their ability to manage patients allocated to them by the caseload holder.

**Enrolled nurse** – nurses do not work as enrolled nurses anymore, they either undertake further training to allow them to register as Level 1 nurses with the NMC. If this is not undertaken they work as healthcare assistants.

**Healthcare assistant** – Is not a qualified nurse and has no professional accountability. They work as assistants to the qualified nurses.

## Appendix 12 Job characteristics of nurses working in the PCT



## Appendix 13 Characteristics of nurses registered with the NMC 2006

Characteristics of nurses that responded to the questionnaire compared with characteristics of nurses registered with the NMC (2006).

Characteristic	NMC	Study participants
20-39 years	10%	11%
30-39 years	26%	22%
40-49 years	35%	44%
50-60 years	28%%	20%
Male	10%	5%
Female	90%	91%

## Appendix 14 Table of drug names generic and marketed as:

Generic	Marketed As
Paracetamol	Tylenol, Acetaminophen
Codeine	Solpadol
Codeine & Paracetamol combinations	Panadol Ultra, Solpadeine MAX, Tylenol 3s
Tramadol	Zydol, Zamadol, Dromadol, Larapam
Ibuprofen	Nurofen, Calprofen
Diclofenac	Voltarol, Voltarol retard
Pethidine	Demerol, Meperidine
Morphine	Oromorph, Sevredol, MST
Oxycontin	Oxynorm, Oxy-IR, Perocet, Roxicodone
Fentanyl patch	Durogesic, Duragesic, Matrifen
Amitriptyline	Elavil, Tryptizol, Laroxyl, Sarotex
Gabapentin	Neurontin
Pregabalin	Lyrica