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# **Chronic Wound Management: A Practice Focused Study**

**By**

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**Nurse Consultant  
Tissue Viability**

**This thesis is submitted in accordance with the  
requirements for the degree of**

**Doctor of Professional Practice**

**Public Health, Primary Care and Food Policy Department  
City Community and Health Sciences  
City University  
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**Department of Tissue Viability  
Newham Primary Care NHS Trust**

**November 2008**



**THE FOLLOWING HAVE BEEN REDACTED AT THE  
REQUEST OF THE UNIVERSITY**

**SIGNATURES AND CONTACT DETAILS ON viii,  
APPENDICES 8 PAGE 5, 10, 11 AND 12.**

**DO NOT SCAN PAGES AFTER 192 TO APPENDIX 1**

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## Declaration to Librarian

This thesis is the result of my own investigations, except where otherwise stated.

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## **Thesis Abstract**

**This thesis is being submitted in fulfilment of the requirements of a degree of Doctor of Professional Practice. This Doctorate consists of five practice based elements: A preface, case study, review of the literature, research report and dissemination artefact. These five practice focused elements are all related to my present position as a Nurse Consultant in Tissue Viability, and to the care of patients with chronic wounds.**

**The preface sets out the starting point of the candidate and the rationale for the work undertaken. Each element of the Professional Doctorate will be outlined and the inter-relationship between each of these elements discussed. The case study is concerned with clinical practice and emphasises the knowledge and skills required to be a reflective practitioner. The study describes the case management of a patient referred to the tissue viability service with a leg ulcer associated with sickle cell disease. The Neuman Systems Model of Nursing (1989) and a case management approach to assessment and management using the SOAPIER format (Cox 1997) was utilized. The critical review of the literature evaluates the available literature pertaining to the use of antimicrobial therapy in wound management, focusing specifically on silver dressings. Clinical practice recommendations are made for the diagnosis and treatment of wound infection and appropriate use of topical antimicrobial dressings.**

**The research project examines the impact of delivering an educational programme utilising the concept of Wound Bed Preparation (WBP) and the associated TIME framework on community nurses wound care knowledge and practice. WBP has gained international recognition as a concept that can provide a structured approach to wound management. The TIME framework was developed in 2002 by the International Advisory Board for WBP, as a practical tool for implementing the concept of WBP in clinical practice. TIME is an acronym summarising the four main components of WBP:**

- Tissue**
- Infection/inflammation**
- Moisture**
- Edge**

**An experimental pre-test post-test design using repeat measures was used for the study. The results showed that community nurses wound care knowledge and practice both improved after the educational intervention, and this improvement was found to be statistically significant ( $p < 0.001$ ).**

**The dissemination artefact is made up of a number of publications and presentations from the work undertaken for this professional Doctorate.**

## **1.0 Preface**

### **Abstract**

**This preface sets out the starting point of the candidate and the rationale for the work undertaken. Each element of the Professional Doctorate will be outlined and the inter-relationship between each of these elements discussed. Common themes throughout the thesis will be identified. The role of the Nurse Consultant in advancing practice through direct patient care and research will be highlighted.**

### **1.1 Introduction**

This thesis is being submitted in fulfilment of the requirements of a degree of Doctor of Professional Practice. This Doctorate consists of five practice based elements: Preface, Case Study, Review of the Literature, Research Report and Dissemination Artefact. These five practice focused elements are all related to my present position as Nurse Consultant in Tissue Viability, and to the care of patients with chronic wounds.

I was appointed as a Nurse Consultant in Tissue Viability for Newham Primary Care NHS Trust in March 2001, having completed an MSc in advanced nursing practice at City University in 2000. The Nurse Consultant role was developed to ensure that advanced practitioners dedicated 50% of their time to clinical practice, thus contributing to advancing practice. The other elements of the role include, research, practice development and contributing to National and International work in the specialist field of practice. I have a keen interest in practice development and improving care for patients with chronic wounds and in an attempt to combine this interest with a research element I commenced my Doctorate in April 2002 (see study timeline: Appendix 1). Each element of this study conducted has contributed to the development of care and services in Newham, to the National wound care agenda through my work as chair of the National TIME Advisory Board, and Internationally through my links with the International Advisory Board for Wound Bed Preparation, a key theme of this practice focused study. Undertaking this Professional Doctorate has been vital to my development as a Nurse Consultant and advanced practitioner, in

allowing me to gain a deeper understanding of the research process and a greater appreciation of the links between theory and practice. This work has also allowed me to develop my competencies as an advanced practitioner in relation to domains 1,3 and 6 of the RCN (2007) domains and competencies for UK advanced nurse practitioners, which are as follows;

1. Assessment and management of patient health/illness status
3. The education function
6. Monitoring and ensuring the quality of advanced health care practice.

I believe my work has not only contributed to improving patient care and practice development, but has also contributed to linking theory to practice. The work demonstrates the importance of the research component of the Nurse Consultant role, as a mechanism for improving patient care and developing the evidence base for the speciality of tissue viability.

The study focuses specifically on chronic wound management, moving from an individual patient care approach using a systems model of nursing, to a treatment focus on the use of antimicrobial therapy, to conclude with a research element using an experimental design that sought to improve chronic wound care management in the community setting utilizing a conceptual framework. The study moves from a specific area of wound care to a more general approach and from the use of a nursing model to evaluation of a conceptual framework.

There are six key themes running through all five elements of this thesis and these are:

- Use of a systematic approach to wound care
- Evidence based practice
- Reflective practice
- Improving patient outcomes
- Wound care education
- Changing nursing practice.

## **1.2 Case Study**

The focus of the case study is on clinical practice outlining the care of a patient with sickle cell disease and leg ulceration. Blood disorders account for 1% of leg ulceration (Callam et al 1985), but the exact population of patients with sickle cell leg ulceration is unknown. There are very few studies that focus specifically on leg ulceration in people with sickle cell disease, and prevalence figures are likely to be dependent on the ethnic mix of the population. Cackovic et al (1998) noted a 25-75% incidence of leg ulcers in patients with sickle cell disease, and suggest that 25-63% of people with sickle cell disease will develop leg ulcers during their lifetime. Leg ulceration is most common in SS disease where prevalences of up to 75% have been reported (Serjeant 1974). These ulcers usually occur in young people aged 10-35 years, and healing can take sixteen times longer than in those with leg ulcers from other causes (Anionwu 2002). They have a significant impact on the patient's quality of life and pose a difficult challenge to wound care practitioners.

This case study, which was carried out in 2002/03 uses a case management approach utilizing the SOAPIER format (Cox 1997, Kettenbach 1995) for history taking, and the Neuman Systems Model of Nursing (1989) which provides a 'total person approach to care' to assess, plan, implement and evaluate care. Decision making analysis (Newell and Simon 1972) was used as a tool to develop the patient care pathway in the absence of robust clinical evidence. Reflection on action and in action was used to evaluate care and make changes to practice. A positive patient outcome was achieved through wound healing and improved quality of life. A greater understanding of the needs of these patients and how they can be met through a multi-disciplinary approach was developed from the work and is highlighted in the dissemination artefact.

## **1.3 Critical review of the literature**

The literature review which was undertaken in 2003/04 critically evaluates the literature pertaining to the use of antimicrobial therapy in wound management, focusing in particular on the use of silver based dressings. Wound infection is one of

the most significant factors that delays wound healing. Additional effects for the patient may be increased pain and discomfort as highlighted in the case study element of this thesis, and even life-threatening illness (White et al 2001).

With problems such as over use of antibiotics and multi-resistant micro-organisms, there has been a renewal of interest in wound management products that incorporate an anti-microbial agent. Although usually recommended and used for infected wounds these products are now being recommended for heavily colonised wounds, and those that are slow to heal. However from experience in clinical practice it would appear that nurses are confused about when to use antimicrobials and how to use them. Company representatives who claim they have the 'best' product compound this confusion. This critical review of the literature has therefore been useful to inform practice and to challenge practices that are not based on the best available evidence.

From the review a number of recommendations are made for practice and these have been incorporated into local wound care educational programmes and practice guidelines. Two papers have been published from the work and are included in the dissemination artefact.

#### **1.4 Research project**

Caring for patients with complex wounds such as sickle cell leg ulcers and appropriate use of antimicrobial therapy make up part of the overall picture of caring for patients with chronic wounds. There are many other factors that need to be considered, including patient factors, wound bed factors and the knowledge and skills of clinicians caring for these patients. This research project which was carried out between 2005/07 examines the impact of delivering an educational programme utilising the concept of Wound Bed Preparation (WBP) and the associated TIME framework on community nurses wound care knowledge and practice. WBP has gained international recognition as a concept that can provide a structured approach to wound management. The concept links treatment to the underlying cause of the wound and focuses on removal of the barriers to healing (Schultz et al 2003). The TIME framework was developed in 2002 by the International Advisory Board for WBP, as a practical tool for use in clinical practice when implementing the concept of WBP. TIME is an acronym summarising the four main components of WBP: tissue

management, infection/inflammation control, moisture balance and edge advancement. An experimental pre-test post-test design using repeat measure was used for the study that involved forty seven community nurses. Multi-methods of data collection including questionnaires, non-participant observation and recording of information from the patients clinical notes, were used to collect the data. Non-participant observation involved accompanying the community nurse to the patients home to observe wound care practice and collecting data from the patients clinical records, using an observation schedule (Appendix 9). The results showed that community nurses wound care knowledge and practice both improved after the educational intervention, and this improvement was found to be statistically significant ( $p < 0.001$ ). A number of recommendations for practice, education and research are provided.

### **1.5 Dissemination artefact**

The main dissemination artefact from this thesis is a paper included in the thesis that has been submitted for publication in the International Wound Journal and a poster presentation that has been accepted for the Third Congress of the World Union of Wound Healing Societies in Toronto in June 2008. Other dissemination artefacts include a number of published papers, conference presentation listings and other successful dissemination projects locally and nationally for each element of the thesis that were undertaken during the course of the research study. Copies of some of these publications have been included in the thesis where relevant.

### **1.6 Summary**

This chapter has outlined the practice focused elements of this thesis and highlighted inter-relationships between each element, focusing specifically on chronic wound management. The Nurse Consultant, in their role as experts, have a role to play in generating evidence that contributes to nursing knowledge and practice. In this Professional Doctorate, evidence is generated from:

- The case study to support the use of a case management approach and compression therapy in patients with sickle cell leg ulceration
- The literature review to identify best practice in the use of silver dressings in wound care

- The research report to support the use of the TIME framework as a systematic approach to improve community nurses knowledge and practice.

The work demonstrates the unique contribution that advanced practitioners such as Nurse Consultants make at an individual direct patient care level and at a wider organisational level, to improve patient care and change nursing practice.

In order to disseminate this evidence and share good practice, a number of papers have been published and the work presented at local, National and International conferences as outlined in section 5.0.



## **2.0 Case Study: Case management of a patient with sickle cell leg ulceration**

### **Abstract**

**This case study is concerned with clinical practice and emphasises the skills and knowledge required to be a reflective practitioner. The study describes the case management of a patient referred to the tissue viability service with a leg ulcer associated with sickle cell disease . The Neuman Systems Model of Nursing ( 1989) and a case management approach to assessment and management using the SOAPIER format (Cox 1997) was utilized. The case is presented, problems identified and a negotiated plan of care discussed. Evaluation of care using reflection 'in action' and 'on action' is discussed and conclusion drawn from the study.**

### **2.1 Introduction**

This case study has been carried out with kind permission of the patient (Chris) whose name has been changed for reasons of confidentiality. The study was carried out in Newham Primary Care NHS Trust in 2002/03.

The case study explores and discusses the case management of a patient presenting with sickle cell disease and associated leg ulceration. Whilst leg ulceration is a common problem affecting 1-2% of the population, it is usually associated with venous disease and a considerable amount of research evidence is available to guide the clinicians practice (Moffatt et al 1995, Royal College of Nursing 1999). Of those patients presenting with leg ulceration approximately 1% is associated with blood disorders such as sickle cell disease . Approximately 25-63% of patients with sickle cell disease will develop leg ulcers during their lifetime (Cackovic et al 1998), and there is very little research evidence to guide the clinician when managing this type of patient's care.

Case management of the patient will be undertaken using the SOAPIER format (Cox 1997, Kettenbach 1995), approach to history taking and the Neuman Systems Model of nursing (1989) which provides a 'total person approach to care' to assess, plan, implement and evaluate care.

The SOAPIER format is a problem-orientated method of structuring documentation that includes the following;

- Subjective: the clients observations
- Objective: the care providers observations and test
- Assessment data: conclusions based on the collected subjective and objective data
- Plans: strategy for reliving the patients problems
- Intervention: measures taken to achieve expected outcome
- Evaluation: an analysis of the effectiveness of the intervention
- Revision: any changes from the original plan.

The Neuman System Model (1989) was chosen as it offers a systems-based perspective that provides a unifying focus for approaching a wide range of nursing concerns. The model is based on the client's continuous relationship to environmental stress factors, which have potential for causing a reaction to stress. In the Neuman System Model, the organisation of the system considers the occurrence of stressors, the reaction or possible reaction of the client to stressors, and the particular client as a system. It takes into consideration the simultaneous effects of the interacting variables – physiological, psychological, socio-cultural, developmental and spiritual.

Assessment knowledge and skills gained by the nurse consultant from advanced nurse practitioner training at Masters level will be used to assess the patient and identify problems which have broken down the patient's normal lines of defence resulting in referral for care. A total patient approach taking into consideration the 'patient's story' and effects of ill health on quality of life will be presented with the rationale and evidence base where available for treatment decisions and actions. In the absence of clinical evidence to manage sickle cell leg ulceration, decision making analysis was used to develop the patient care pathway drawing on evidence from venous leg ulcer management presented in the literature. The patient's case management will be evaluated using a reflective approach to practice and recommendations will be made for future practice.

## **2.2 Extent of the problem**

Large-scale studies both in the U.K and in mainland Europe, suggest that 1-2% of the population develop a leg ulcer at some point in their lives (Laing 1992). About one fifth of these people have an open ulcer at any one time (Callam et al 1985).

Unfortunately there are no recent studies on the prevalence and incidence of leg ulceration, and caution should be applied to comparison of regional or International differences as a variety of methods have been used to estimate ulcer prevalence. Some estimation can be derived from questionnaires that survey the population (Dale et al 1983, Wright et al 1992). The Lothian and Forth Valley study was a pilot study of 800 subjects aged 65-80years, on the list of one general practitioner (Dale et al 1983), whilst the Riverside study (Wright et al 1992) used a random sample of approximately 2000 subjects aged 35-70 years on the list of three general practitioners. The response rates were good with 72% response in the Lothian and Forth Valley study and 64% in the Riverside study. It is important when considering the prevalence of leg ulcers, to look at the patient population studied. One study included few elderly people and studied a predominately male population (Widmer 1978). Given that the prevalence of leg ulceration increases with age and there is a higher incidence of venous ulceration in older women, the results should be interpreted with caution.

Management of these patients usually takes place in the community setting. Eighty five percent of leg ulcer patients are treated in the community by district nurses and General Practitioners (Callam et al 1985); therefore it seems appropriate to survey this group of practitioners and their patients. In 1995 an audit of leg ulcer services in Newham showed that out of 1327 patients receiving care from community nurses 164 (12%) had leg ulceration (Dowsett 1997). Most of these patients (65%) were over the age of 75years (Dowsett 1997). At this time there was no systematic approach to leg ulcer management and the current nurse led community leg ulcer clinics had not been established. When nurse led community leg ulcer clinics were subsequently developed and a referral pathway put in place it became apparent that many additional patients with leg ulcers had been self-treating. This may still be the case in areas where services have not developed, which makes it difficult to acquire true prevalence figures for the U.K.

Although the problem of leg ulceration increases with age, it would be wrong to assume that leg ulceration is a problem of old age as many patients will have their first episode of ulceration before the age of fifty. Callam et al (1987) found that more than a third of patients had ulcers before they were fifty and more than two thirds before the age of 65 years. Many patients will have several episodes of ulceration. Approximately two thirds of patients will experience two or more episodes and 21% of patients more than six episodes (Jones & Nelson 1988). More recently Lewis (1999) reported a recurrence rate of 11.1% in seven community leg ulcer clinics. However the sample size was small (N=46) and the clinics were well established, so it is difficult to generalise from the results.

Our awareness of the principal cause of leg ulcers in the U.K arises chiefly from two studies, the Lothian and Forth Valley study, which studied 800 patients (Callam et al 1985) (Table 1.), and a smaller one conducted in Harrow (Cornwall et al 1986) which included 357 people with ulceration. The results of detailed patient examination from these two surveys identified the most common cause of ulceration to be chronic venous disease. Other causes include arterial disease, rheumatoid arthritis and diabetes. Other factors were also implicated in the development of leg ulceration, but were shown to be less common. The fact that the % totals more than 100% in the table indicates that some patients had ulcers of mixed aetiology, where more than one factor was present.

**Table 1.**  
**Factors associated with leg ulceration** Adapted from Callam et al (1985)

<b>Venous disease</b>	<b>70%</b>
<b>Arterial disease</b>	<b>22%</b>
<b>Rheumatoid arthritis</b>	<b>8.5%</b>
<b>Diabetes</b>	<b>5.5%</b>
<b>Burns</b>	<b>2.5%</b>
<b>Infections</b>	<b>1%</b>
<b>Blood disorders</b>	<b>1%</b>
<b>Lymphoedema</b>	<b>0.5%</b>

Blood disorders account for 1% of leg ulceration (Callam et al 1985), but the exact population of patients with sickle cell leg ulceration is unknown. There are very few studies that focus specifically on leg ulceration in people with sickle cell disease, and prevalence figures are likely to be dependent on the ethnic mix of the population. Cackovic et al (1998) noted a 25-75% incidence of leg ulcers in patients with sickle cell disease, and suggests that 25-63% of people with sickle cell disease will develop leg ulcers during their lifetime. These ulcers usually occur in young people aged 10-35 years, and healing can take sixteen times longer than in those with leg ulcers from other causes (Anionwu 2002). The events surrounding initial ulceration of patients with sickle cell disorder suggest two different causes: traumatic and spontaneous. In the traumatic ulcer a clear history of trauma, even minor trauma such as insect bites, is recalled. The lesion fails to heal and develops into a large, infected ulcer that commonly runs a healing/relapsing course over many years. In the spontaneous type, a painful area develops spontaneously, becomes hyper-pigmented and indurated, and a necrotic lesion develops within the dermis with, initially, an intact overlying epidermis. This subsequently breaks down leaving a small but deep, painful lesion that heals relatively quickly, usually within six to nine months (Serjeant 1994).

The management of patient's with leg ulcers is costly both financially and in human terms. In the U.K the reported costs of managing leg ulcers has ranged from £150-600 million per annum. A study by the Office of Health Economics estimated the cost in the U.K. of venous disease of the leg including varicose vein management, to be £294 million in 1989 (Laing 1992). The Riverside leg ulcer project investigated the cost of treating leg ulcer patients continuously over a two-year period and found the cost to be £1067 per patient per annum (Bosanquet 1992). Most of these costs will be for the primary care setting with up to 80% of patients being treated in the community by district nurses and/or General Practitioners (Callam et al 1985). These high costs have been shown to be reduced in areas where leg ulcer services have been developed (Moffatt et al 1992).

Ellison et al (2002) in a prospective study comparing two health authorities investigated the cost and efficacy of leg ulcer care over a three-month period during 1993, 1994 and 1999. The study demonstrated improved healing rates and a reduction

in costs in the health authority where community leg ulcer clinics had been established. Leg ulcer clinics have also been shown to improve patient's quality of life. Liew et al (2000) found an improvement in patient's pain, sleep and mobility over an average of eight weeks treatment involving visits to designated leg ulcer clinics. These improvements were associated with the implementation of evidence based practice in leg ulcer management. In Newham there are four nurse led community clinics and this case study took place in one of the clinics.

The impact of leg ulceration on the patient's quality of life has been reported in several studies. Moffatt et al (1992) found that patients with leg ulcers not only experienced pain and worry as a consequence of having a leg ulcer, but that it also interfered with their ability to perform housework and engage in a social life. Hyland (1994) used a disease specific quality of life questionnaire in focus group sessions and found that leg ulcer patients reported pain and a reduction in their usual level of activity as a result of their ulcer. Some patients reported depression, loss of power and feelings of helpless. A health-related quality of life study involving 758 patients (Franks & Moffatt 1989) found increasing age led to greater deficits in energy and mobility for leg ulcer patients, with greater social isolation. The study also concluded that leg ulceration has a higher impact on perceived quality of life in young patients and confirmed that this is much stronger in men than in women. This research is significant given that sickle cell leg ulceration occurs predominantly in young males, like Chris who have to balance coping with leg ulceration and maintaining family life, work and other social activities. The impact of Chris's leg ulcer on his quality of life is discussed in more detail in section 2.11.1.

### **2.3 Sickle cell disease and leg ulceration**

Although leg ulcers are common in haemoglobinopathy patients with between 10-20% of patients with sickle cell disease developing debilitating leg ulcers, there is very little research into their assessment and management to guide the practice of the clinician. Some understanding of the disease and the pathophysiology is therefore essential when deciding how best to manage these patients.

Sickle cell disease is a term used to describe an illness attributed to the presence of the sickle haemoglobin. It is an autosomal recessive inherited condition in which sickle haemoglobin replaces all or most of the normal adult haemoglobin. It is estimated that in England, there are more than 12,500 people with sickle cell disease and 240,000 healthy carriers of the sickle gene variant (Bennett 2005). Approximately 300 babies are born each year with sickle cell disorder and more than 1 in every 2,400 births in England is affected by sickle cell disease (Streetly 2004). Sickle haemoglobin is more prevalent in people of African and African-Caribbean origin, but also found in other groups such as those with origins in the Mediterranean or Indian subcontinent (Modell 2005). An understanding of ethnicity and cultural diversity is therefore essential when managing these patients.

The international classification of disease in the U.K (ICD – 10) identified four principle genotypes causing sickle cell disease. These are:

- Homozygous sickle cell disease                      HbSS
- Sickle haemoglobin C disease                      HbSC
- Sickle haemoglobin D disease                      HbSD
- Sickle haemoglobin E disease                      HbSE

Leg ulceration is most common in SS disease where prevalences up to 75% have been reported (Serjeant 1974). Under conditions of low oxygen tension sickle haemoglobin molecules polymerise converting haemoglobin from a fluid to a viscous or ‘gel’ state. Stiff rods of sickle haemoglobin are formed leading to the deformation of red cells into an elongated or sickle shape. Polymerisation will only take place if cells contain predominantly sickle molecules, and under conditions where arterial oxygen pressures fall below 40mmHg. If the polymer dissolves in reversibly sickled cells they will regain their normal shape and resume cell function in the presence of oxygen. After repeated sickling episodes or long episodes, cells become irreversibly sickled and are permanently deformed (Cackovic et al 1998). The cells form crystals that twist the red blood cells out of shape. This combination of crystallised haemoglobin and the damaged red blood cell membrane results in small blood vessels becoming clogged, tissue hypoxia, pain and the destruction of irreversibly sickled cells which leads to severe anaemia (Docherty 1999). Sickle cell crisis which is associated with a sudden

worsening of anaemia accompanied by pain, fever and shortness of breath frequently requires hospitalisation. Pain can occur anywhere in the body but often occurs in the limbs, back and abdomen and the frequency and severity of attacks can vary hugely (Anionwu 1992). Treatment of sickle cell disease is aimed at preventing crisis, controlling anaemia and relieving symptoms (National Institute of Health 1995).

Leg ulcers are a well-recognised complication of sickle cell disease. They are more common in people with HbSS than with any other form of sickle cell disease, and males appear to be more commonly affected than females. Ulceration may follow trauma, but can also occur spontaneously, as previously outlined. Other possible factors include venous incompetence and vasoconstriction on dependence (Anionwu 2002). The ulcers can develop from minor disruptions in the skin in the region of the ankles or lower half of the leg. They are difficult to heal, possibly because of the decreased oxygenation to the area and impediment in blood flow from sickled red cells. One theory to explain the more common occurrence of leg ulcers in patients with sickle cell disorder concerns the effects of blood. When injury occurs to cells in the lower leg or around the malleoli, proteins and other constituents of plasma in the blood vessels are lost into the surrounding tissue. This results in oedema of the leg or ankle with resulting compression of tissue around the injury. Blood flow through the capillaries is decreased and arterial pressure is increased, causing expansion of the pre-capillary arterioles. Tissue oxygen to the wound is therefore reduced, causing hyper-pigmentation and roughening of the skin. This can then progress to a nodular swelling associated with purities, pain and tenderness (Docherty 1999). These patients are also prone to haemolytic crises with an acute accelerated drop in haemoglobin levels which again has an adverse effect on healing.

Sickle cell ulceration usually begins as small, elevated, crusting sores on the lower leg, usually around the ankles or above the medial and lateral malleoli. They can be single or multiple and often have a punched out appearance with well-defined margins and a slightly raised edge. Patients often present with multiple small ulcers that merge to form a larger lesion. These ulcers can be very painful and often are accompanied by reactive cellulitis and regional adenitis. Warmer temperatures, lower steady-state haemoglobin and lower foetal haemoglobin appear to enhance ulcer formation (Cackovic et al 1998). Chris's ulcers began in this way but soon enlarged due to the



presence of a wound infection and increased amounts of wound exudate which lead to maceration of the surrounding skin. On his return to Nigeria for his father's funeral in November 2002 his ulcers which were at the time improving suddenly deteriorated. This could in part be attributed to the change in temperature and also to the personal stress of bereavement. He also noted that his ulcers reoccur or deteriorate in the two-week period prior to him having a sickle cell crisis. It is not unusual for Chris to be an in-patient twice a year as a result of a sickle cell crisis. Managing and maintaining his ulcers was a constant challenge for those clinicians involved in his care.

## **2.4 Leg ulcer assessment and management**

Good patient assessment is the key to leg ulcer management. The aim is to identify the underlying aetiology of the ulcer within the context of a holistic assessment.

Assessment of past medical history and presenting signs and symptoms, together with simple investigations, will usually provide sufficient evidence to determine the broad underlying aetiology and to make a differential diagnosis. This assessment should be part of the broader assessment that includes psychosocial issues and the effect of the ulcer on the patient's quality of life. Patient assessment should include:

- The immediate cause of the ulcer
- Any underlying pathology in the lower limb
- Any local problems at the wound site which may delay healing
- Other more general medical conditions which may delay healing
- The patient's social circumstances and the optimum care setting (Moffatt 1998).

The significance of the patient's arterial status is always the governing feature when deciding on the most appropriate treatment for the patient. Part of the assessment process should establish whether the patient has an adequate arterial blood supply.

Assessment of both limbs is recommended and palpation of foot pulses alone to determine the arterial blood supply is not recommended (Moffatt & O'Hare 1995).

The patient's ankle/brachial pressure index (ABPI) should be recorded using Doppler ultrasound. An ABPI of between 0.8 and 1.2 together with a clinical picture of venous hypertension indicates the patient is suitable to have compression bandaging (RCN 1999). This investigation is particularly pertinent for patients who have sickle cell disorder and leg ulceration as signs of venous insufficiency may be present such as hyper-pigmentation and oedema but arteriolar occlusion can occur from sickled cells,

causing tissue hypoxia to the wound bed.

The main management priorities for a patient with a leg ulcer are:

- To correct the underlying cause of the ulcer. This normally means improving the patient's venous and/or arterial circulation in the affected limb
  - To create the optimum local environment at the wound site
  - To improve all the wider factors that might delay healing especially poor mobility, malnutrition and psychosocial issues
  - To prevent avoidable complications such as wound infection or tissue damage due to poor bandaging technique
  - To maintain healed tissue
- (Morrison & Moffatt 1995).

Where the underlying cause of the ulcer is due to venous disease the recommended treatment is graduated sustained compression with pressures of 40mmHg at the ankle graduating to 18mmHg below the knee (Blair et al 1988). This can be achieved through the application of compression bandages or compression hosiery. In the U.K the most common form of treatment is the use of multi-layer bandage systems in particular 4 layer bandage. Where the patient's underlying aetiology is arterial disease the recommended treatment is to improve the blood supply to the lower limb with angioplasty or bypass surgery. If the patient is not suitable for bypass surgery then good wound management; non-compression bandaging and health education with regular follow up is the recommended treatment pathway (Fahey 1988).

The management of patients with more unusual causes of leg ulceration is not clearly documented and generally there is lack of scientific evidence to support any one treatment. In terms of sickle cell leg ulceration a variety of treatments have been reported, many of which are based on expert opinion. Serjeant (1994) suggests that the cornerstone of therapy is to keep the lesion clean and provide firm supporting bandages to reduce haemostasis and lymphoedema if the patient is ambulant. A number of other recommendations have been made many of which have little or no research evidence to support their use and some that could potentially be detrimental to the patient. The Sickle Cell Information Centre Guidelines (Sickle Cell Information Centre 1997) suggest using liquid household bleach to clean the ulcer and wet-to-dry

gauze to debride the wound. Studies have shown that antiseptics should not be used routinely in wound management (British Medical Journal 1977) and the National Institute for Clinical Excellence (NICE) (2001) do not advocate using wet-to-dry gauze for the debridement of wounds as this causes pain and trauma for the patient and delays wound healing. Other recommendations from the literature include bed rest, blood transfusions, skin grafting and surgery although these have not been shown to improve healing rates or to prevent recurrence (Serjeant 1994, Cackovic et al 1998). Given the lack of clinical evidence to support the management of patients with sickle cell leg ulceration, the nurse needs to combine good clinical judgement, clinical reasoning and knowledge of the individual patient when assessing these patients and recommending treatments. Decision making analysis (Newell and Simon 1972) can be used as a tool to facilitate the process of decision making and to determine the best intervention.

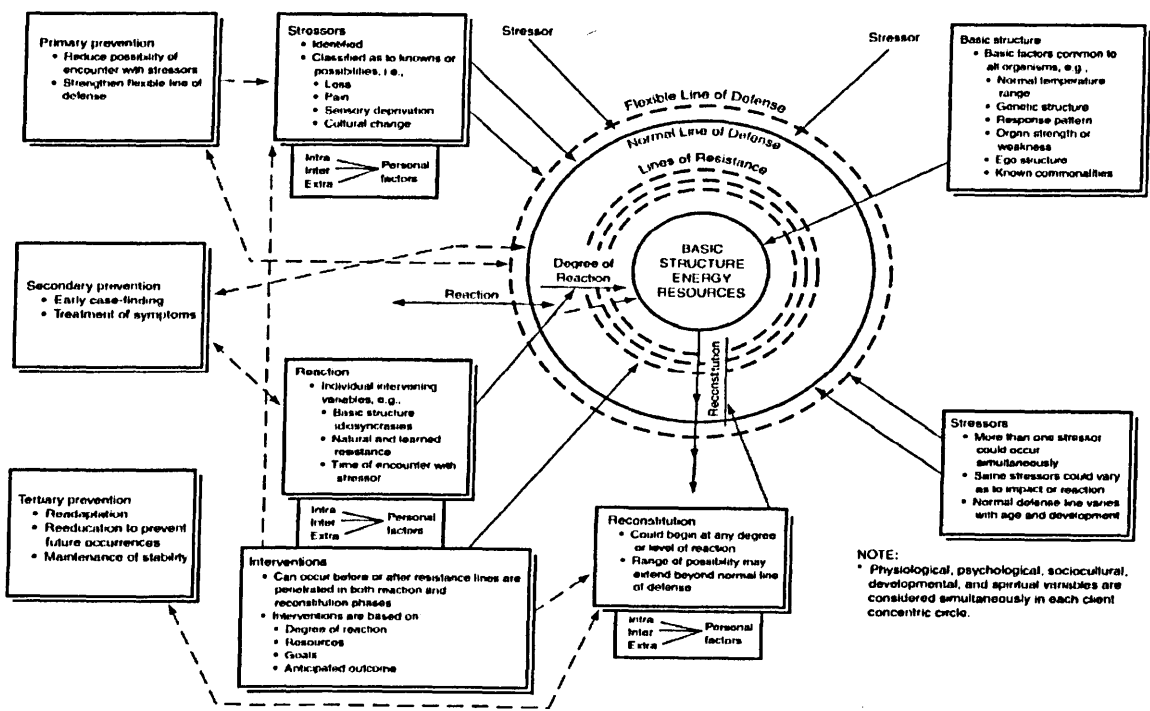
## **2.5 Case Management**

Case management involves early assessment, early intervention, and comprehensive planning of care, referrals and discharge (Cohen & Cesta 1997). Fifty percent of the nurse consultant's time is dedicated to direct patient care and by using advanced nursing knowledge and skills they are ideally placed to provide expert case management. Nurse Consultants are also in a position to work outside traditional care pathways and contribute to new knowledge and practice that can influence patient case management.

History taking is an essential element of case management. The SOAPIER format (Cox 1997, Kettenbach 1995) is a useful approach to structuring history taking when assessing, planning, implementing and evaluating care for a patient. This approach combined with Neuman Systems Model of Nursing (1989) was used for the purpose of assessing and managing this patient's care. Neuman systems model (Diagram 1.) focuses on a 'total person approach to care' and emphasises prevention, health education and an interdisciplinary approach to care. It is particularly useful and appropriate for use in the community setting and encourages the clinician to work with the patient in managing the stressors that break down the normal lines of defence resulting in ill health. The normal line of defence is the models outer circle which represents a stability state for the individual's usual wellness. It includes system

variables and behaviours such as the individual's usual coping patterns, lifestyle and development stage. The model also has a flexible line of defence, which is perceived as a protective buffer for preventing stressors from breaking through the usual wellness state as represented by the normal line of defence. The ring surrounding the basic core structure represent resource factors that help the client defend against a stressor (Neuman 1985).

**Diagram 1.**  
The Neuman System Model Diagram reproduced with permission



The Neuman Systems Model. (Original diagram copyright © 1970 by Betty Neuman.)  
Reproduced with permission <http://neumansystemsmodel.org/>

The ‘Neuman Model’ draws on systems theory and stress adaptation and suggests three basic principles to be considered in relation to nursing assessment. These are:

- Good assessment which requires knowledge of all the factors influencing a patient’s perceptual field
- The meaning that a stressor has to the patient should be validated by the patient as well as the care giver
- Any factors in the perceptual field of the caregiver that influence review by the assessor of the patients situation should become apparent.

## **2.6 Patient referral**

Mr Chris Obeh aged 39 years who lives with his wife and daughter aged 2 1/2 years was referred to tissue viability services in March 2002 by the haemoglobinopathy Clinical Nurse Specialist, who was concerned that his leg ulcers were not progressing and that he was managing the ulcer himself. Chris was sent an appointment to attend one of the nurse-led community leg ulcer clinics for a full assessment by the Nurse Consultant. A general assessment of the patient as well as a more specific assessment of the leg ulcer including Doppler ultrasound was carried out in line with Neumans recommendations.

### **2.6.1 Subjective assessment**

Chris's chief complaint was that his leg ulcers were extremely painful and offensive smelling. He had had the ulcers on and off since the age of 35 years and usually they healed with self-management, using a variety of dressings, which he purchased, from the local chemist. Chris could recall at least four episodes of ulceration during this time. He had recently been an inpatient for management of a sickle cell crisis and associated this with the problem. His sickle cell crisis and resulting ulceration had contributed to a breakdown in his normal lines of defence and thus his ill health (Neuman 1989).

### **2.6.2 Past medical history**

- Sickle cell disease
- Leg ulceration – four episodes in 3 years
- Nil else of note

### **2.6.3 Diet**

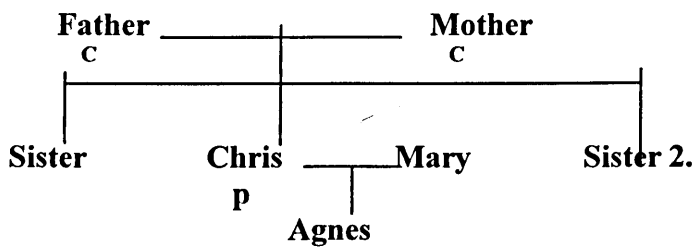
Recently his appetite has been poor due to sickle cell crisis and hospitalisation. Chris finds he does not want to eat when he feels lethargic. Antibiotic therapy, which he has been having intravenously in hospital, also suppresses his appetite. When he feels well his diet is good. His wife does not work and usually does all or most of the cooking. Chris is aware that his fluid intake is important as dehydration can lead to sickle cell crisis. He usually drinks not less than 2.5 litres of fluid per day.

2.6.4 Medication

- Co-dydramol – 2 tablets four times a day
- Voltarol – 50mgs twice daily
- Folic acid – 5mgs once daily

2.6.5 Family history

Diagram 2. Family Genogram



Symbols

- Sickle cell carrier c
- Sickle cell positive p

2.6.6 Psycho-social history

Chris was born and raised in East London the oldest of three children. Both of his parents were from Nigeria and had come to the U.K to study. When Chris was seven years old he returned to live in Nigeria with his mother and his father followed two years later. Chris then returned to the U.K at the age of 22 years and started a degree in business studies at a London University. He married in 1999 and has a daughter aged 2 ½ years. His wife cares for their daughter and therefore they are completely dependent on his income. Chris eats a well balanced diet although his appetite is poor during periods of illness. He does not smoke and only drinks alcohol occasionally. He currently works for a London council as an independent consultant in the housing department. He is also eligible for and claims disability allowance. As a self employed person Chris does not get paid during periods of illness and hospitalisation with sickle cell crisis and this leads to financial pressures for him and his family which breaks down his normal lines of defence and causes him great anxiety.

Although Chris can identify the relationship between his sickle cell disease and his leg ulcers, he does not fully understand the pathophysiology. He has in the past been seen by the vascular consultant at the local hospital and was told ' he had poor circulation'. For this reason he had some anxieties when the compression bandages were applied to his legs. This was resolved by explaining the underlying problems in his blood vessels and the meaning and interpretation of the Doppler ultrasound results.

## **2.7 Objective assessment**

Initial observations revealed ulceration of the lower right leg both on the medial and lateral aspect. The wound bed was mainly sloughy (90%) with some granular areas (10%) on the medial ulcer. Chris was distressed due to the pain associated with the removal of his dressing, despite having taken analgesia (Co-Dydramol 2 tablets) prior to attending the clinic. Large amounts of exudate were present both at the wound site and on the dressing. Further assessment and history taking revealed the following information.

### **2.7.1 Skin, hair and nails**

Hair, skin and nails well attended to. Right leg oedematous and ulcerated with maceration of surrounding skin associated with wound exudate. Brown staining of the skin around the ulcer site, which is suggestive of venous hypertension when red blood cells leak out into the capillaries due to poor venous return.

### **2.7.2 Muscular-skeletal**

Chris has restricted movement in his right ankle due to pain and ulceration. He is currently using a walking stick to aid his mobility. No notable swellings of joints or bony deformities.

### **2.7.3 Head and neck**

Nil of note.

### **2.7.4 Endocrine**

No history of diabetes or other endocrine disorders.

### **2.7.5 Cardio-vascular**

No history of chest pain or heart disease. History of heart disease in family. Father died of myocardial infarction, November 2002.

**2.7.6 Peripheral vascular**

Hands and feet warm to touch. No pallor noted but difficult to note on black skin. Ulceration on both medial and lateral malleolus on the right leg. Oedema present in the right leg. No history of deep vein thrombosis or varicose vein surgery, which are contributory factors to venous ulceration (Morrison 1991).

**2.7.7 Respiratory**

No breathlessness, wheeze,cough or sputum. Chris does get breathless when he is having a sickle cell crisis and usually has to have oxygen.

**2.7.8 Genitourinary**

No dysuria or polyuria.

**2.7.9 Gastrointestinal**

Appetite has been poor recently. No nausea or vomiting. Bowels open daily.

**2.7.10 Neurological**

Nil of note.

**2.8 On examination**

How much of the physical assessment that needs to be done on any patient will depend on the purpose for which the assessment is being undertaken (Cox 1997). It will also be guided by the information given by the patient during the history taking. Having recorded Chris’s health history the following relevant examination was performed.

**2.8.1 Cardiovascular system**

<b>Inspection</b>	Pulsation evident at point of maximum impulse (PMI) at the 5 <sup>th</sup> intercostal space. No abnormalities observed.
<b>Palpation</b>	No evidence of thrills. Heart rate 80 beats per minute and regular.
<b>Percussion</b>	Cardiac dullness not extending beyond the right edge of the sternum. Apex not displaced.
<b>Ausculation</b>	No evidence of murmurs, rubs, clicks or bruits. Blood pressure elevated 140/85.

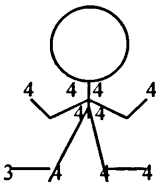


2.8.2 Peripheral vascular system

**Inspection** Skin colour good. No jaundice or pallor. Hands and feet warm.  
Feet remain warm on elevation. Some brown staining and induration around ulcer site. Also warm to touch with inflammation present. Some oedema of the right leg. No varicose veins present.

**Palpation** The following pulses were palpated: Carotoid, brachial. radial, femoral, popliteal, posterior and anterior tibial, dorsalis pedis and peroneal.

Diagram 3. Pulses palpated and degree of impairment



- 1: markedly impaired
- 2: moderately impaired
- 3: slightly impaired
- 4: normal

All pulses normal with diminished pedal pulse in the right leg, possibly due to the presence of oedema making palpation difficult. Capillary refill time normal, with good colour returning to nail beds within a second following application of pressure.

**Auscultation** Research shows that palpation of foot pulses is not sufficient to make a differential diagnosis of a leg ulcer, and recommends the use of Doppler ultrasound to measure the ankle brachial pressure index (APBI) as part of assessment (Moffatt & O’Hare 1995).

<b>Doppler Readings</b>	Right brachial	140	Left brachial	140
	Right pedal	142	Left pedal	140
	Right posterior tibial	150	Left posterior tibial	148

**Ankle Brachial Pressure index** ABPI = 1.07 ABPI = 1.05

## Ankle circumference

Right = 24.5 cms                      Left = 23 cms

Measurement of the ankle circumference is significant if compression bandaging is the treatment option, as the amount of pressure achieved with bandaging is directly related to the size of the ankle. This is based on the Theory of Laplaces Law, which states

$$P = \frac{TN}{C \times W} \times 4630$$

**C W**

Where P = pressure, T = tension, C = circumference of the limb, W = bandage width and N = number of layers (Thomas 1990). It is therefore important that the ankle circumference is measured on initial assessment and periodically during treatment. A reduction in ankle circumference may necessitate a reduction in the number of layers of bandage being applied to the patients limb.

**2.8.3 Respiratory**    Chest clear bilaterally. No breathlessness noted

**2.8.4 Neurological**    Power and sensation normal in both arms and legs. Chris normally gets pain stiffness in arms when he has a sickle cell crisis, but no problems noted on examination.

## 2.9 Wound assessment

<b>Site</b>	Ulcers on the right leg in the gaiter area (lower two thirds of the leg), both medial and lateral.
<b>Size and depth</b>	Lateral ulcer 6.5cms x 5cms. Medial ulcer 5cms x 4cms as measured using Polaroid grid camera. Ulcers superficial with sloping edges. Ulcers started as small lesions (typical of sickle cell ulcers), but opened into one large lesion.
<b>Appearance</b>	Sloughy (90%)with some granulation tissue dispersed throughout the wound bed.
<b>Surrounding Skin</b>	Inflamed and indurated. No evidence of varicose eczema.

<b>Exudate</b>	Large amounts of copious exudate which is offensive smelling.
<b>Infection</b>	Evidence of clinical infection. Heat, inflammation, oedema, pain. Excess exudate and offensive smelling. Wound swab sent for culture and sensitivity.
<b>Pain</b>	Pain described by patient as moderate both day and night, but severe during dress severe during dressing change. Pain confined to the ulcer No evidence of intermittent claudication, or pain on elevation which would indicate the presence of arterial disease.

Leg ulcer assessment form and wound assessment form completed as a baseline and to allow for weekly monitoring or change in condition (Appendix 2 & 3).

Photographic record of wound progress included (Appendix 4).

## **2.10 Problems identified**

- 1. Anxiety and reduced quality of life**
- 2. Leg ulceration associated with sickle cell disorder**
- 3. Wound infection**
- 4. Pain, especially at dressing change**

## **2.11 Case Management: negotiated care plan and rationale**

Determining what is best for a particular patient, given the individual circumstances is 'best practice' and this is a combination of evidence-based practice, clinical judgement/reasoning, and the patient's preference (Byers & Brunell 1998). In the absence of good clinical evidence, as in the management of patients with sickle cell leg ulceration, the nurse has to draw on clinical reasoning based on patient assessment, together with clinical risk management and patient consultation. Dowie (1993 p8) defines judgements as 'the assessment of alternatives' and decisions as 'choosing between alternatives'. In the absence of robust scientific evidence such as randomised controlled trials the clinician is forced to consider the alternatives available. Chris was made aware that sickle cell leg ulceration was not a common problem and that the research evidence and clinical expertise in this area was still growing.

Presented with the findings from the assessment the care plan was developed through the process of decision analysis using descriptive theory (Newell & Simon 1972) and included the patient's perspective as recommended by Neuman. Decision analysis which offers a systematic means of considering the risks, benefits, harm and eventualities associated with the various treatment options is encouraged by health providers under the clinical governance framework within the NHS, in a bid to ensure high quality cost effective care (DOH 2002). Descriptive theory allows the clinician to reflect on how the clinical decision was made and provides an audit trail which supports the decision making process. Elstein et al (1978) suggests that people go through a number of phases in their reasoning process when they process information. He identifies four stages in the process, which have been incorporated into the case management of this patient.

These are:

- Cue acquisition: this included the clinical information obtained such as past medical history, current history and presenting clinical problems
- Hypothesis generation: which is the explanation for the cue acquisition in this case sickle cell disease and the onset of leg ulceration
- Cue interpretation: this is supported by the results of physical examination and Doppler investigations such as hyperpigmentation, oedema and an ankle Brachial pressure index of greater than 1.0, indicating an underlying venous insufficiency.
- Hypothesis evaluation: This in assessing how accurate the hypothesis was and evaluating the decision arrived at.

According to Elstein et al (1978) this information based process of clinical reasoning reduces diagnostic error where uncertainty may lead to incorrect patient management. Accurate and timely diagnosis is essential when managing patients with leg ulceration as inappropriate treatments can delay wound healing and the use of compression therapy can be detrimental in those patients with compromised arterial blood supply.

### **2.11.1 Anxiety and reduced quality of life**

Chris was encouraged to express his anxieties and concerns in a relaxed environment away from the activities of the leg ulcer clinic. He expressed feelings of failure in that he had to seek healthcare advice to manage his ulcer. He was also concerned about the amount of time he was having off work to attend clinics and the effect that his reduced income was having on his family welfare. During this time he became distressed and tearful. Social support has been described as one of the most important factors in coping with sickle cell disorder (Bennett 2005). Ensuring that patients are informed and receive the correct benefits to support their social situation is essential. Secondary intervention (Neuman 1989) focused on allowing Chris to have these feelings and not to be embarrassed or ashamed of what he was going through. Chris was encouraged to consider the issues that had contributed to a breakdown in his flexible and normal lines of defence being broken down and how these could be rebuilt so that he could develop his lines of resistance in order to cope with the weeks of treatment ahead. Many of his anxieties related to other issues of care such as pain he was experiencing particularly at dressing change and to the odour from his wound that work colleagues had commented on, which was a result of infection. Some of these anxieties were relieved by exploring the treatment regimes that would address the pain and odour management. Research into the effects of leg ulceration on the patient's quality of life were discussed with Chris which in turn allowed him to recognise that he was not alone in his feelings or the issues he was facing in his daily life. During this time a bond developed between the patient and the nurse, which was to set the scene for the case management. Chris story unfolded during the assessment and during subsequent consultations.

Chris was born in the U.K in 1964. His parents were Nigerian living and studying in London. His father qualified as a mechanical engineer and his mother obtained a degree in home economics. Both of his parents had sickle cell trait. Chris was diagnosed as having sickle cell disorder at the age of 4 years, when he became unwell and was admitted to hospital. There was no family history of sickle cell disorder and Chris had two sisters living back in Nigeria who were both well. Chris returned to Nigeria with his family to live in 1971, and remained there until he was 22 years of

age. During this time he studied and achieved a national diploma in business studies. His sickle cell disorder dictated this early part of his life with at least two admissions into hospital each year with a sickle cell crisis. This trend continues here in the U.K where Chris now lives. He describes the care as very different in Nigeria, where treatments such as Novogene injections and indocid injections are used. These treatments were apparently discontinued in the U.K. in the 1970's. The current treatment in the U.K is analgesia (peithidine or diamorphine- high dose), intravenous fluids, antibiotics and rest.

Chris developed his first leg ulcer at the age of 35 years. There is no history of leg ulceration in the family and Chris was shocked to discover that he had this problem. Over a four year period he could recall at least four episodes of ulceration. He describes the main problem as pain, especially when the dressing is changed and not being able to carry out his normal day-to-day activities. Swimming was one of his family pastimes, giving him time with his family and a general feeling of well being. He can no longer do this due to his ulcer and bandages. He also worries considerably about having time off work both for financial reasons and in terms of career progression.

Chris feels that his ill health has had a detrimental effect on his career progress, but remains optimistic about the future. He is currently considering studying at a higher level through the Open University. When asked about what keeps him going Chris says that the "spirit of not accepting defeat" is always with him. He feels he has to "fight his ulcer" and not allow it to "wear him down". His wife and daughter and the responsibilities of family life are always paramount in his mind. He describes his daughter as "the joy of my life".

He does however admit that having the leg ulcer is the worst thing that has happened to him in his life and that at one point he felt depressed and considered having his leg amputated so that he could "regain control of his life". This feeling has now left him as his ulcer has started to reduce in size. A study by Midence et al (1993) reported a link between symptoms of depression and poor body image in patients with sickle cell disease. It is also possible that depression and other related problems may increase

the incidence and severity of painful episodes by disrupting coping behaviour (Midence and Elander 1996).

Chris’s other main concern is his home. He currently lives in rented property which he says is too small to accommodate his family. His wife has been looking at houses out of the area, but Chris says he is “afraid to move away” in case he can not access the same treatment for his sickle cell disease and his leg ulcer.

**2.11.2 . Leg ulceration associated with sickle cell disease**

Chris had over time adjusted his normal line of defence so that he was able to cope with living with sickle cell disease. However the development of his leg ulcer had penetrated through his flexible lines of defence and broken down his normal lines of defence. Ensuring the correct diagnosis by accurate and timely leg ulcer assessment aimed to reduce his stress and return his normal lines of defence to their former state. The assessment process identified some factors that were indicative of venous hypertension and a normal Doppler reading of greater than 1.0. This information together with the limited amount of research into the treatment of sickle cell leg ulceration which indicates using elevation and compression dictated the treatment option, which was to commence compression bandaging. There are a number of compression bandaging systems available for use and these are divided into the amount of pressure they produce (Table 2.)

**Table 2.**  
**Compression bandages classification**

Bandage class	Definition	Pressure produced (ankle)
3a	Light compression	14 – 17mmHg
3b	Moderate compression	18 – 24mmHg
3c	High compression	25 – 35mmHg
3d	Extra high compression	Up to 60mmHg

The ideal compression bandage can be defined in terms of its pressure profile; that is, the magnitude, distribution and duration of pressure achieved. There is evidence that high compression is more effective than moderate compression in healing leg ulcers and preventing recurrence (Blair et al 1988). Multi-layer compression bandages are

used predominately in the U.K and if applied correctly give pressures of 40mmHg at the ankle graduating up the leg. Multi-layer (4-layer) compression bandage system, have been shown to heal up to 74% of venous leg ulcers in 12 weeks (Moffatt 1992). This was the bandage system that was applied to Chris's leg. The four layer bandage system contains an orthopaedic wool layer for protection and absorption, a crepe bandage and two compression layers. Layer three is classified as a type 3c bandage and gives pressures of 18-24mmHg and layer four is a cohesive bandage giving pressures of approximately 22mmHg. Together a pressure of 40mmHg is achieved.

The bandage system is bulky which can make it difficult for the patient to wear their normal footwear. For this reason the bandages were not applied on the first consultation, but two days later when Chris had had time to purchase some larger footwear. As Chris had concerns about the financial cost of purchasing foot wear, he was given advice and information about specialist NHS suppliers who provide low cost foot wear. The bulk of the 4-layer bandage system has been criticised and many patients, particularly those on low incomes are reluctant to purchase extra footwear. This can lead to a lack of concordance in keeping the bandages on. Multi-layer bandaging systems are designed to give graduated sustained compression of 30-40 mmHg at the ankle graduating at the calf to 15-20mmHg (Stemmer 1969), and usually remain in place for one week. The pressure achieved is based on Laplace's law as previously explained, but relies not only on the number of layers, but on the curvature of the patient's leg. Some patients have what is termed a 'straight leg' with little calf muscle to alter the bandage pressure. This was the case with Chris and the nurses therefore had to be trained in how to pad out the calf area with orthopaedic wool in order to achieve the correct pressure. Because Chris had an underlying wound infection as confirmed by a wound swab the frequency of dressing change and bandage renewal was increased to twice a week for the first two weeks of treatment, due to the high level of exudate and malodour present. Chris was given a choice of clinics that he could attend at various times to suit his work commitments. The Nurse Consultant was able to review and contribute to his care at whichever clinic he decided to attend. The 4 layer bandage system is expensive to purchase, (approximately £10 a box) for those patients not eligible for free prescriptions. However Chris was eligible for free prescription as he was on income support.



When the ulcer had reduced significantly in size Chris was measured for class 2 compression hosiery. Compression hosiery has been shown to reduce recurrence of venous leg ulceration (Effective Health Care Bulletin 1997), and can also be used as a treatment as the ulcer improves (Dealey 1999). A waterproof dressing was used as a primary dressing so that Chris could return to his weekly swimming activity with his family. Neuman (1989) describes this as tertiary prevention which restores the normal line of defence and restores wellness.

### **2.11.3 Wound infection**

The presence of a wound infection had further contributed to breakdown in Chris's normal lines of defence. When this line is broken down patients present with symptoms, in this case pain, increased wound exudate and malodour as a result of infection. Wound infection is one of the most significant factors that delays wound healing. Additional effects for the patient may be increased pain and discomfort and even life-threatening illness (White et al 2001). It also makes it difficult for the patient to self-care as healthcare interventions are required to eradicate the infection, and the wound needs close monitoring. Chris was identified as having a wound infection due to the presence of criteria associated with infection such as inflammation, pain, increased exudate levels and malodour (Cutting & Harding 1994), and confirmed by a wound swab showing gram-positive, gram negative and anaerobic organisms reported back to the clinic by the General Practitioner. Although there is some evidence to suggest the routine use of antibiotics in the management of clinically infected leg ulcers is of no benefit (Alinovi et al 1986), other evidence suggests that acute episodes of infection should be treated with antibiotics ( Bowler et al 2001, O'Meara et al 2000, 2001). Therefore systemic antibiotics (Flucoxacillin 500mgs three times a day) and a topical antimicrobial dressing; Iodoflex were prescribed. At the time of carrying out this study nurse prescribers, in this case the Nurse Consultant were only able to prescribe dressings for wounds but not antibiotics. This can delay the start of treatment for the patient and as a result prolong problems for the patient. It is vital therefore that there is good communication between the primary health care team in the management of chronic wounds, so as to provide a seamless service. Chris's care was discussed in detail with his General Practitioner and a plan of care agreed.

Chris's plan of care included cleansing the wound at each dressing change. The value of cleansing wounds rests with the removal of excess exudate, foreign bodies, including dressing residues and necrotic/sloughy tissue. Cleansing that does not seek to achieve any of these aims is unlikely to be of value and is more likely to cause harm by damaging fragile new tissue growth and delay wound healing (Dealey 1999). Chris had his wound cleansed due to the presence of infection, excess exudate and sloughy tissue. This was achieved by washing the leg in warm tap water using a bucket with a sterile liner. For wounds healing by secondary intention such as leg ulcers tap water is recommended. Studies on traumatic wounds by Hall Angeras et al (1992) suggest there is no quantifiable infection risk with tap water. A Cochrane review of water for wound cleansing (Fernandez and Griffiths 2007) found that tap water was more effective than saline in reducing the infection rate in adults with chronic wounds. There was also no significant difference in infection rates when wounds were cleansed with tap water. This process also has the added advantage of cleansing the surrounding skin.

In terms of dressing selection there are a variety of wound dressing products available on prescription with various levels of evidence to support their use from randomised controlled trials to case study analysis. Because infection was present in the wound an antimicrobial dressing (Iodoflex) was chosen as the primary wound dressing. Topical antimicrobial agent's help to reduce the bioburden of the wound thus reduce infection (White et al 2001). A critical review of the literature pertaining to the use of topical antimicrobials has been carried out and is available in Section 3.0 of this thesis.

Iodoflex is a cadexomer iodine, which provides slow release in the wound and is a useful bacteriostatic and bactericidal agent that is active against MRSA (Methicillin-resistant *Staphylococcus aureus*) and other pathogens (Mertz et al 1999). It also absorbs exudate, which was present in large volumes at the wound site. As the bacterial load reduced so too did the pain and the odour from the wound. This resulted in reduced anxiety for Chris, both in terms of when he was having the dressing renewed and in his confidence at work. Whilst Iodoflex is recommended for the use of non-healing and infected wounds, once the infection or critical colonisation has reduced and the wound shows signs of healing it is advisable to change the dressing

for one appropriate to the needs of the wound (Gilchrist 1997). The Iodoflex dressing was discontinued on the 23/4/02, after six weeks of treatment and a non-adherent dressing prescribed as a primary dressing. Research shows that it is not the primary dressing that heals a venous leg ulcer, but the graduated sustained compression (Backhouse et al 1987). Chris also had his dressings reduced to once a week as the infection had subsided and exudate levels had reduced. However on his return visit, the non-adherent dressing had adhered to the wound, and this was painful to remove. A foam dressing (Allevyn) which is non-adherent and absorbent was then chosen and applied. Chris found this dressing comfortable and acceptable. It is also cost effective in that it can remain in place for up to a week under compression therapy. These are key recommendations for the ideal wound dressing (Thomas 1990). It is worth noting that silver dressings had not become available for use in primary care when this case study was carried out, but could have been an alternative treatment choice for infection management if they had been available (Dowsett 2004).

#### **2.11.4 Pain, particularly at dressing change**

Pain was another symptom presenting as a result of a breakdown in Chris's normal line of defence, caused by his leg ulcer and associated infection. Pain is a complex, subjective and perceptual phenomenon which is influenced by physiological, psychological, emotional and social factors. There is an increasing acknowledgement that pain is a major issue for patients suffering from many different wound types (Briggs & Hoffman 1999). Much of the research in wound care has in the past focused on healing as an outcome and issues such as pain have been largely forgotten. However there is an increasing body of research which is focused specifically on reducing pain in wound care patients (Franks et al 1994, Briggs 1999, Hollinworth 1999, Naylor 2001, European Wound Management Association 2002). Pain during dressing changes is such an important aspect of practice that the European Wound Management Association chose this topic for its first position document (European Wound Management Association 2002). The vision for this document, published in English and four other languages was to provide clear clinical advice on the assessment and management of pain during wound dressing changes. The document recognised that there is limited evidence to support current professional practice in managing wound pain. Since this case study was undertaken, the World

Union of Wound Healing Societies have produced a consensus document 'Principles of Best Practice' Minimising pain at wound dressing-related procedures (WUWHS 2004) which makes recommendations for understanding, assessing and managing pain in patients with wounds.

It has been established that patients with wounds such as leg ulceration experience significantly greater bodily pain than the normal population, which is not merely a consequence of leg ulcers affecting an older population, but a feature of the wound and associated underlying abnormal pain mechanisms (Franks & Moffatt 1989). Studies show that pain improves with effective treatments that facilitate healing (Franks et al 1994). The focus of most of this research was on patients with venous leg ulceration and no major study has considered pain in patients with sickle cell leg ulceration. There are also cultural variations in the experience of pain that need to be taken into account, especially working in a multi-cultural society such as that in East London. However in this case study the patient's pain did improve with the use of evidence based dressings and compression bandaging as well as the use of analgesia.

Research has shown that practitioners are often complacent or unwilling to accept the degree of suffering of patients from wound related pain (Hollinworth 1999). While many practitioners may be aware of issues surrounding wound pain, all too often they fail to manage that pain effectively at dressing change (Hollinworth & Collier 2000). It was not unusual to find that the community nurse undertaking Chris's dressing change accepted the fact that he was in pain as part of the process and did not explore ways in which this could be avoided.

The Nurse Consultant addressed these issues in a number of ways that included:

- Reducing anxiety
- Ensuring adequate analgesia
- Ease of dressing removal
- Appropriate dressing choice
- Education and training of other nurses involved in care
- Ongoing evaluation and monitoring.

Time invested in talking to the patient prior to removing the dressing is well spent.

Discussing measures that have been taken to reduce pain also helps to reduce feelings

of fear and anxiety. Anxiety, like pain, is influenced by physiological and psychological factors. It generates an autonomic response and this, together with past pain experience and attention to current pain, can contribute to the interpretation of painful stimuli (Vingoe 1994). Taking time to talk to Chris specifically about his pain became part of his visits for dressing change and supported him in developing his lines of resistance so that he could rebuild his normal lines of defence.

Ensuring adequate analgesia was taken was also a priority in his management. Chris usually took his Pethidine tablets at noon, but changed this on the days he was having his dressing renewed to half an hour before attending the clinic. He found this eased the pain considerably. Irrigation of the wound dressing with warm normal saline was also recommended to ease removal. This intervention also contributed to a reduction in pain. The type of dressing in use was reviewed so that there was minimal sensory stimuli to the sensitised wound area on removal. Soft silicone products have been recommended to help minimise pain and trauma at dressing removal (Hollinworth 1999, Naylor 2001). For this reason a foam dressing (Allevyn) was chosen as the primary dressing as the non-adherent dressing had caused pain on removal.

## **2.12 Evaluation and reflection**

An evaluation of the problems identified and outcomes resulting from primary interventions, demonstrated that overall the plan of care and nursing actions had been successful. Chris had become less anxious as the treatment progressed and his normal lines of defence were restored so that he was able to cope with his ill health. Restoring his flexible line of defence by appropriate management of his wound infection and odour together with a reduction in the size of the wound led to an improved quality of life, as exudate levels reduced and he no longer had to worry about wound odour. His leg ulceration responded well to the application of graduated sustained compression bandaging which restored and supported his normal lines of defence and gradually the frequency of treatment was reduced from twice a week to once a week. Changing from bandages to compression hosiery as a treatment option in the latter stages of healing allowed Chris to become more involved in his care and to resume his family activity of weekly swimming. This in turn contributed to his feelings of well being which proved to be a valuable resource for Chris in helping him to defend against the stress of ill health and protect his basic structure energy resources (Neuman 1985).

Chris's ulcer healed at the end of the period of care and he said that he was "glad to have his life back again". He was referred to the healed leg ulcer clinic for tertiary prevention.

Evaluation of nursing interventions to reduce pain were not as successful as other interventions. Although his pain reduced he was never totally pain free. Chris and the nurses caring for him found this the most difficult aspect of care. Although his normal defence lines were restored, at times his flexible lines of defence continued to break down when his pain was poorly controlled. Further reflection by the nurses involved in his care has been encouraged, so see if lessons can be learnt for the future. The World Union of Wound Healing Societies (2004) 'Principles of Best practice' Minimising pain at wound dressing-related procedures has been incorporated into the wound care educational programme in the Primary Care Trust.

It is important that nurses reflect on the care that is given to the patient, both at the time the care is given and after an episode of care, to learn new ways of working for the future. Learning by thinking on experience is not a new concept. Schon (1983, 1987) posits that knowledge is embedded in and demonstrated through the artistry of everyday practice, in clever things done 'on the job' and yet which are typically so difficult to describe linguistically. The idea of 'theory in use' has been developed by Argris & Schon (1974,1978) which proposes that practitioners choose their actions carefully for a particular situation based on theories generated from their experiences, education, values, beliefs and past strategies. This is a useful approach that can assist the practitioner when reflecting in action and on actions retrospectively. It takes reflection to the bedside and makes it a realistic and applicable concept for practice.

Using self awareness as a tool for reflection, the Nurse Consultant was able to identify feelings of helplessness at the despair shown by Chris when he was first referred to the service. It was difficult to find the words to comfort him and because of the lack of documented case studies in this area, it was difficult to predict what the outcome from nursing interventions would be. Recognising and sharing these limitations in terms of personal knowledge and available research proved to be a useful way forward. Lack of knowledge and experience in general in the management of sickle

cell disorder was also identified by the Nurse Consultant and the other nurses involved in his care. This raised issues around expanding the focus of tissue viability and working collaboratively with the haemoglobinopathy service to develop patient care pathways. Patient's with sickle cell leg ulceration and other complex wounds need a multi-disciplinary approach to ensure better outcomes.

The process of reflection in action during the implementation phase allowed for the treatment programme to be altered in response to the patient's identified needs. Examples of this included changing from four layer bandaging to three layer to reduce pain, altering the time analgesia was taken, and changing from a non-adherent dressing to a foam dressing to reduce pain and discomfort at dressing change. Reflecting on actions has demonstrated a need to improve communication links between the tissue viability service and the haemoglobinopathy service so that patients with sickle cell disease and leg ulceration can be referred earlier. It has also raised issues around patient's pain management at dressing change. The nurses involved in changing the dressings and bandages paid very little attention to the amount of pain that Chris was in. It was as though they accepted it as part of the process of dressing the wound. Few nurses were aware when asked of the EWMA (2000) position document on pain at dressing change. Recommendations from this and WUWHS (2004) have now been incorporated into local wound management guidelines

This case study has impacted on practice in a number of ways. It has improved referral pathways between two specialist areas of practice, so that when patients present with leg ulceration in the haemoglobinopathy department, they are directly referred to the tissue viability service. It has raised nurse's awareness of the significant impact that this type of leg ulcer has on the patient's quality of life, particularly focusing on pain. Incorporating the recommendations from EWMA (2000) and WUWHS (2004) into education and training for clinicians will hopefully improve practice and the patient's experience. This however will need to be audited for the future to determine the impact. Finally the case study has contributed to the body of knowledge that exists on managing these types of wounds as it has been

published in a peer review journal. The work supports the theory that compression therapy has a role to play in the management of patients with sickle cell leg ulceration.

### **2.13 Conclusion**

Managing patients with sickle cell disease and leg ulceration is challenging for clinicians due to the multi-dimensional nature of the problems they present with and the lack of robust clinical evidence to support practice. There are also considerable challenges for the patient who experiences pain, wound infection, depression and social problems as a result of the problem. Using a systems model (Neuman 1989) to identify the stressors that have lead to a break in the patient's flexible and normal line of defence and a structured approach such as case management can improve the care offered to these patients, as clearly demonstrated by this case study.

To ensure future success when managing these patients, clinicians need to reflect on their experiences and those of their patients, and learn from these reflections, so that care can advance in a sometimes neglected area of practice.



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### **3.0 Critical Review of Literature: The use of antimicrobial therapy in wound management: a focus on silver dressing**

#### **Abstract**

**This critical review of the literature evaluates the available literature pertaining to the use of antimicrobial therapy in wound management, focusing specifically on silver dressings. For many clinicians confusion exists over the use of topical antimicrobials and this confusion is compounded by the number of silver dressing's available and conflicting information from wound care companies. Silver dressings have a role to play in the management of critically colonised and infected wounds or where delayed wound healing suggests that this may be a problem. When choosing a dressing, the clinician should consider the condition of the wound, exudate levels, adaptability of the dressing to suit the wound and patient preference. Long term use of antimicrobial dressings should be avoided and all wounds should be regularly reviewed and referred for specialist advice if not progressing to healing.**

#### **3.1 Introduction**

This critical review of the literature is a coherent analysis of the literature on the use of antimicrobial therapy in wound management with a focus specifically on the use of silver dressings. The review took place in 2003 when an abundance of silver dressings became available for use in the community setting and clinicians expressed confusion when making choices for their patients. The literature review was undertaken for the period 1985 – 2003, using the following databases, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, The Cochrane Library and World Wide Wounds web. Non-English language studies were excluded. Key search words used were:

- Wound infection
- Antimicrobials/antibacterials
- Silver compounds
- Silver dressings.

Hand searches of wound care journals including the Journal of Wound Care, Journal of Tissue Viability, British Journal of Nursing, recent wound care conference abstracts and company literature on silver dressings were undertaken. References lists from key articles were used to further search for data. An updated search using Pubmed was carried out on 11/5/04 using key words 'silver dressings' for recent publications, and 2004 conference proceedings reviewed.



A number of overall issues emerged from analysis of the literature including:

- Wound infection
- Use of topical antimicrobials
- Silver as an antimicrobial agent
- Silver resistance, safety and toxicity
- Silver in wound care
- Modern silver dressings.

Not all patients will experience a wound infection that necessitates the use of topical antimicrobials. For the majority of individuals, wound repair is thought of as an ordered set of occurrences that proceeds relatively quickly and with few complications. Typically, the wound repair process involves steps that include inflammation around the site of injury, angiogenesis and the development of granulation tissue, repair of the connective tissue and epithelium, and ultimately remodelling that leads to a healed wound.

This acute wound-healing model does not apply well to chronic wounds and many of these wounds such as leg ulcers and pressure ulcers will take many months and some times even years to heal. Chronic wounds become stuck in the inflammatory and proliferative phases of wound healing (Ennis and Meneses 2000). There also appears to be an abnormal over-expression of extracellular matrix molecules, which result from cellular dysfunction and dysregulation within the wound (Schultz et al 2003). Whilst there may be abundant growth factors within the wound, these become trapped and are no longer available to the repair process.

Most chronic wounds such as leg ulcers and pressure ulcers are treated in primary care with up to 80% treated by community nurses and GPs (Callam et al 1985). Treatment of these wounds is costly both for the patient in terms of reduced quality of life and financially for healthcare providers. Franks et al (1994) in a study of 758 patients with leg ulceration found that this condition caused pain, reduced mobility, poor energy and social isolation. The cost of treating this patient group was estimated to be as high as £230-400 million in 1991, of which nursing time is a major contributor (Bosanquet 1992). Good patient assessment and treatment of the

underlying cause of the wound is essential if local wound care intervention is to be successful. Patient factors such as poor peripheral perfusion, diabetes, poor nutrition and smoking will all delay wound healing and increase the risk of wound infection, as will local factors at the wound bed such as the presence of necrotic tissue and infection (Dowsett and Ayello 2004).

Provision of the optimum wound healing environment is one of the most crucial determinants of wound closure rate once the underlying cause has been addressed, and is founded on the practitioner's ability to select the most appropriate dressing for the type of wound and objective of treatment. That selection needs to be based on the most up to date evidence and this is an ongoing challenge for practitioners given that new and varied dressings become available for use on a regular basis. Recent advances in biotechnology and original research have provided unique opportunities to develop dressings that are closely tailored to the type of wound to be treated. They are biocompatible and are proving to be of value in advancing wound healing in difficult to heal wounds, while alleviating patient discomfort. The most recent dressings that have become available for practitioners are those containing silver. They are recommended for the prevention and treatment of infection in surgical wounds, burns and chronic wounds such as leg ulcers. However there appears to be some confusion among practitioners about when to use a particular silver dressing and for how long they should be used.

Silver has a long history of medical use, notably in the treatment of burns. Elemental silver, its salts and ionic form are antiseptic active against a wide range of micro organisms, including bacteria and fungi. Topical silver preparations have been widely used in burns therapy and the successful use of silver sulphadiazine on infected acute and chronic wounds, and traumatic wounds has also been demonstrated (White 2001). This literature review investigates the evidence to support the use of silver dressings in wound care, provides an overview of the dressings available at the time of this review, and recommendations for practice.

### **3.2 Wound infection**

One of the events that impedes wound healing is colonization of the wound bed by micro-organisms, the bacterial flora found in chronic wounds being different from that found in acute wounds (Hegggers 1998; Bowler and Davies 1999). In addition to the production of a variety of toxins and proteases, the presence of micro-organisms in a wound may also lead to a prolonged inflammatory response. The host inflammatory response is remarkably effective at eliminating the invading microbial population, but that same process over time may damage the surrounding skin (Wright et al 1998). Inflammatory response may also be reduced in patients who have diabetes or are immunosuppressed (Dow et al 1999).

Chronic wounds are often heavily colonised with bacteria or fungal organisms. This is due in part to the fact that chronic wounds remain open for prolonged periods, but also related to other factors such as poor blood supply, hypoxia and underlying disease processes (Hunt and Hopf 1997). The presence of bacteria in chronic wounds does not necessarily indicate that infection has occurred or that it will lead to impaired wound healing (Kerstein 1997, Dow et al 1999). Micro-organisms are present in all chronic wounds, and it has been suggested that certain low levels of bacteria can facilitate healing (DeHann et al 1974, Pollock 1984). Bacteria produce proteolytic enzymes such as hyaluronidase, which aids wound debridement and stimulates the release of proteases (Stone 1980).

Bacterial involvement in a wound can be divided into four categories, contamination, colonization, critical colonization and wound infection. Wound contamination is the presence of non-multiplying bacteria in a wound (Ayton 1985). Wound colonization is the presence of replicating micro-organisms adhering to the wound without a host reaction. The microbial flora of chronic wounds changes with time and wounds of several months duration develop a 'microbial soup' of different organism types (Dowsett et al 2004). If mixtures of potential pathogens are multiplying, this may lead to a delay in wound healing and the 'critical colonization' stage is reached (Kingsley 2001; Schultz et al 2003). Unsuppressed, the natural progression from this stage is to wound infection. This is when the bacterial load and the virulence factors that bacteria produce are greater than the host's immune defences, resulting in harm to the host (Dow et al 1999).

Wound bacteria can be acquired from the patient's own flora, from the environment or from other people. The most common bacteria found in acute and chronic wounds are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, with anaerobes and various coliforms occurring frequently in chronic wounds (Bowler et al 2001). The probability of healing is significantly lower if four or more bacterial groups are present in a wound, suggesting that they interact to enhance pathogenic effects. Factors such as organism type and numbers, their synergistic interactions and the virulence factors they produce, all affect the healing outcome (Trenegove et al 1996). However the greatest single influence is the host resistance. The quantity of bacteria required to generate an infection may also vary with the type of predominant bacteria. Robson and Heggers (1970) stated that the  $10^5$  cfu/g or  $\text{cm}^2$  levels of bacteria are usually required to generate an infection. This information is based on quantitative biopsies and this method of wound sampling is not practical in most clinical settings.

Alternatively, it is suggested that some bacteria at critical levels of inoculum may provide a stimulus to healing (Tenorio et al 1976; Raju et al 1977). The resulting confusion has prompted the generation of a novel approach, that of the concept of critical colonization (Davies 1997). Organisms can work in synergy for example aerobic organisms consume oxygen, inducing tissue hypoxia and thus favouring the growth of anaerobes. Additionally one organism may produce nutrients that allow multiplication of a more fastidious and possibly a more pathogenic second organism, and some anaerobes may impair the host immune response improving survival chances over those of other cohabiting organisms (Bowler et al 2001). Anaerobes have been shown to constitute 30%-60% of the microbial species in colonized chronic wounds and infected chronic wounds (Bowler et al 2001), yet microbiology laboratories often fail to isolate them in routine wound swabs.

More recently, the importance of biofilms has become apparent in the context of wound infection, and these may contribute to delayed healing in chronic wounds (Enoch and Harding 2003). Until recently microbial cells were thought to function independently, but research into bioluminescence of marine bacteria during the 1960s showed that cells within a community communicated by chemical signals, and acted co-operatively depending on cell density (Rumbaugh et al 1999). For Gram-negative

bacteria, the signalling molecules are acyl homoserine lactones; and, for Gram-positive bacteria, peptides. Bacteria sense these chemical signals, and the number of cells within a community is detected so that when a critical cell density is exceeded, changes in gene expression are triggered. For some species, biofilm formation is initiated with collective synthesis of extracellular matrix and the formation of complex three-dimensional structures (O'Toole et al 2000). These biofilms are micro colonies that become attached to the wound bed and secrete a glycocalyx or biofilm that helps to protect the micro-organisms from antimicrobial agents such as silver dressings and can contribute to a delay in wound healing. Treatment of the biofilm is essential for effective use of antimicrobial dressings.

It is not easy to predict whether a wound will develop an infection or not. Factors that predispose a wound to bacterial invasion include the size and shape of the wound location on the body, duration, the presence of foreign material, and local oxygen levels which all influence the ability of micro-organisms to survive. However, the greatest single influence is the immuno-competency of the patient, which is affected by several genetic and environmental factors (Heinzelmann et al 2002). Partly in response to concerns regarding bacterial proliferation in moist wound beds and to the rapid and steady increase in the number of antibiotic resistant bacteria, novel methods of managing wounds are being developed. One of the strategies for preventing and treating wound infection that is gaining renewed attention is the use of topical antimicrobial agents. The most frequently used topical antimicrobials in modern wound care practice include iodine or products containing silver (Cooper 2004).

### **3.3 Topical antimicrobials**

The control of wound bio-burden is believed to be valuable in avoiding possible deterioration into infection; in reducing critical colonization; and in treating frank infection. While the immune response is the governing factor in the development of infection, the reduction of bio burden, can enable host defences to regain control. Topical antimicrobial agents, carefully selected and correctly dosed, can help achieve these goals.

Antimicrobial agents have been applied to wounds for thousands of years (Moellering 1995), but the relentless emergence of resistant strains has forced the continued search

for novel agents. As each new type of antimicrobial agent has been discovered and introduced into clinical practice, changes in microbial sensitivity have occurred. A new antimicrobial agent limits the growth of susceptible strains of bacteria, but eventually resistant strains emerge. These agents do not induce the formation of resistance genes, but merely provide an environment in which sensitive species are curtailed and resistant species flourish.

Resistance can arise by mutation and also by the exchange of resistance genes between resistant and non-resistant strains of bacteria. The emergence of wound pathogens with patterns of multiple antibiotic resistance is having serious consequences in the hospital environment (Morgan et al 2000), nursing homes (Fraise et al 1997), and in the community (Moreno et al 1995). The situation is compounded by the increasing costs of searching for new antimicrobials and the decreasing rate of discovery of new agents (Moellering 1995). Appropriate use of topical antimicrobial is therefore essential in order to minimise or reduce resistance.

### **3.3.1 Antibiotics**

Guidelines for the correct use of antibiotics have been defined (Berendt and Lipskay 2003). Appropriate systemic antibiotics are deemed essential for the treatment of clinically infected wounds, especially where there is spreading infection e.g. cellulitis (Bowler et al 2001). Conversely Robson (1997) showed that systemic antibiotics do not reach the intended target of infected tissue in chronic wounds at sufficient levels to ensure a therapeutic effect. The European Pressure Ulcer Advisory Panel (1999) does not recommend the administration of systemic antibiotics for local infections in pressure ulcers. However Edmonds et al (2004) recommends that systemic antibiotics should always be used when infection is present in the patient with diabetic foot ulceration. This would suggest that the use of antibiotics is dependent on the patient and the type of wound being treated. The use of topical antibiotics should however be avoided in most cases (Dow et al 1999) and is not justified for the routine treatment of colonized or infected wounds (Drug and Therapeutics Bulletin 1991). Topical antibiotics can cause hypersensitivity reactions (Zaki et al 1994) and selection for resistance (British Medical Journal 1977). There is evidence that the routine use of antibiotics in the management of clinically infected leg ulcers is of no benefit (Alinovi et al 1986). In a meta-analysis of randomised trials, Cummings and Del Beccaro

(1995) could not find any evidence that antibiotics prevent infection in simple wounds. Periti et al (1998) suggests that prophylactic antibiotics should not be used for simple, uncomplicated, surgical or traumatic wounds. They do however recommend prophylaxis for these wounds if they are heavily contaminated.

### **3.3.2 Antiseptics**

For many clinicians involved in wound care confusion exists over the use of antiseptics. The value and use of eusol has led to vigorous debate and polarization of healthcare professionals into a majority that oppose its use under any circumstances (Leaper 1992). The UK consensus on the use of eusol is that it has no place in wound care (Roe et al 1994). This view is based on evidence that it is rapidly deactivated in the presence of pus, is painful to the patient and delays wound healing by damaging cells and capillaries (Leaper 1988). Iodine compounds have also been the subject of criticism on the basis that they are potentially toxic (Lawrence 1998) and have been shown to delay wound healing (Brennan and Leaper 1985). A review of the literature on the clinical evidence for the use of topical antiseptics in wound management suggests that use should be subject to a risk-benefit assessment of possible local toxicity with beneficial antibacterial action (O'Meara 2001). Inappropriate use of antiseptics may be uncomfortable for the patient, time consuming and costly (Scanlon and Dowsett 2003). Brennan and Leaper (1985) advise balancing the beneficial antimicrobial effects and bioavailability with possible cellular toxicity before use. If antiseptics are used in solution form to irrigate or cleanse the wound they are usually in higher concentrations and therefore more likely to cause tissue toxicity and delayed healing. Antiseptic agents incorporated into dressings are in contact for much longer and therefore more dilute with less toxicity and a more prolonged antimicrobial effect. Morison (1990) suggests the following key attributes of an ideal antiseptic; broad spectrum of activity; low potential for resistance; non-toxic; rapid action; non irritant or a sensitizer; and effective even in the presence of wound exudate, pus and slough.

Topical antimicrobials are most appropriate when used to decrease the bacterial burden in chronic wounds with active but local infection. They are not suitable for highly infected wounds with soft tissue invasion or systemic sepsis and should not be used as a substitute for debridement. Increasing antimicrobial resistance means these agents should not be used for extended periods of time and should be followed by

using an appropriate wound dressing once the bacterial burden has been reduced (Dowsett et al 2004).

### **3.3.3 Iodine as an antimicrobial agent**

There is continuing controversy over the use of this antiseptic (Gulliver 1999). Concerns have generated from toxicity reports that generally refer to older preparations such as tinctures and solutions of higher concentrations of iodine (Gilchrist 1997). Iodine, particularly in the safe, modern iodophor povidone-iodine (polyvinylpyrrolidone iodine complex, or PVP-1) and the cadexomer is a very useful bacteriostatic and bactericidal agent being active against MRSA and other pathogens (Mertz et al 1999). The cadexomer is a polysaccharide starch lattice containing 0.9% elemental iodine that is released on exposure to exudates (Lawrence 1998) and has antimicrobial activity for up to three days (Mertz et al 1999). It has been extensively evaluated in a variety of acute and chronic wounds and found to be safe and effective (Sundverg and Meller 1997). A positive case study evaluation has previously been described in this thesis, section 2.11.3.

### **3.3.4 Silver as an antimicrobial agent**

Silver has been used for medicinal purposes for several thousand years (Goodman and Gilman 1975). It has a widely recognised as an effective broad-spectrum antimicrobial agent (Burrell et al 1999, Thomas and McCubbin 2003a). Metallic silver is relatively un-reactive, but in aqueous environments silver ions are released and antimicrobial activity depends on the intracellular accumulation of low concentrations of silver ions. These avidly bind to negatively charged components in proteins and nucleic acids, thereby effecting structural changes in bacterial cell walls, membranes and nucleic acids that affect viability (Lansdown 2002). In particular silver ions are thought to interact with thiol groups, carboxylates, phosphates, hydroxyls, imidazoles, indoles and amines either singly or in combination, so that multiple deleterious events rather than specific lesions simultaneously interfere with microbial processes (Grier (1983). Hence silver ions that bind to DNA block transcription, and those that bind to cell surface components interrupt bacterial respiration and ATP (adenosine triphosphate synthesis) (Trevors 1987).



Silver is effective against a broad range of aerobic, anaerobic, Gram-negative and Gram-positive bacteria, yeast, filamentous fungi and viruses (Lansdown 2002). Silver has also been shown to be effective against methicillin- and vancomycin-resistant strains and no resistant strains have been encountered (Lansdown 2002). Thurman and Gerba (1989) suggest that the antimicrobial effects of silver are usually attributed to; interference with bacterial electron transport; binding of DNA of bacteria and their spores thus increasing the stability of the double helix and impairing cell replication; cell membrane interactions causing structural and receptor function damage; and formation of insoluble and metabolically ineffective compounds. In combination with its broad antimicrobial properties, silver also appears to have anti-inflammatory properties (Demling and DeSanti 2001). Wright et al (2002) studied matrix metalloproteinases (MMPs), cell apoptosis and healing in a porcine wound model, where wounds were dressed with nanocrystalline silver, silver nitrate and saline soaks. They suggest that the nanocrystalline silver may modulate the actions of the MMPs, and thereby create an anti-inflammatory effect. This suggests that in clinical practice silver dressings may also be suitable for use in wounds where the underlying cause is due to inflammation such as pyoderma gangrenosum and vasculitis; however more evidence is needed to support this view.

In the early 20<sup>th</sup> century silver proteins and colloidal silver preparations became popular. Silver as an antimicrobial for the treatment of mucous membrane infection was highly effective, in contrast to other antimicrobial agents, with little recognised development of resistance. However, the antimicrobial potency was closely related to the amount and rate of silver released (Lansdown 2002). The first silver salt used clinically was a topical solution of 0.5% silver nitrate, which represented the lowest concentration at which antibacterial action was obtained with no toxic effects on growing epidermal cells (Klasen 2000). However, clinical experience showed the silver was rapidly deactivated and to maintain efficacy, large quantities of dressings soaked in this solution had to be applied regularly to the burned area (Fox 1983). Silver sulphadiazine cream was developed in the 1960s and is still used today. It has been widely accepted as a treatment for burns and chronic wound; however, it required frequent applications to maintain its antimicrobial control (Dowsett 2003).

Silver is an inert metal and does not react with human tissues in its non-ionised form. In the presence of moisture such as wound exudates, silver readily ionises to release  $\text{Ag}^+$  or other biologically active ions, which bind with proteins on cell surfaces, including bacteria and fungi. Silver is contained in wound dressings in a variety of forms, which vary in their capacity to liberate silver ions. They range from silver metal in microcrystalline form, prepared using nanotechnology as in Acticoat (Smith & Nephew) dressing, and silver-impregnated 'activated' charcoal such as actisorb silver 220 (Johnson & Johnson), to inorganic silver compounds such as nitrate, chloride and sulphadiazine.

The solubility and ionization of the silver sources used in wound dressings vary greatly (Burrell 2003). Silver nitrate is freely soluble and ionizes readily, whereas silver chloride is largely insoluble in water at room temperature and releases only about 1.3  $\mu\text{g Ag}^+/\text{ml}$ . Gibbons (2003) suggests that an ionic concentration of 1.43 parts per million (ppm) is sufficient to kill or inhibit a wide range of micro organisms. Silver products based on micro fine particles of silver metal with a particle size of  $< 20\text{nm}$  release 70-100ppm silver ions into a wound within four hours (Wright et al 1998, Burrell 2003). What is not clear from the literature is the minimum amount of silver needed in a wound care dressing to be effective in killing bacteria without causing local reaction or increasing the possibility of resistance developing. This lack of evidence makes it difficult for clinicians when choosing a silver dressing, with each wound care company giving conflicting advice. Many clinicians do not understand the significance of parts per million and are unable to apply this information to practice. Further research is needed to address these questions.

### **3.3.5 Silver resistance, safety and toxicity**

Bacterial resistance to silver was documented by Lowbury (Lowbury et al 1976; Lowbury 1977) in clinical trials with silver nitrate and silver sulphadiazine (1%) and a cream containing silver nitrate (0.5%) and 2% chlorhexidine were comparably effective in protecting burns from infection, but silver nitrate compresses were less effective against Gram-negative bacilli. Resistance to silver has been studied in laboratory strains of *E.coli* and *Pseudomonas* species. Starodub and Trevors (1990) found that silver accumulation by a sensitive strain of *E.coli* was more than five times higher than that seen in resistant strains. Silver sensitive bacteria produced 33% less

hydrogen sulphide. It has been suggested that resistance to silver may be attributed to the formation of silver-sulphide complexes within the cell and intracellular 'protective system' involving cytoplasmic particles or plasmids (Starodub and Trevors 1998, 1990).

Silver compounds may react with environmental pollutants to form the black silver sulphide. When this occurs to topical or systemically applied silver medicaments the result is a grey discolouration (argyria) of the skin, sclera, nails and mucous membranes (Pariser 1968; Lansdown 1995). This is particularly evident after prolonged use of silver nitrate (Marshall and Schneider 1977), but occurs very rarely when using silver sulphadiazine (Dipuis et al 1985). There are no reported cases of argyria in the modern silver wound care dressings.

The safety of silver has also been investigated. In a review of 650 cases of children treated with topical silver sulphadiazine 1% for burns and scalds over a five year period, Lockart et al (1983) found four instances of neutropenia and two of erythema multiform rash. All were attributed to the sulphadiazine moiety. Urinalysis showed a mean urinary concentration of sulphadiazine of 31.8mg/l. . In another study by Kulick et al (1985) on severely burnt patients evidence of sulphadiazine sensitization in the form of circulating IgG antibodies were found. There was however no reference to toxicity to silver. Overall the evidence in the literature, although limited, demonstrates that it is safe to use silver in wound care. Silver nitrate topical and systemic dosage forms have been found to give rise to toxicity in the intestine (Monafo and Moyer 1968) and to new kinin cells (Demling and DiSanti 2001). However this toxicity has been attributed to the nitrate component, which is a potent oxidizing agent and not to the silver. Silver nitrate is no longer used routinely in wound care practice.

### **3.4 Silver in wound care**

References to the use of silver on chronic wounds date back to studies on ulcers in the 17<sup>th</sup> and 18<sup>th</sup> centuries (Klasen 2000). According to Klasen (2000a) one of the earliest texts to mention silver nitrate was by John Woodall in 1617, where silver nitrate is referred to as either 'infernal stone' or 'lunar caustic'. It was regarded as an essential component of every surgeon's equipment and was used to treat venereal disease, to open abscesses, and to 'reduce proud flesh and sores'. This term refers to hyper

granulation, which is often seen in healing chronic wounds and up until recently silver nitrate sticks were in use for the same purpose in chronic wound care.

The use of silver nitrate on burns and in ophthalmology appears to have begun in the early 19<sup>th</sup> century. Klasen (2000a) highlights the work of Rust in 1803, which used a dilute solution of silver nitrate (0.2%) to successfully manage third degree burns. Silver nitrate solutions continued to be used until the advent of antibiotics, penicillin and sulphonamides, when its use declined (White 2001). A renewal in the use of silver began in the 1960s when the American surgeon Moyer began using it to reduce the risk of infection in burns and grafted areas (Moyer et al 1965). He found that using silver nitrate dressings on these wounds was effective against *staphylococcus aureus*, *pseudomonas aeruginosa* and haemolytic streptococci without resistance developing.

Silver sulphadiazine (SSD) was first formulated as an ointment and an aqueous cream in 1967 (Fox 1983). Although primarily intended for the treatment of burns, SSD has been used successfully in the treatment of leg ulcers (Margraf and Covey 1977; Blair et al 1988; Bishop et al 1992). In a recent systematic review of antimicrobial agents for chronic wounds, evidence was found supporting the use of SSD as a topical antimicrobial in the management of infected wounds (O'Meara et al 2001).

Clinical and experimental studies claim that silver released from dressings promotes or kick starts wound healing by promoting haemostasis, reducing inflammation, and enhancing re-epithelialization and neovascularization, but these claims are still the subject of debate (Kjolseth et al 1994; Lansdown 2002; Sibbald et al 2000; Karlsmark et al 2003). There do not appear to be any studies which demonstrate that silver released from any product influences haemostasis in acute or chronic wounds, even though experimental studies suggest that local calcium concentrations may be raised (Lansdown et al 1997). Whilst acute wounds with low levels of infection and minimal systemic or other complications do seem to heal better in the presence of silver, some chronic or indolent wounds exposed to silver sulphadiazine or silver-containing dressing may persist for many months with questionable signs of improvement (Ballard and McGregor 2002). It has to be remembered that acute wound healing is different from chronic and that there are many underlying reasons why chronic wound do not heal, such as poor general health, immobility and poor

nutrition. Not all wounds that are slow to heal are critically colonised with bacteria or infected, and therefore correct diagnosis of the problems contributing to non-healing is critical.

### **3.5 Modern silver dressings**

A number of wound dressing products containing silver have been developed in the last decade. These are intended for use on colonized or infected wounds or as a prophylactic measure in patients at-risk of infection. The rationale behind these products is to use a safe and effective topical antimicrobial that provides sustained effect over days with zero potential to develop resistance (White 2001). A variety of topical silver preparations have been evaluated on chronic wounds (O'Meara et al 2000, 2001) in controlled trials with favourable results. More recently a number of new silver-containing dressings have become available including; Acticoat (Smith & Nephew), Aquacel Ag (Convatec), Contreet (Coloplast), Actisorb 220 (Johnson & Johnson), Urgotul S Ag (Urgo) and Advance (SSL International). Clinicians have become confused by the number of new products available and the way in which they are marketed for use in the clinical environment.

Acticoat (Smith and Nephew) is a silver dressing with nanocrystalline silver, consisting of two sheets of high-density polyethylene mesh coating with nanocrystalline silver with a rayon-polyester core. These nanocrystals provide rapid yet sustained release of silver to the wound bed at 70mg/l (ppm) making it a highly effective antimicrobial agent. The dressing core absorbs and retains moisture, thus helping to maintain a moist environment at the wound/dressing interface. It has been shown to effectively inhibit more than 150 organisms including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococi (VRE) (Smith & Nephew 2001). Acticoat is designed to stay in place for up to 3 days and Acticoat 7 for seven days. It is activated by using water (sterile or tap) and the use of saline should be avoided, as this de-activates the silver in the dressing.

Aquacel Ag (Convatec) is a silver impregnated antimicrobial absorbent dressing in a soft sterile, non-woven pad or ribbon dressing composed of hydrofiber and ionic silver. The dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface and maintains a

moist environment, aiding autolytic debridement. It has been shown to provide broad-spectrum activity against a variety of microorganisms including anti-biotic resistant bacteria. Aquacel Ag can be used in chronic wounds for up to 7 days (Convatec 2004).

Contreet (Coloplast) comprises of polyurethane foam dressing, containing antibacterial silver complex homogeneously dispersed throughout the foam. Silver is released from the dressing into the wound bed when in contact with wound exudates. Contreet foam dressing is effective against certain bacterial strains known to be detrimental to wound healing such as *Pseudomonas aeruginosa* and *staphylococcus aureus*, B-haemolytic streptococcus, MRSA, and VRE. Depending on the amount of exudate, the release of silver will continue for up to 7 days or for the life of the dressing (Coloplast 2003).

Actisorb 220 (Johnson and Jonhson) consists principally of activated carbon impregnated with metallic silver. The carbonised fabric is enclosed in a sleeve of spun-bonded non-woven nylon, sealed along four edges. It is an antibacterial with a broad spectrum of activity against bacteria and fungi (Russell and Hugo1994) and reduces malodour by eliminating those bacteria that give rise to the problem, and by adsorption of odour molecules onto the activated charcoal layer. Actisorb silver 220 can remain in situ for up to 7 days depending on the level of exudate; while the secondary dressing is changed as required. Initially it may be necessary to change Actisorb silver 220 every 24 hours. (Johnson and Johnson 2001).

Urgotul SSD (URGO) is a hydrocolloid dressing which is non-adhesive and non-occlusive, which consists of polyester web which is impregnated with hydrocolloid particles (carboxymethyl cellulose), vaseline and silver sulphadiazine. It is indicated in the local treatment of superficial or deep 2<sup>nd</sup> degree burns where there is a risk of infection. The presence of silver sulphadiazine, which is an antibacterial agent, confers on the Urgotul SSD dressing the ability to act on the organisms, which are most frequently responsible for infecting wounds. Silver sulphadiazine has a wide spectrum of antimicrobial activity covering the Gram+ve and Gram-ve bacteria and certain moulds and yeasts (URGO 2004).

Avance (SSI International) is an absorbent polyurethane foam dressing containing a silver complex. According to the manufacturer, Advance decontaminates the exudate absorbed into the polyurethane foam, so can be used to prevent cross and self-infection. Clinical data on the use of the dressing is limited.

There are wide variations in the amount of in-vitro and in-vivo data to support these dressings. In-vitro studies need to be balanced with the clinical data such as prospective trials; outcome tracking and case studies combined with expert opinion when making a decision about which product to use. Guidance is provided on what to consider when choosing a silver dressing in the clinical environment (Table 1).

**Table 1 Guidance on choosing a silver dressing**

<b>Evidence for use of the dressing</b>
<b>Suitability for wound type</b>
<b>Is the wound critically colonized or infected?</b>
<b>Does the dressing fulfil the objective of treatment</b>
<b>What are the patient preferences</b>
<b>Cost effectiveness of the dressing</b>

**(Dowsett 2004)**

A number of laboratory studies have made comparisons between different products, but varying silver concentrations and different modes of delivery of silver ions make direct comparisons inappropriate. Thomas (2003a) compared the antimicrobial effects of four silver-containing dressings, namely Acticoat, Actisorb Silver 220, Advance and Contreet-H, on three organisms, in laboratory tests. The results showed that Acticoat was likely to produce the most rapid antimicrobial effect in vivo because of the rapid release of relatively large concentrations of highly active silver ions. Contreet-H has a broadly similar antimicrobial activity to Acticoat, but has a slower onset of action. Actisorb Silver 220 appears to offer fewer prospects of killing bacteria within the wound itself, but the dressing is capable of removing microorganisms from wound exudates and sequestering them until the silver within the charcoal fibres inactivates them. Little convincing evidence for any antimicrobial activity of Avance was found. A further analysis by Thomas (2003b) of ten silver-

containing dressings concluded that whilst the total amount of silver present in a dressing influenced its antimicrobial activity, the distribution of the silver within the dressing (whether it is present as a surface coating or is dispersed through the structure), its chemical and physical form (whether it is present in a metallic, bound or ionic state) and the dressing's affinity for moisture, a prerequisite for the release of active agents in an aqueous environment all influenced a dressing's ability to kill micro-organisms.. Products in which the silver content is concentrated on the dressing surface rather than 'locked up' within its structure performed well, as did those in which silver was present in the ionic form. Whilst these results may be useful to clinicians, it is important to remember that these are laboratory based studies and there are many factors in the clinical situation that will determine a dressing's acceptability and clinical effectiveness.

At the time of completing this review human studies with silver containing dressings were rather limited. Tredget et al (1998) described a randomised prospective clinical study involving 30 patients, each of whom had two burns comparable in size, depth and location. The wounds in each pair were treated with Acticoat dressing or a fine mesh gauze soaked in 0.5% silver nitrate solution and remoistened every two hours. Frequency of burn sepsis was found to be less in wounds treated with Acticoat dressing than in those treated with silver nitrate. Secondary bacteraemias arising from infected wounds were less frequent with Acticoat. The healing rates of the wound however were comparable. In an uncontrolled prospective study of 29 chronic wound patients not healing at the expected rate, Sibbald et al (2001) applied nanocrystalline silver dressings after baseline superficial bacterial swabs and quantitative biopsy. Improved healing was related to improvement in the semi-quantitative surface swabs. The majority of the chronic wounds showed improvement in the surface swabs, however quantitative bacterial biopsy results did not demonstrate any improvement in the deep compartment quantitative bacterial count.. If the deep compartment was out of bacterial balance and this was delaying healing, topical silver dressings did not reverse the impaired healing response or the increased bacteria in the deep compartment. A dramatic decrease in pain was also noted in a number of the patients who took part in the study.



Mozingo et al (2003) conducted a pilot prospective clinical assessment of the impact of Acticoat on cytokines, growth factors and MMPs in non-healing wounds. Ten patients with non-healing venous leg ulcers were randomly assigned to treatment. The results concluded that Acticoat dressing influenced the molecular composition of the wound, suppressing MMPs and tumour necrosis factor alpha (TNF-alpha) levels over the treatment period. This may further accelerate healing in previously static wounds. On an individual patient basis a number of case studies show improved healing with the use of Acticoat on chronic wounds (Dowsett 2003). However it is difficult to generalise from individual case studies.

In a controlled comparative trial of Actisorb activated charcoal cloth dressing in the community on 97 patients with chronic wounds (Mulligan et al 1986) the dressing produced a marked increase in healing rates ( $p < 0.05$ ). There was also a significant reduction in the level of exudate from the wounds ( $p < 0.005$ ) and this in turn reduced the number of dressing changes required with a cost reduction in nursing time and product usage. However the trial could be criticised as it did not compare like for like in dressing products and one might expect to see a difference when comparing occlusive dressings to silver dressings. Other conventional dressings were used in the control group but only identified as antibacterial. It might have been more useful to compare a traditionally used antibacterial to the Actisorb dressing. Additionally the patients in the test group also had their wounds desloughed with hydrogen peroxide (an antiseptic) prior to commencing the study and this could have had an impact on the level of exudate as it potentially reduces the bacterial load in the wound bed.

Karlsmark et al (2003) examined the clinical performance of Contreet Foam silver dressing in chronic exuding venous leg ulcers. The dressing was studied over four weeks in 25 patients with moderately to highly exuding delayed-healing venous leg ulcers. 23 out of the 25 patients completed the study. In the course of the four week treatment period a mean reduction in ulcer area of 56% from 15.6cms (range 3.0-58.1cms) to 6.9 (range 0.1-38.4cms) was recorded. All but one ulcer reduced in size and one healed completely after four weeks of treatment with Contreet Foam. Over the study period the dressing also dramatically transformed the visual appearance of the ulcer site from a state of unhealthy dull granulation tissue with slough and fibrin deposits to one of healthy, well vascularised granulation tissue. Blood levels were also analysed for silver levels and only five patients who had the dressing exhibited a rise

in blood silver levels, but these levels reduced after the first week of treatment. There was no consistent relationship between blood silver, ulcer size and the number of dressing changes. The patients remained in the same compression therapy during the trial (short stretch bandage). Although it is difficult to generalise from this study, due to the small patient sample, it would appear that Contreet Foam silver dressing is safe and efficacious in the treatment of chronic non-healing venous leg ulcers.

Sustained silver-release dressings are mostly well tolerated without serious side-effects (Lansdown 2004, Karlsmark et al 2003). Staining of the skin has been seen on the skin surface following application of some silver dressings (Lansdown 2004), but this is readily removed by washing and should not be confused with argyria. Argyria (grey colour of skin and conjunctiva) results from the deposition of minute granules of silver sulphide in the dermis around the basement membrane and sweat ducts. There are limited reports of argyria. Wang et al (1985) reported eleven cases out of a patient population of five hundred and nine treated with silver sulphadiazine over a ten year period. Concerns have also been expressed about silver resistance, as discussed in section 3.3.5.

Available evidence suggests that most, if not all of the sustained silver ion-release products are effective against methicillin and vancomycin resistant strains of bacteria and that no resistant strains have been encountered. Lee et al (1997) suggested that resistance could be induced using low concentrations of silver. This emphasises the importance of using clinically relevant levels of silver, and using products appropriately for short periods of time to ensure this does not become a problem for the future. Recommendations from the literature on the use of silver wound care products are provided (Table 2).

**Table 2**  
**Recommended use of silver wound care products.**

<b>Critically colonised wounds</b>	
<b>Infected wounds</b>	
<b>Delayed healing which may suggest infection or critical colonization</b>	
<b>Burns wounds</b>	<b>(Dowsett 2004).</b>

Overall the evidence concerning the efficacy of topical antimicrobial agents in the management of wounds is confusing. The evidence originates from many sources, which are not directly comparable and the results of laboratory studies will not necessarily be replicated in clinical practice as there are many patient factors to be considered. In laboratory studies the evaluation of antimicrobial agents often uses the minimum inhibitory concentration (MIC) test to determine potency and rates of inhibition, but activity can be influenced by temperature, the type of species tested and the number of organisms present. Animal models may also yield inconsistent evidence as they utilise different species, different types of wounds and different challenge organisms (Cooper 2004). The surrogate endpoint in many of the clinical studies on silver dressings has been reduction in ulcer size and not complete wound healing. This is probably appropriate because the silver may not be necessary when bacterial balance has been achieved. Other clinical criteria may be important to measure the effect of silver, such as decreased exudates, improvement in the quality of granulation tissue, odour reduction and the absence of dead or devitalized tissue on the ulcer surface.

### **3.6 Conclusions and recommendations for practice**

Treating chronic wounds is costly for the patient and the healthcare team. These wounds such as leg ulcers and pressure ulcers are predisposed to developing infection, which can lead to further complications and can be life threatening. Silver is recognised as an effective broad spectrum antimicrobial agent and is effective against a broad range of aerobic and anaerobic, Gram-negative and Gram-positive bacteria, yeasts, filamentous fungi and viruses (Lansdown 2002). Silver has also been found to be effective against methicillin- and vancomycin resistant strains of bacteria which given the problem of MRSA and the potential for this to infect wounds is of great benefit.

An increasing number of silver dressings have become available for use, but confusion exists as to when they should be used and which dressing is the most effective. Whilst much of the original work on silver dressings has taken place in laboratories, the literature shows an increasing number of clinical studies demonstrating the efficacy of these dressings. They clearly have a role to play in

managing infected wounds but are best reserved for the management of critical colonization (localized infection, covert infection or increased bacterial burden). However it is clear from the literature that where the patient has deep and surrounding skin infection systemic antibiotic therapy should be prescribed.

What is clearly lacking in the literature is evidence to support one particular silver dressing over another, as no direct comparisons in clinical practice have been carried out. What does appear to be important when making a choice is the amount of silver contained in the dressing, its distribution and the dressing's affinity for moisture. Choice of dressing will of course be influenced by the patient's preference as some dressings will be found to be more comfortable than others. What is important is that this is an informed decision and that the patient is aware of the effects and potential side effects.

As yet there are no reported cases of silver resistance in wound care. However Lee et al (1997) suggests that resistance could be induced using low concentrations of silver. This emphasises the importance of using clinically relevant levels of silver in dressings, and using products appropriately for short periods of time to ensure that resistance does not become a problem in the future. Experience from clinical practice suggests that frequently these dressings are used for long periods of time without evaluations and occasionally they are used where there is no evidence of infection or delayed healing.

There will continue to be advances in biotechnology and further research into the use of antimicrobial therapy in wound management. Silver dressings clearly have a role to play, but further research is needed to determine how much silver is needed in a dressing to kill bacteria, how long the dressing should be used for, and which dressing is the most effective in terms of efficacy and cost. In the meantime it is the responsibility of senior nurses in wound care to ensure that clinicians are kept well informed and up to date in new developments on the use of antimicrobial agents and in particular silver dressings, so that they can be of maximum benefit to patients.

### 3.7 Silver dressings update

Since this literature review was undertaken in 2004, evidence of the effect of silver dressings in the treatment of chronic wounds has expanded (Coutts and Sibbald 2005, Jorgensen et al 2005, Meaume et al 2005, Munter et al 2006)). Two key position documents have also been produced by the European Wound Management Association (2005, 2006).

- Identifying criteria for wound infection (2005)
- Management of wound infection (2006)

A randomised controlled trial (Jorgensen et al 2005) comparing the effect of a sustained-release foam dressing with a foam dressing without added silver in critically colonised venous leg ulcers with delayed healing showed significantly faster wound area reduction when treated with the silver-releasing dressing. Other advantages of the silver-releasing foam dressing included a significant decrease in wound odour, reduced leakage and maceration, contributing to an improvement in the patient's quality of life. The results of this RCT that included 129 patients, suggest an important role of sustained silver-releasing dressings in the treatment of critically colonised chronic wounds.

The CONTOP study (Munter et al 2006) also produced some good clinical evidence to support sustained silver-releasing dressings in delayed wound healing. This comparative open prospective parallel and block-randomised evaluation examined the effect of a sustained silver-releasing dressing on ulcers with delayed healing. The study included a total of 619 patients with ulcers of varying aetiologies that were treated for four weeks with either a silver foam dressing (Contreet) or local best practice. The results showed that the silver foam dressing achieved faster healing of delayed healing wounds ( $p = 0.0019$ ). Additionally the condition of the peri-ulcer skin improved ( $p = 0.038$ ), exudate reduced ( $p = 0.001$ ) and reported pain was lower ( $p < 0.0001$ ) in the silver foam group. There was also a reduction in frequency of dressing change with a longer wear time for the silver foam dressing (3.1 days) than local best practice (2.1 days).

These studies clearly support the use of silver dressings in managing wounds where there is evidence of infection and delayed wound healing. However a recently published Cochrane Review (Vermeulen et al 2007) of topical silver for treating infected wounds concluded that there is not enough evidence to recommend the use of silver-containing dressings or topical agents for treating infected or contaminated chronic wounds. Only three RCT on silver dressings as previous discussed met the criteria to be included in the study, although a total of 347 potentially relevant studies were identified. The nature of systematic reviews are such that many studies are excluded, some of which may show real and meaningful improvements in patient outcomes, particularly in relation to improvements in quality of life.

In the healthcare setting commissioners of services often look to this type of evidence when making investment decisions and this can restrict the availability of silver dressings for patient use. It is therefore important that other types of evidence such as patient satisfaction studies, case studies and expert opinion are considered when selecting and using silver dressings in the clinical practice setting.

The following recommendations for practice have been developed from this literature review and the two position papers and have been incorporated into local wound management guidelines and education for community clinicians (Table 3 and 4).

**Table 3**

**Wound infection: recommendations for practice**

<b>Not all wounds that contain bacteria are infected</b>
<b>Diagnosis is a clinical decision based on a full assessment of the patient</b>
<b>Host issues should be taken into account when assessing a patients susceptibility to infection</b>
<b>Different wound types may exhibit different signs and symptoms</b>
<b>Treat patient concerns and other related factors such as poor nutrition, uncontrolled blood glucose</b>

**Table 4**

**Topical antimicrobials: recommendations for practice**

<b>Topical antimicrobials (iodine and silver) have a role in the management of wounds with a high bacterial burden or signs of early localised infection.</b>
<b>When choosing a dressing consider the condition of the wound, exudate levels and adaptability of the dressing to suit the wound.</b>
<b>Long term use of antimicrobial dressings should be avoided.</b>
<b>Antibiotic use should be limited to specific clinical situations where there is evidence of deep and surrounding skin infections and directed towards susceptible organism. The wound should be reviewed regularly.</b>

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#### **4.0 Research Report: Utilizing the TIME framework to improve community nurses wound care knowledge and practice: An experimental study**

##### **Abstract**

**This research project aims to examine the impact of delivering an educational programme utilising the concept of Wound Bed Preparation (WBP) and the associated TIME framework on community nurses wound care knowledge and practice. WBP has gained international recognition as a concept that can provide a structured approach to wound management. The concept links treatment to the underlying cause of the wound and focuses on removal of the barriers to healing (Schultz et al 2003). The TIME framework was developed in 2002 by the International Advisory Board for WBP, as a practical tool for implementing the concept of WBP in clinical practice. TIME is an acronym summarising the four main components of WBP:**

- Tissue**
- Infection/inflammation**
- Moisture**
- Edge**

**There is a wealth of literature that describes the process involved in WBP and each of the TIME elements, but there is no work to examine the impact of a TIME based educational programme on nurse's knowledge and practice. This research project sought to address this gap. An experimental pre-test post-test design using repeat measures was used for the study. Multi-methods of data collection including questionnaires, non-participant observation and recording of information from the patients clinical notes, were used to collect the data. The results showed that community nurses wound care knowledge and practice both improved after the educational intervention, and this improvement was found to be statistically significant ( $p < 0.001$ ). The research concluded that the TIME framework is a useful tool that can improve community nurses wound care knowledge and practice and therefore improve patient care. A number of recommendations are made for practice, education and research.**

#### **4.1 Introduction**

This research project explores the literature pertaining to the concept of Wound Bed Preparation (WBP) and the TIME framework which was developed to support practical application of the concept. The literature provides the rationale for undertaking this study and the supporting evidence on which the research tools and educational programme were developed. The literature was further explored in terms of wound assessment, wound measurement and wound care education to identify best practice and education delivery methods, to support the implementation of best practice in wound care.

Caring for people with wounds is costly, both financially and in terms of the impact on the patient's quality of life. The cost of wound care in the United Kingdom accounts for 3% of the annual National Health Service expenditure, which has been estimated at £2.3-£3.1 billion per year (Drew et al 2007). This does not reflect litigation costs that result from complications or indeed the hidden cost to the patient, such as pain, depression and social isolation. The majority of these wounds are chronic in nature such as leg ulcers and pressure ulcers, and are cared for in the community setting by General Practitioners and community nurses. Evidence from the literature shows that there are variations in wound care practice (Harding 2000), leading to inequalities in the care provided to patients. The concept of WBP was developed as a structured approach to the management of chronic wounds, and therefore may offer a solution in terms of addressing these inequalities.

WBP has been defined as 'the management of a wound in order to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures' (Falanga 2000, p347). The concept focuses the clinician on optimising conditions at the wound bed so as to encourage normal endogenous healing. It is an approach that should be considered for all wounds that are not progressing to normal wound healing. Four main components are proposed as the mainstay of treatment using WBP. These include regular debridement of the wound to remove sloughy and necrotic tissue, the control of bacteria and infection prevention and management, maintenance of a moisture balance and epidermal advancement (Schultz et al 2003).

These four components make up the TIME table (Appendix 5) that was developed in 2002 by the International Advisory Board for WBP, as listed (Appendix 6), as a practical framework for implementing WBP. There have been several publications explaining the concept of Wound Bed Preparation and introducing the TIME table, and its practical use (Sibbald et al 2000, Schultz et al 2003, Dowsett and Ayello 2004). However to date there is no research to demonstrate that if the concept is implemented in clinical practice that it can improve nurses knowledge and practice. This research sought therefore to explore the impact of WBP and the use of the TIME framework on clinical practice, through the use of an educational programme.

The research study aims, design, sample, instruments and procedures will be discussed in detail in section 4.3. An experimental pre-test post-test design using repeat measures was used for the study. It was hypothesised that a structured educational intervention based on the concept of WBP and the TIME framework would positively impact on community nurses knowledge and practice in wound care. The dependent variable was defined as the level of change in wound care knowledge and practice as demonstrated by community nurses. The independent variable was defined as the educational intervention, the presumed cause of changes in knowledge and practice. The dependent variable was measured by the use of questionnaires, non-participant observation of clinical practice in wound care, and information from patient's records, before and after the introduction of an educational programme. The independent variable was operationalized by delivering an educational programme on the TIME framework to community nurses.

The educational programme consisted of two modules that were delivered over a series of two half-study days. Adult learning theory (Knowles 1984 p18), and evidence based practice provided the underpinning for the development of the training programme. Module 1 consisted of an introduction to the concept of WBP, the WBP 'care cycle' and the TIME framework. Module 2 covered the TIME framework in detail, drawing on the most up to date evidence for practice in terms of tissue debridement, infection control, moisture balance and monitoring and managing the wound edge. Case study examples were utilized to demonstrate key concepts such as local and systemic infection and wound edge problems. The photographs used for the

questionnaire were used in the delivery of the educational programme as case study examples when discussing the T and E of TIME. A practical demonstration of the wound measurement device Visitrak, section 4.2.4.2 also took place, and a practical workshop followed that allowed the nurses to practice using the device and recording wound measurements.

The results of the study are presented in section 4.4: the results of the questionnaire exploring knowledge, the observed visits examining practice, and the associations between the two findings. Data was analysed using the computer software package Statistical Package for Social Sciences (SPSS) version 14.0. Parametric and non-parametric statistical tests were used to analyse the data, based on the distribution and the level of significance of the findings reported. An overview of the tests used will be provided. Further analysis of the data using descriptive statistics as well as themes and categories based on the literature reviewed will be presented. The key themes are as follows:

- Patient assessment knowledge and practice
- Wound assessment knowledge and practice
- Use of the TIME framework
- Nursing interventions and treatment.

A discussion follows in section 4.5, which will focus on examining the results in detail in relation to the available literature and previous work in the area. Initial discussion will focus on the changes to community nurses knowledge, followed by practice changes in relation to patients assessment, wound assessment, and identification and management of the four elements of the TIME framework; tissue, infection/inflammation, moisture and edge advancement. This will be followed by a discussion on the challenges of changing clinical practice in the current NHS climate.

This research project has demonstrated that a structured educational intervention based on the concept of WBP and the TIME framework positively impacted on community nurses knowledge and practice in wound care. The changes in knowledge and practice were found to be statistically significant. The implications of the study for practice, education and research are discussed in the concluding section 4.6. The limitations of the study are also acknowledged.

## **4.2 Literature Review**

This review intends to discuss the literature pertaining to the concept of WBP, and the TIME framework which was developed to support implementation of the concept of WBP in clinical practice. Evidence with respect to the key elements of the TIME framework is explored in relation to identification and management of the barriers to healing and recommendations made for best practice. These recommendations from the literature were used to develop the data collection tools and the content of the educational programme for this research project. Further literature on the current state of wound care assessment and management is also discussed, with gaps in practice identified. This theory-practice gap will be further discussed including the literature on getting evidence into practice, and facilitation of change management. Finally the chapter explores the evidence from the literature on the use of education as an intervention to improve knowledge and practice.

A literature review was undertaken for the period 1985 – 2007, using the following databases, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, The Cochrane Library and World Wide Wounds web. Non-English language studies were excluded. Key search words used were; Wound Bed Preparation, TIME, and wound assessment. A further search in relation to wound care education, education and practice and implementing evidence in practice was undertaken. Hand searches of Wound Care Journals including the Journal of Wound Care, Journal of Tissue Viability, British Journal of Nursing, recent wound care conference abstracts and company literature on the topic were undertaken.

### **4.2.1 Wound Bed Preparation**

The management of chronic wounds such as leg ulcers and pressure ulcers are costly both for the patient in terms of reduced quality of life, and for the health service in terms of nursing time and dressing costs. The cost of wound care accounts for 3% of the annual National Health Service expenditure which has been estimated at £2.3-£3.1 billion per year (Drew et al 2007). This does not reflect litigation cost that result from complications or indeed the hidden cost to the patient, such as pain, depression and social isolation. The majority of these wounds are cared for in the community setting, with up to 80% of patients with leg ulcers cared for by their General Practitioner or

community nurse (Morison and Moffatt 1994). There is evidence to suggest variations in the way in which these wounds are managed (Harding 2000) and the way in which management is documented (Tapp 1990). Any advances in wound care or new concepts such as that of 'Wound Bed Preparation' that have the potential to make a contribution to how these wounds are managed are worth further consideration in terms of their impact on patient care.

WBP has gained international recognition as a concept that can provide a structured approach to wound management. Sibbald et al (2000 p14) defined WBP as 'a changing paradigm that links treatment to the cause and focuses on three components of local wound care: debridement, wound-friendly moist interactive dressing and bacterial balance. Thirteen recommendations for wound management were provided that began with a comprehensive assessment of the patient's overall health status to establish the cause of the wound and to identify factors that may be impairing healing. Falanga (2000 p347) defined WBP as 'the management of a wound in order to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures'. The concept focuses the clinician on optimising conditions at the wound bed so as to encourage normal endogenous healing. It is an approach that should be considered for all wounds that are not progressing to normal wound healing.

Wound healing is a complex series of events that are interlinked and dependent on one another. Acute wounds usually follow a well-defined process described as: coagulation: inflammation; cell proliferation and repair of the matrix: and epithelialization and remodelling of scar tissue (Schultz et al 2003). In the past this model of healing has been applied to chronic wounds, but it is now known that chronic wound healing is different from acute wound healing. Chronic wounds become 'stuck' in the inflammatory and proliferative stages of healing (Ennis and Menses 2000) which delays healing. The epidermis fails to migrate at the wound margins which interfere with normal cellular migration over the wound bed (Schultz et al 2003). Clinicians involved in wound care need to understand these differences if they are to provide effective wound care.



In chronic wounds there appears to be an over production of matrix molecules resulting from underlying cellular dysfunction and dysregulation (Falanga 2000).

Fibrinogen and fibrin are also common in chronic wounds and it is thought that these and other macromolecules scavenge growth factors and other molecules involved in promoting wound repair (Falanga 2002). Chronic wound fluid is also bio chemically distinct from acute wound fluid; it slows down, and can block the proliferation of cells, which are essential for the wound healing process (Schultz et al 2003). WBP as a concept allows the clinician to focus systematically on all of the critical components of a non-healing wound to identify the cause of the problem, and implement a care programme so as to achieve a stable wound that has healthy granulation tissue and a well vascularised wound bed (Dowsett and Ayello 2004).

Four main components are proposed as the mainstay of treatment using WBP. These include regular debridement of the wound to remove sloughy and necrotic tissue, the control of bacteria and infection prevention and management, maintenance of a moisture balance and epidermal advancement (Schultz et al 2003). There have been several recent publications explaining the concept of WBP and introducing the TIME table, and its practical use. However to date there is no research to demonstrate that if the concept is implemented in clinical practice that it can improve knowledge and patient care. This research is therefore keen to explore the impact of WBP and the use of the TIME framework on clinical practice, through the use of an educational programme.

Many clinicians use a tool such as the Waterlow risk assessment tool (Waterlow 1985) for assessing pressure ulcer risk, and wound assessment charts to document the status of the wound and the type of treatment in use. These tools offer a useful step in developing a systematic approach to the management of chronic wounds (Dealey 1999). They do not however, link observations with recommended interventions, nor do they provide any understanding of the underlying abnormalities that would enable the clinician to understand the reasons why a wound was not healing. In clinical practice it is the researcher's experience that if one intervention does not work another one is tried in a random fashion, rather than trying to gain an understanding of why the first had failed to work.

Clinical studies have shown that a systematic approach to the management of patients with leg ulcers can reduce both the healing time and costs (Moffatt et al 1992).

However, often the management of these patients is based on experience rather than research-based knowledge, and research findings are not always implemented in practice (Luker and Kenrick 1992). Very often this means that the clinician goes from using one dressing product to another, often using high cost treatments with little success. The TIME framework can be used as a tool not only to assess the wound but also to identify the most appropriate intervention and dressing product to use in each individual patients case.

#### **4.2.2 TIME framework**

The TIME framework was developed in 2002 by the International Advisory Board for WBP of which the researcher was a member. It was developed as a practical tool for use when managing patients with wounds (Schultz et al 2003). The TIME framework summarises the four main components of WBP: tissue management, control of infection and inflammation, moisture balance and advancement of the epithelial edge of the wound. It is a useful practical tool based on identifying barriers to healing, understanding the underlying wound pathology and the recommended interventions designed to restore the normal biological environment at the wound bed so as to promote healing, or to provide an environment suitable for the application of advanced wound therapies. The framework facilitates clinical decision- making and has the potential to justify the cost efficacy of advanced treatments, which are recommended for use when the wound fails to epithelialise after addressing the other problems. The literature pertaining to the elements of the TIME framework is vast and the evidence supporting some elements is stronger than others. Each element is further explored in this section.

##### **4.2.2.1 Tissue**

The specific characteristics of the tissue within a wound bed play a very important role in the wound healing continuum. Accurate description of this tissue is an important feature of wound assessment. Where tissue is non-viable or deficient wound healing is delayed. It also provides a focus for infection, prolongs the inflammatory response, mechanically obstructs contraction and impedes re-epithelialisation (Baharestani 1999). Necrosis, eschar, and slough are terms that

describe non- viable tissue, however little is known about their constituents. Work undertaken by Thomas et al (1999) found that devitalised tissue has a defined structure similar to human dermis however there were areas of scattered degraded or disrupted tissue present. For epidermal cells to migrate across a wound surface a well built extra cellular matrix is required. Therefore early intervention to remove devitalised tissue is an essential part of wound management.

Necrosis or eschar on a wound is usually identified through its black / dark grey appearance and when dried out is tough and leathery to touch. Wound eschar is full thickness, dry devitalised tissue that has arisen through prolonged local ischaemia (Gray et al 2005). It is derived from granulation tissue after the death of fibroblasts and endothelial cells and may also contain inflammatory cells (Thomas et al 1999) which increases the risk of chronic inflammation of the wound and delays extra cellular matrix formation. Necrotic tissue acts as a physical barrier to epidermal cell migration and hydration at the wound interface is significantly reduced. Slough is adherent fibrous material derived from proteins, fibrin and fibrinogen (Tong 1999). It is usually creamy yellow in appearance and can be found dehydrated and adhered to the wound bed, or loose and stringy when associated with increased wound moisture. It can be found in patches or completely covering the wound surface and is often associated with the end of the inflammatory phase of healing when the dead cells have accumulated in exudate (Dealey 1999). It is important that clinicians can recognise the significance of necrotic and sloughy tissue and be aware of the available methods of debridement.

The promotion of healthy tissue growth and a well vascularised wound bed is essential (Schultz et al 2003). The presence of devitalised tissue in a wound is often a challenge to health care professionals. Many debridement methods are available and highlighted in the literature, but not all are utilized in practice. Using some debridement methods such as sharp require advanced knowledge and skill, and the availability of resources. Patient acceptability can also be an issue for example when using larvae therapy (Thomas et al 1998). Assessment of the wound can sometimes be difficult as the extent of the problem is not always easily identifiable. It is difficult for clinicians to accurately assess the depth of a wound that is covered or filled with necrotic or sloughy tissue and, until removed, the true extent may not be realised. In

the majority of clinical cases there is a need to remove the devitalised tissue through a process of debridement however, it is important to assess the blood flow to the affected area first particularly if the wound is on the lower leg or foot. In cases where the limb requires revascularisation it may not be appropriate to undertake tissue debridement until the viability of the limb is determined (Sibbald et al 2000). These key messages from the literature have been incorporated into the educational programme as part of the research project.

Debridement is seen as an important element of wound care practice where devitalised tissue is present (National Institute for Clinical Excellence 2001). In many cases this process occurs naturally however some patients have underlying pathology, which affects the ability of the body to naturally debride the wound. In a chronic wound debridement is often required more than once as the healing process can stop or slow down allowing further devitalised tissue to develop. Where debridement needs to be performed the literature identifies a number of options.

Surgical and sharp debridement are the fastest methods of removing devitalised tissue and have the benefit of converting a non healing chronic wound to that of an acute wound within a chronic wound environment (Schultz et al 2003) Surgical debridement is normally performed where there is a large extent of devitalised tissue present and where there are significant infection risks. Sharp debridement is more conservative however still requires the skills of an experience practitioner. Clinical competencies such as knowledge of anatomy, identification of viable or non viable tissue, ability and resources to manage complications such as bleeding and the skills to obtain patient consent are all essential prior to undertaking this procedure (O'Brien 2000).

Autolytic debridement is a highly selective process involving macrophage and endogenous proteolytic enzymes which liquefy and separate necrotic tissue and eschar from healthy tissue (Schultz et al (2003). This natural process is further enhanced by the use of occlusive and semi occlusive dressings and those, which interact to create a moist environment. Phagocytic activity is enhanced and increasing the moisture at the wound interface promotes tissue granulation. This method of debridement, in the experience of the researcher is what is mostly used in community nursing. Enzymatic

debridement is a less common method of debridement however it is effective in the removal of hard necrotic eschar where surgical debridement is not an option.

Exogenous enzymes are applied to the wound bed where they combine with the endogenous enzymes in the wound to break down the devitalised tissue. In a randomised clinical trial comparing autolytic debridement to enzymatic, no statistical differences were found (Koing et al 2005). However the sample size was small in this study n=24 patients, which may account for the results.

Larval therapy is a quick efficient method of removing slough and debris from a wound however not all patients or staff find this debridement method socially acceptable. Sterile larvae secrete powerful enzymes to break down devitalised tissue without destroying healthy granulation tissue (Thomas et al 1998). Mechanical methods of debridement such as irrigation and wet to dry dressings are rarely used as they can cause increased pain and can damage newly formed granulation tissue. If debridement is effective the T of TIME is removed and wounds can progress through the remaining phases of wound healing.

In the field of wound care, robust evidence such as randomised controlled clinical trials are not always available and very often in comparing products or debridement interventions, like for like comparisons are not made or relevant . Even when the evidence is strong, the debridement method used needs to be appropriate to the patient and their wound and the clinician needs to have the skill to perform the intervention.

#### **4.2.2.2 Infection/inflammation**

Wound infections make up a small but important part of overall infections, with recent figures suggesting they account for 13.8% of all hospital infections (Hospital Infection Society 2007). Infection in a wound causes pain and discomfort for the patient, delayed wound healing and can be life-threatening. Infected wounds are often malodorous and again this can impact on the patients quality of life. Clinical infections as well as having serious consequences for the patient can add to the overall cost of care, adding an additional five to twenty increased bed days in hospital (Melling et al 2001).

All wounds contain bacteria at levels ranging from contamination, through critical colonization to infection (Cooper 2005). The increased bacterial burden may be confined to the superficial wound bed or may be present in the deep compartment and surrounding tissue of the wound margins (Schultz et al 2003). Several systemic and local factors increase the risk of infection. Systemic factors include diabetes, vascular disease, smoking and poor nutrition. Local wound factors include the size and duration of the wound as well as the presence of necrotic tissue and foreign material such as fragments of gauze and dressings (Cutting and White 2005). Emphasis is often placed on the bacterial burden, but in fact host resistance is often the critical factor in determining whether infection will occur. Host resistance is lowered by poor tissue perfusion, poor nutrition, local oedema and other behavioural factors such as smoking and drinking excess alcohol (Schultz et al 2003).

When a wound is infected it contains replicating micro-organisms which cause injury to the host. In an acute wound, infection is met by a rapid inflammatory response which is initiated by the release of cytokines and growth factors (Dow et al 1999). The inflammatory cascade produces vasodilation and a significant increase of blood flow to the injured area. This also facilitates the removal of micro-organisms, foreign bodies, bacterial toxins and enzymes by phagocytic cells, complements and antibodies. The coagulation cascade is activated which isolates the site of infection in a gel matrix to protect the host (Dow et al 1999). In a chronic wound however, the continuous presence of virulent micro-organisms leads to a continued inflammatory response which eventually contributes to host injury (Schultz et al 2003). There is persistent production of inflammatory mediators and steady migration of neutrophils which release cytolytic enzymes and oxygen-free radicals. There is localized thrombosis and the release of vasoconstricting metabolites which can lead to tissue hypoxia, bringing further bacterial proliferation and tissue destruction (Sibbald et al 2003).

It is evident from the literature that the presence of bacteria in chronic wound does not necessarily indicate that infection has occurred or that it will lead to impaired wound healing (Cooper and Lawrence 1996). Micro-organisms are present in all chronic wounds and low levels of certain bacteria can facilitate wound healing as they produce enzymes such as hyaluronidase which contributes to wound debridement and

stimulates neutrophils to release proteases (Stone 1980). It is the researcher's experience that oral antibiotic therapy is often used inappropriately in particular when low levels of bacteria are present in the wound or when infection is localised to the wound bed.

Two recent documents inform the literature pertaining to the identification and management of infection (European Wound Management Association, EWMA 2005, 2006). They stipulate that the diagnosis of infection is primarily a clinical skill and microbiological data should be used to supplement the clinical diagnosis. The classical signs of infection in acute wounds include; pain, erythema, oedema, purulent discharge and increased heat. For chronic wounds it has been suggested that other signs should be added: delayed healing, increased exudate, bright red discolouration of granulation tissue, friable and exuberant tissue, new areas of slough, undermining, malodour and wound breakdown (Cutting and Harding 1994). Sibbald et al (2000) suggest that diagnosis should differentiate between superficial and deep infection, with deep infection identifiable by a sudden emergence of wound-related pain or an increase in existing pain, , increased size, erythema greater than 1-2cms and ability to probe to bone or bone exposed. Pain that begins or increases around the wound area may be an indication of deep infection. In the researchers experience this differentiation does not always occur in clinical practice and therefore the resulting intervention may not always be appropriate for the problem.

Clinicians may find the mnemonics, or enablers, NERDS and STONES developed by Sibbald et al (2006) helpful in making wound infection assessments. NERDS relates to superficial infection: Nonhealing wounds, Exudative wounds, Red and bleeding wound surface granulation tissue, Debris on the wound surface, Smell or unpleasant odour from the wound. Clinicians need to look for 2 or 3 of the signs and symptoms of NERDS before making a diagnosis of increased superficial bacterial burden. STONES relates to deep infection: Size is bigger, Temperature increased, Os (probe to or exposed bone), New or satellite areas of breakdown, Exudate, erythema, oedema, Smell. Sibbald et al (2006) suggest that by using this superficial and deep separation, clinicians can identify wounds with increased superficial bacterial burden that may respond to topical antimicrobials and deep infections that usually require the use of systemic antimicrobial agents.

Treatment of infection should first of all focus on optimizing host resistance, and underlying conditions which reduce immunity should be addressed (EWMA 2006). Systemic antibiotics are not necessarily the most appropriate way of reducing bacterial burden in wounds, particularly because of the threat of increasing bacterial resistance and should only be used where there is evidence of deep infection or where infection can not be managed with local therapy (Bowler et al 2001, Schultz et al 2003). Local methods include: debridement to remove devitalized tissue, wound cleansing and the use of topical antimicrobials such as cadexomer iodine and silver.

There is renewed interest in the selective use of topical antimicrobials as bacteria become more resistant to antibiotics. Studies show that some iodine and silver preparations have bactericidal effects even against multi-resistant organisms such as Methicillin-Resistant *Staphylococcus aureus* (Wright et al 1998, Sibbald et al 2001). A review of the literature pertaining to the use of topical agents such as silver has already been presented in section 3.3.4. Where infection in the wound has extended beyond the level that can be managed with local therapy, systemic antibiotics should be used. Systemic signs of infection, such as fever, cellulitis extending at least 1cm beyond the wound margin and underlying deep structures will require systemic antibiotic therapy (Schultz et al 2003). Where systemic antibiotic therapy is required it needs to be specific to the type of bacteria present in the wound.

#### **4.2.2.3 Moisture**

Creating a moisture balance at the wound interface is essential if wound healing is to be achieved. Exudate is produced as part of the body's response to tissue damage and the amount of exudate produced is dependant upon the pressure gradient within the tissues (Trudgian 2005). An ideal level of exudate is unknown and it has been suggested that the variance is probably due to the fact that each wound has its own unique characteristics (Scanlon 2004). A wound which progresses through the normal wound healing cycle produces enough moisture to promote cell proliferation and supports the removal of devitalised tissue through autolysis. If however the wound becomes inflamed and/or stuck in the inflammatory phase of healing exudate production increases as the blood vessels dilate.



Evidence also suggests that there are significant differences between acute and chronic wound fluid (Parks et al 1998). Acute wound fluid supports the stimulation of fibroblasts and the production of endothelial cells as it is rich in leukocytes and essential nutrients. Chronic wound fluid however has been found to have high levels of proteases which have an adverse effect on wound healing by slowing down or blocking cell proliferation (Schultz et al 2003) in particular keratinocytes, fibroblasts and endothelial cells. Increased levels of proteolytic enzymes and reduced growth factor activity all contribute to a poorly developed extra cellular wound matrix. This in turn affects the ability of the epidermal cells to migrate across the surface of the wound to complete the healing process.

Factors such as the underlying condition of the patient, the pathology of the wound and the dressing selection all affect the production of exudate (White 2001). Moisture in a wound enhances the natural autolytic process and also acts as a transport medium for essential growth factors during epithelialisation (Cutting and Tong 2003). If a wound bed becomes too dry however a scab will form which then impedes healing and wound contraction. The underlying collagen matrix and the surrounding tissue at the wound edge become desiccated (Dowsett and Ayello 2004). If a wound produces excessive amounts of exudate the wound bed becomes saturated and moisture leaks out onto the peri-wound skin causing maceration, often recognised as white boggy tissue and excoriation which presents as redness around the wound margins. If left untreated this can lead to erosions in the skin and an increase in the size of the wound. Additionally if a dressing product is not managing the exudate this can lead to an increased risk of infection.

The literature identifies the assessment of exudate as an important aspect of wound management. The type, amount and viscosity of exudate should be recorded and dressings selected based on the exudate characteristics. In the researchers experience clinicians do not objectively assess exudate and frequently use descriptors such as 'exudate ++' and 'wet' to describe wounds. A user-friendly validated tool specifically for the assessment of exudate is currently not available. However a consensus document on best practice principles on wound exudate has recently been developed

by World Union of Wound Healing Societies (WUWHS) (2007). This document presents information in relation to interaction between the exudate status of the wound and the dressing, which is valuable for practice. Unfortunately as this document has only recently become available, it was not included in the educational programme as part of this research project; however some of the best practice recommendations made are already standard practice in the Primary Care Trust.

If a wound is too dry, unless contraindicated as in the case of ischaemic disease, rehydration should be the principle of management. Occlusive dressing products promote a moist environment at the wound interface. As wounds heal the level of exudate gradually decreases. The management of excess exudate in chronic wounds however presents a challenge to many health care professionals. Vowden and Vowden (2004) suggest that an understanding of the systemic and local conditions influencing exudate production, and knowledge of the potential damaging chemical constituents of exudate should inform a management strategy.

The literature suggests that dressing selection should be based on the context of an integrated patient management plan (WUWHS 2007). When selecting a dressing it is important to remember that the dressing should be able to manage the exudate in such a way as to enhance the wound environment to favour healing as opposed to simply mopping up exudate. Consideration should be given to the volume of exudate and the viscosity as some dressings absorb a higher volume of fluid than others and some are more efficient when dealing with viscous exudate. A number of factors have been identified in the literature as important when selecting a dressing and these were used to benchmark the responses to question fourteen in the questionnaire (Appendix 3).

The condition of the surrounding skin is important in managing exudate, as vulnerable skin can react to excess exudate and cause maceration, excoriation and irritant dermatitis. Maceration has been identified as an under recognised problem and it has been suggested that early recognition of the problem and application of a protective skin barrier film can minimise the problem (Cutting 1999). Health care professionals need to be aware of the exudates handling properties of wound dressings and the recommended wear time. Reactions on the skin are often caused by inappropriate dressing selection and insufficient dressing changes. If a wound is clinically infected

exudate levels can be high and therefore dressing changes may be required daily initially until the infection is under control. This then links back to the I in the TIME framework and highlights the inter-relationship between each element.

Individual patient and wound assessment is paramount if dressing selection is to be effective (Vowden and Vowden 2004). The larger and deeper the wound, generally the levels of exudate increase. Equally if a wound is stuck in the inflammatory phase of healing due to chronicity there is the likelihood that more exudate is produced. There are a variety of dressing products available for the management of exudate ranging from foams, hydrocolloids, alginates, hydrofibres, and capillary action dressings. All play a role in the removal of fluid away from the wound surface however many through their ability to gel on contact with wound exudate maintain a moisture balance on the wound surface itself (World Union of Wound Healing Societies 2007). Compression bandages also play a role in the removal of excess fluid in lower limbs. Wound dressings should be used as part of a treatment plan which also supports the management of any underlying clinical condition (Newton and Cameron 2003). If moisture imbalance is not corrected there will be delayed wound healing or in some cases wound deterioration, the risks of infection are increased, the demand on nursing time is increased and there will be increased costs of dressings (Vowden and Vowden 2004).

#### **4.2.2.4 Edge**

When the epidermal margins of a wound fail to migrate across the wound bed or the wound edges fail to contract and reduce in size consideration needs to have been given to the T, I and M first to ensure that all aspects of WBP have been considered. The final stage of wound healing is epithelialisation, which is the active division, migration and maturation of epidermal cells from the wound margin across the open wound (Dodds and Haynes 2004). There are many factors, which need to be present in order for epithelialisation to take place. The wound bed must be full of well vascularised granulation tissue in order for the proliferating epidermal cells to migrate. This also ensures that there is adequate oxygen and nutrients to support epidermal regeneration. There needs to be a rich source of viable epidermal cells which can undergo repeated cell division particularly at the edge of the wound (Falanga 2000). Where cells have become senescent the process slows down or stops

completely. Wounds that have a significant number of fibroblasts that are arrested due to senescence, damaged DNA or enduring quiescence do not heal. (Vande Berg and Robson.2003). Other factors such as bacteria or the presence of devitalised tissue, which interfere with epidermal cell growth, need to be removed to ensure complete wound closure.

There are many reasons why the epidermal margin fails to migrate including hypoxia, infection, desiccation, dressing trauma, over growth of hyperkeratosis and callus at the wound margin (Dowsett and Newton 2005). For wound healing to be effective there needs to be adequate tissue oxygenation. Decreased oxygen levels impair the ability of the leucocytes to kill bacteria, lower production of collagen and reduce epithelialisation (Schultz et al 2003). It is important to remember that wounds rely on both macro and microcirculation particularly in the lower limb. A baseline assessment needs to be undertaken to determine the degree of ischaemic disease and the ability of the wound to heal without vascular intervention. Wound infection as discussed previously (section 4.2.2.2) is extremely destructive to a healing wound. Inflammation caused by bacteria causes the extra cellular matrix to degrade and therefore epidermal cell migration is interrupted. Dressing products particularly if adhered or made of fibrous materials also cause trauma and inflammation of the wound bed which in turn delays healing. In managing the E of TIME it is important to select dressing products which are non adherent, which will not dry out or leave fibres in the wound bed.

Certain clinical conditions such as diabetic neuropathy can also contribute to wound edge problems as there is an over production of hyperkeratosis and callus formation. It has also been noted that the epidermis of surrounding skin of venous leg ulcers was thicker than normal skin and highly keratinised (Schultz et al 2005). This proliferative, thickened tissue needs to be removed by the clinician in order for the wound to epithelialise. Failure of a wound edge to migrate is also thought to be associated with the inhibition of the process of normal programmed cell death (apoptosis) which particularly affects fibroblasts and keratinocytes (Falanga 2000). Cells undergo a characteristic series of changes following mechanical damage to the cell and on exposure to toxic chemicals. Cells become unresponsive and die. Whilst it

is not possible for clinicians to observe this when assessing the wound, it is important that they are aware of it as a potential barrier to healing.

Undermining or rolling of a wound edge can also influence the ability of the wound to heal. Undermining can be indicative of a chronic wound and in particular those wounds that are also critically colonised with bacteria or infected. Translucent rolled edges can present in wounds that have an inflammatory origin such as Pyoderma gangrenosum (Sibbald et al 2003). Early diagnosis is important in these cases as failure to provide the appropriate second line therapy such as oral steroids or tissue biopsy and excision can result in poor healing outcomes.

The E in the time framework is also utilized as an opportunity to evaluate the wound, as this is the only means of determining if the wound edges are coming together (Dowsett and Newton 2005). Measuring a wound at the start of treatment is seen as best practice to enable accurate assessment of the impact of a clinician's intervention. Subsequent measuring can identify whether or not a wound is failing to heal or deteriorating. The edge of the wound will not epithelialise unless the wound bed is well prepared. It is important when using the TIME framework that the clinician should consider the elements of T, I and M first to ensure that the use of advanced therapies are appropriate and if used are applied to a well prepared wound bed to ensure optimal effect. Accurate and timely documentation of this assessment and re-assessment is considered good practice and can improve continuity of care (Sterling 1996; Russell 2000).

#### **4.2.3 Wound Bed Preparation Care Cycle**

The TIME framework is wound focused and needs to be used within the context of a total patient care approach. If a wound fails to heal there is often a complex mix of local and host factors which will need to be assessed and treated. A full and detailed patient assessment will highlight the underlying aetiology of the wound and other factors that may impede wound healing such as pain and poor nutrition (Dealey 1999). For this reason the Wound Bed Preparation 'Care cycle' (Appendix 7), was developed in 2004 (Dowsett 2004) to use in conjunction with the TIME framework as part of a total programme of care. The 'care cycle' starts with the patient and their environment of care. Individual patient's concerns need to be addressed as well as

quality of life issues in order to achieve a successful care programme (Sibbald 2000). Patients also need to understand the underlying cause of their wound and the rationale for treatments. Assessment and treatment of the underlying condition is essential as the type of wound bed preparation implemented may vary with wound type. For example sharp debridement is common in the management of patients with diabetic foot ulceration, whilst compression therapy is the recommended treatment in venous leg ulcers (EWMA 2004). The cycle moves from patient assessment and diagnosis to assessing and treating the wound using the TIME framework. The importance of evaluation in terms of evaluating the effectiveness of the treatment is highlighted in the cycle. Those patients who have healed come out of the cycle into a 'prevention programme' and patients who have not progressed to healing or who have palliative wounds remain in the cycle and are reassessed, using the TIME framework. Good wound assessment and documentation is essential for evaluating the effectiveness of care, and to inform the decision making process when utilising the TIME framework.

#### **4.2.4 Wound care practice**

##### **4.2.4.1 Wound assessment**

Wound care has evolved into a complex science, with advanced procedures and treatments now available. Nurses play an active role in the assessment, treatment and continuous evaluation of a patient with a wound. Successful outcomes for the patient rely on good patient assessment, treatment of the underlying cause and addressing other patient related factors. However the evidence suggests that this practice is varied and that documentation in relation to wound care assessment and measurement is poor. Huynh and Forget-Falcicchio (2005) in a retrospective analysis of patients notes, showed that there were wide variation in the number of dressings used and the frequency of dressing change, with no clear rationale for the variation. More interestingly they also demonstrated that there was no correlation between the number of treatment procedures and the rate of healing, which questions the optimum frequency of dressing change.

Documentation is an important activity for clinicians involved in wound care and relates to issues such as quality assurance, demonstration of standards of care, continuity of care and accountability. Tapp (1990) found that many nurses prioritise

hands-on care above documentation and feel that there is insufficient time to document care. Wound assessment and evaluation forms and charts have been developed by many tissue viability clinicians and are recommended for use in practice as part of clinical guidelines. The use of wound assessment and evaluation forms can assist with monitoring the progress of the wound and allow for more objective reporting of findings (Dealey 1999). Sterling (1996) found that wound assessment was documented more frequently when a wound assessment chart was used. Information also appeared more accessible when a wound assessment chart was used than when a nursing transcript was used. This research study supports these findings. Wound assessment documentation is also important for continuity of care, particularly in the community setting where many different clinicians visit the patient without supervision to carry out wound care treatments. It ensures that they all have the same information and up to date plan of care.

#### **4.2.4.2 Wound measurement**

Clinicians involved in wound care are often faced with difficult and confusing choices due to the number of available wound care products. In order to demonstrate clinical effectiveness objective measurement of the physical parameters of the wound is essential. It records wound progress of healing and can assist in determining the treatment choice. For length and depth measurements rulers are normally the preferred method (Kundin 1989), while wound area is traced through a sterile sheet of acetate (Bohannon, Pfaller 1983). Samad et al (2002) reported no significant difference in the accuracy of inter-observer reproducibility of leg ulcer measurements made using digital images and conventional contact tracing.

In clinical trials many methods are used to evaluate healing rates, the majority being change in area or volume. The former provides an indication of epithelial growth and the latter of granulation tissue (Flanagan 2003). Careful contact tracing of the wound circumference captures the plane dimension, and therefore the area more accurately than a photograph. Convenient, portable and inexpensive devices such as Visitrak are now available for use in the community. As part of this research project these devices were made available to the community nurses to make wound measurement easier and more accurate.

Wound measurement can help to monitor wound progress. The most effective way to measure wounds is to calculate the percentage reduction of wound area over time, particularly within the first four weeks of treatment. However Flanagan (2003) suggests that clinicians rarely estimate wound area in everyday practice. Many clinicians do not record the size of the wound and some clinicians guess from estimation. Given that wound measurement is probably the easiest way to determine whether a wound is responding to treatment, it is not professionally acceptable not to measure and document this aspect of wound care.

Some form of wound measurement is essential not only to evaluate treatment but also to predict the time it will take for the wound to heal, thus avoiding unrealistic expectation and identifying those wounds that may be non-healing and suitable for advanced wound care products. Studies have shown that a reduction in ulcer area between two and four weeks of treatment is independently predictive of time to heal (Tallman et al 1997, Kantor and Margolis 2000). A percentage reduction of over 40% over the first two to three weeks of treatment indicates the wound is healing (Flanagan 2003). It is important that regular re-assessment of the size of the wound takes place. The recommended optimal time is between two and four weeks (Philips et al 2000). This will highlight potential problems and avoid weeks of inappropriate treatment. It could also be used to justify the selection and use of advanced treatments. In relation to the TIME framework it should be noted that wound surface area increases when necrotic or sloughy tissue is debrided, and when infection is present (Plassmann et al 1994). It is important that both clinicians and patients are aware of this so that they do not set unrealistic goals for reduction in wound size.

#### **4.2.5 Wound care education**

A prerequisite of good wound management is a sound knowledge base, including knowledge of wound healing, the factors that affect healing and wound care products, as well as the skills to perform an accurate assessment (Jones 1997). Flanagan (1992) suggests that there is widespread ignorance of basic current philosophies of wound management and that this is responsible for deficiencies in the clinical management of patients with compromised tissue viability. This is supported by Bell (1994) who found that nurses lacked sufficient knowledge of the stages of wound healing.



Evidence from the literature supports the theory that education does improve knowledge; however it is more difficult to measure the impact of improved knowledge on practice. Luker and Kendrick (1995) used a validated questionnaire to measure knowledge and reported practice of community nurses concerned with the treatment of leg ulcers generally. The results were calculated in terms of the difference between pre and post-educational intervention scores and were the total scores for the sub sections on assessment, treatment and knowledge. From the available score of 62, the pre-educational intervention mean score was reportedly 26 (42%). Knowledge and reported practice scores increased from 26 (42%) to 33 (53%) post-educational intervention. The result was found to be highly significant ( $t = 10.54$ ,  $P = 0.000$ ).

The effect of continuing education on practical wound management was examined by Allison (1995). A three day educational programme in wound management was evaluated to determine its success in changing clinical practice. Twenty four nurses completed three questionnaires, on knowledge base and current practices prior to the course, on completion of the course and two months after the course. The study showed increased knowledge and reported practice as a result of the course which was sustained at two months. Whilst respondents reported increased knowledge, some of the respondents reported that the problems they experienced in wound care practice continued to exist due to the difficulties in changing nursing practice.

Jones and Nelson (1997) audited community nurses training needs and developed a programme on leg ulcer management generally. The twelve week half day training programme comprised of theoretical input and practical training sessions at leg ulcer clinics. Post training, 58% of nurses felt adequately prepared to assess and treat leg ulcers. No information was reported on nurse's increase in knowledge. Jones and Nelson (1997) reported on the impact of a leg ulcer educational intervention upon knowledge base and reported practice. They conducted a study involving 264 community nurses, using a knowledge and reported practice questionnaire before and after an educational intervention. The results were calculated in terms of the difference in pre and post-educational intervention scores. A significant increase in scores was reported for the experimental group from 25 to 34 (55%).

A survey approach was used by Couilliet et al (2001) to examine the knowledge and practice of nurses in chronic wound management. A questionnaire was used to collect data on knowledge and practice in relation to leg ulcer, pressure ulcers, plantar ulcers of the feet and the types of dressing in use. The research did not examine practice in the real life setting. The results showed that knowledge was poor and that there were discrepancies between local practices and actual knowledge. An educational programme was developed to address the problem.

Wong (2003) undertook a study in Hong Kong involving 42 community nurses to examine the effect of a teaching programme on community nurses knowledge of leg ulcer management. Pre and post-educational intervention knowledge scores were obtained by totalling responses to each of the four sections of a knowledge questionnaire. Knowledge scores were reported to increase from 10.3 (34%) to 20.4 (68%) following a three hour educational intervention, where the total score availability was thirty. A collective case study design was used by Dealey (2000) to determine the level of knowledge of nurses providing care for patients with leg ulcers in an acute trust. This collective case study design used knowledge questionnaires and observation of practice using field data collection forms to record observations. The study showed variations in both knowledge and in the care of the patient group and recommended an educational programme to address this. The study did not investigate nurse practice in wound assessment, or address barriers to healing as identified in the TIME framework.

Lloyd Jones et al (2003) implemented an educational programme on pressure ulcer prevention and management and used pre-post course questionnaires to assess students 'theoretical knowledge'. The study showed an increase in nurse's knowledge of pressure ulcer prevention and management post education with mean scores improving from 63% to 88%. Again the study did not focus on the impact of the education on practice. The authors did however suggest that the development of clinical practice must be supported by education that is able to combine theory with practice and have direct relevance to clinicians.

The literature reviewed outside of the wound care field also suggests that education does improve knowledge. Wallace et al (2006) developed, implemented and evaluated

a geriatric nurse education programme to ensure nurses met the needs of the increasing elderly population. A total of 18 registered nurses took part in this pre-test post-test design study, which utilized a scale to measure knowledge of common geriatric syndromes and an attitudes towards older people scale. Pre-test knowledge scores were ( $\bar{X}$  = 151.94; SD = 11.75) and post-test scores ( $\bar{X}$  = 153.94; SD = 16.5). A significant improvement in knowledge was found ( $t$  = 2.582;  $P$  = < .020). The authors suggested that the improved knowledge was likely to improve practice but this was not investigated further.

Dauer et al (2006) evaluated the effectiveness of a radiation safety training intervention for oncology nurses using a pre-test –intervention- post-test design. . As a result of the educational intervention there was a significant difference in nurse's cognitive knowledge as measured with the test instrument from pre-test (58.9%) to post-test (71.6%). Again this study did not seek to examine nurse's practice in this area. A study by Davila (2006) shows similar findings. A two-phase, mixed method design was used to examine nurse's knowledge and skills for enhanced response to intimate partner violence. Whilst no significant difference was found in knowledge ( $p$  = .107) mean skills had improved significantly after training ( $p$  = .003). Again the results support the use of a training programme as an effective method of improving clinical skills of nurses.

Objectively measuring practice is difficult. One method put forward to address this is the use of objective structured clinical examination (OSCE). This approach as a method of assessment of clinical practice has received positive evaluation (Harden and Gleeson 1997, Khattab and Rawlings 2001) . Seeley (2005) used OSCE to examine the impact of two education intervention types on clinical practice in venous leg ulceration. The results showed that practical skills had improved post the educational intervention, but this was not found to be significant. However the OSCE is more focused on physical assessment skills and was not considered an appropriate approach to measuring wound care practice in the patient's home environment. There are also cost issues in running OSCE exams that made it an impractical method of reporting community nurses practical skills.

The available literature on the use of the TIME framework in relation to knowledge and practice is limited. Watret (2005) describes the use of TIME as a theoretical framework to structure education. Key lectures and work based learning strategies were utilized to teach the components of the TIME framework. The sessions were well evaluated by those who attended. However the work did not examine the implications for knowledge or practice, or demonstrate improvements in wound care practice. Shorney (2006) used a survey methodology to assess the perceived value of the TIME framework as an educational tool. His work evaluated the perceived value of two national study days focusing on the TIME framework, organised by a wound care company. The results showed an improvement in knowledge and a belief that this would impact on practice. However he did not investigate practice, but recommended this for future research.

It was concluded from the literature that there was no work currently available to demonstrate the impact of an educational programme that incorporated the TIME framework on knowledge and practice in wound care. This research sought therefore to address this gap by examining nurse's knowledge and practice before and after an educational intervention using the TIME framework.

#### **4.2.6 Education Programme**

Adult learning theory (Knowles 1984) and evidence based practice provided the underpinning for the development of the training programme. A basic premise of this theory is that learning occurs when a learner recognises that existing knowledge is either defective or deficient. Knowles (1984) emphasised that adult learning is self directed and adults expect to take responsibility for their own decisions. He believes that they are goal oriented, in that they know what they want to achieve from an educational programme and also have their own stock of experience and knowledge on which to draw. His theory assumes that the learner has enrolled voluntarily for the training which was central to this research as all participants were invited to take part. The research was also seen as highly relevant to practice by those who took part.

According to Knowles (1984) learners learn best in informal, comfortable, flexible, non-threatening settings. To support this assumption, the training sessions were delivered in the community nurses bases, at a time that was agreed as convenient for

them. Several educational sessions were offered and the nurses had the opportunity to attend a session at another base if unable to attend at their own. Another assumption of the theory is that adults are life-centred in their orientation to learning (Knowles et al 2005). Adults are motivated to learn to the extent that they perceive that learning will help them to perform tasks they encounter in their daily life situations. The use of case-study examples and practical skills workshops were included to address the need for improving wound care performance in daily practice.

The literature also suggests the importance of having respect for individual styles of learning and ensuring balance of variety in the design of the programme (Cotton 2004). For this reason the programme included theoretical knowledge, use of case study examples, question and answer to draw on participants experience and encourage group interaction. A practical skills hands on workshop was also included using the Visitrak wound management measurement device. It is evident from the literature that changing nursing practice involves more than the provision of education. Improving wound care requires not just improved knowledge but additional skills in the management of change and the formulation of clinical guidelines and care pathways (Richens et al 2004). A positive organisational culture is also crucial to ensure effective evidence-based practice implementation (Closs and Chealer 1994). There are many reasons why there are gaps between what is known and what nurses practice, and this is discussed below.

#### **4.2.7 Implementing best practice in wound care**

Changing nursing practice remains a challenge for many clinicians, educators and researchers. There are many reasons why implementation of effective wound care practice is so variable. Historically nursing knowledge has been associated with practical know-how, which was traditionally seen as having greater importance than theory (Flanagan 2005). Although theory and practice are inextricably linked they are often seen as separate, and this has implications for practice development. Much work has been conducted in relation to the theory-practice gap that is thought to exist between classroom taught theory and what is actually implemented by nurses working in clinical practice (Mc Caugherty 1992, Rafferty et al 1996). These authors support the view that continuing education should be undertaken by nurses, but little evidence exists as to the actual impact that continuing education has on the delivery

of higher standards of patient care. Improving knowledge does not necessarily improve practice. There is evidence from the medical literature to demonstrate that education does not always have a positive effect on patient outcomes (Davies et al 1995). There are many variables that influence the practice of health care providers, and primary strategies such as education must be supported by other secondary strategies, for example in this case the TIME wound care formulary, for effective changes in practice. It is also important to consider the practice environment and social influence such as habit and custom, beliefs and norms which can all influence the translation of guidelines into practice (Conroy and Shannon 1995). Introducing and sustaining research evidence into practice remains challenging for both commissioners and providers of healthcare. A Department of Health sponsored review of research and development confirmed that too few clinicians are aware of research and that efforts to improve the situation had not been successful (DOH 2000).

Practice-based knowledge is a major influence on clinical decision-making in wound management (Luker and Kenrick 1995). Clinicians own experience and the opinion of colleagues can impact on wound care practice and in the choice of treatments used such as dressings. They may be aware of the necessity for utilizing evidence based information, but may consider it irrelevant due to lack of confidence and time (Guyatt et al 2000). Boxer and Maynard (1999) examined the factors that affected nurses' decision making in the management of chronic wounds, in a sample size of 140 nurses. Their findings suggest that decision making was not informed by established protocols for wound management, research findings or in-service education. They in fact relied on their own experience and the opinion of colleagues to direct practice. In one study community nurses used the materials supplied by drug or product companies representatives as a regular source of clinic up-date, describing this as a source of scientific knowledge (Luker and Kenrick 1992). Given the number of wound care companies, the variety of products available and competition for sales this can be both confusing and misleading for community nurses.

The role of opinion leaders can have a significant impact on the implementation of evidence-based practice in wound care (Jeffcoate and Harding 2003). Resistance to changes in practice can be reduced by using a respected change agent (Smith and

Masterson 1996). Tissue Viability Nurse Consultants and Specialists are in an ideal position to bridge the 'theory-practice gap' in wound care practice and to have a positive impact on patient care. Francke et al (1995) asserts that, on the evidence of scientific knowledge, it appears that the support of colleagues and superiors is the most important factor in determining the positive influences of education upon practice development.

Clinical guidelines are also reported in the literature as a means of bridging the theory-practice gap. Guidelines in wound care have been developed to support the implementation of evidence based practice for example the National Institute for Health and Clinical Excellence Guidelines on pressure ulcer prevention (NICE 2003). However guidelines often remain ineffective as clinicians are often unaware of their existence (Flanagan 2005). For guidelines to be useful for practice they need to be available in summary format and incorporated into local guidelines (Dowsett 2002). Incorporating the guideline information into education and training can also be a useful approach (Richens et al 2004), as in the case of the educational programme for this research project. Implementing best practice in wound care is therefore not just about delivering education, but also provision of the tools and support to enable practice to change. The utilization of clinical guidelines as part of the educational programme and the recognition of opinion leaders as key change agents, is also seen as important.

This literature review has explored the concept of Wound Bed Preparation and the associated TIME framework. It has identified variations in wound care knowledge and practice, which supports the theory-practice gap. There is a considerable body of literature that introduces the concept of WBP and presents evidence to support each element of the TIME framework. There are also studies to show the impact of education on nurses knowledge in the field of wound care and other areas. There are however no studies that have observed practice in relation to the provision of an educational intervention in wound care. There is also no evidence that supports the use of the TIME framework in relation to improving community nurses or any other health professional wound care knowledge and practice. This study is unique in that it sought to examine knowledge and practice using a new approach to wound care.

### **4. 3 Methods**

This section is concerned with the research study design and methods aimed specifically at investigating the impact of an educational intervention incorporating WBP and the TIME framework on community nurses knowledge and practice in wound care. The research objectives, study design, sample, instruments and procedures will be discussed. Consideration will also be given to ethical approval, pilot studies and data analysis.

#### **4.3.1 Research question:**

Does providing an educational programme incorporating the TIME framework improve community nurses knowledge and practice in chronic wound management?

#### **4.3.2 Research aims:**

To examine the impact of utilisation of the concept of WBP and the TIME framework on community nurses wound care knowledge and practice.

To explore the process of implementing the concept and the framework using an educational approach with community nurses.

#### **4.3.3 Research Design**

This experimental design study hypothesised that a structured educational intervention based on the concept of WBP and the TIME framework would positively impact on community nurses knowledge and practice in wound care. The dependent variable was defined as the level of change in wound care knowledge and practice as demonstrated by community nurses. The independent variable was defined as the educational intervention, the presumed cause of changes in knowledge and practice. The dependent variable was measured by the use of questionnaires and non-participant observation of clinical practice in wound care, before and after the introduction of an educational programme. The independent variable was operationalised by delivering an educational programme on the TIME framework to community nurses over a series of two half day modules.

This experimental pre-test post-test design using repeat measures was used as it is a reliable method for testing hypotheses of cause and effect relationships between



variables. Dugard and Toolman (1995) suggest that pre-test-intervention-post-test designs are uniquely appropriate for investigating the effects of educational innovations and are commonly used in educational research. Strict experimental designs suggest the use of a two-group pre-test-intervention-post-test design with a control group that receives no training and a group that receives the training. In the occupational training environment where evidence based practice is encouraged it is often not possible to have different levels of training for staff. It was decided not to have a control group because the withholding of training from the control group would represent a differential service for patients inconsistent with the philosophy of implementing evidence based practice. It would also have been difficult to ensure reliability on the prevention of cross contamination of knowledge, as the community nurses frequently change teams and their work bases. The pre-test post-test design used addresses some of these difficulties. However on reflection a cross-over design where a control group received the educational intervention at a later date may also have been appropriate to use, and may be useful for delivering future educational programmes with healthcare professionals.

Multi-methods of data collection were used for the study. This multi-method approach allows for triangulation of data in order to converge on an accurate representation of the phenomenon under investigation (Denzin and Lincoln 2003). Non-participant observation, questionnaires and retrieval of information from the patients clinical notes, were used to gather data on community nurses knowledge and skills, pre and post the introduction of the educational programme. Quantitative data was analysed to provide measurement and focus and qualitative data was collected to address issues of context, meaning and complexity. The data was triangulated to test one source of information against another and to increase the reliability of the findings. The findings have been and continue to be used to inform current practice and to further develop clinical practice in the area of chronic wound management. Some of these developments will be discussed in section 4.4.

#### **4.3.4 Sample**

A sample of n=48 community nurses were invited to take part in the study from one Primary Care Trust in London. Forty seven (99 %) were recruited to the study and gave written consent to take part. This strategy of non-probability sampling used the

researcher's knowledge of the population to pick the cases to be involved. Although advantageous in that it is practical and economical, the researcher does recognise that it increases the likelihood of bias. However as the phenomenon under investigation could only be studied where wound care was being carried out it was considered an appropriate sample selection. Full participation was defined as taking part in a non-participant observation visit, to a patient requiring wound care before and after attending an educational programme, and completing a questionnaire before and after the event. Statistical power analysis was used to estimate the sample size required to adequately test the hypothesis (Cohen 1977). A statistician at City University was consulted to calculate the variation, power the difference and determine the sample size needed to be able to generalise from the study. To detect a medium effect size, with 85% power at the 5% level, allowing for attrition, a minimum sample size of 31 participants were required. However all community nurses were invited to take part to ensure they received a wound care update and so that no nurse would feel excluded from training. Including the total sample of community nurses also reduced the likelihood of bias associated with selecting a sample from nurses who express an interest in wound care. A total of 47 nurses took part in the study. However 15 were lost to follow up, making the final sample size 32, which fulfilled the sample size requirements. The sample was made up of all registered general nurses working in the community who were involved in the assessment and management of patients with wounds. Their clinical banding varied between bands five and seven. During the course of the research fifteen participants withdrew from the study for the following reasons: five left the trust, two changed roles within the trust, three were on sick leave, one on maternity leave, one on annual leave at the time of follow up visits and two withdrew without reason.

#### **4.3.5 Instrumentation**

Data were collected by means of non-participant observation, questionnaires and recording of information from patients' clinical notes pre and post the introduction of an educational programme on the concept of WBP and the TIME framework. For the purpose of non-participant observation an observation schedule was developed to collect information in a structured format based on details of the patient's assessment, their management and treatment, with respect to the TIME framework. The questionnaire was developed and distributed prior to the educational programme and

again on completion of the programme to identify the effects of the educational programme on nurses knowledge levels. Data collected was treated in the strictest of confidence. The research data was registered with data protection through the Trusts I.T department and was kept in a locked filing cabinet in a locked office. Observation schedules and questionnaires were coded so that no community nurse or patient could be identified. For the purpose of analysis the computer software package Statistical Package for Social Sciences (SPSS) version 14.0 was used and the data stored on the main server of the PCT.

#### **4.3.6 Questionnaire**

A literature search was undertaken to determine if a validated questionnaire was available that examined nurse's knowledge in relation to WBP and the TIME framework. Databases searched included CINAHL, EMBASE, MEDLINE and the Cochrane Library (2000-2005). Discussions with senior colleagues in the area of tissue viability, also took place, but showed no previous questionnaire designed to collect data on the TIME framework, at this time. More recently Shorney (2007) developed and used questionnaires to collect data on nurse's evaluation of two national study days on the TIME framework. The questionnaires used in this study were reviewed but found to be inappropriate for use or adaptation for this research question. The results of this descriptive study reported retrospectively on nurse's perceived value of an educational day on their wound care knowledge. Ninety five percent of those who attended reported improved knowledge following attendance. The research did not however explore how this perceived improvement in knowledge impacted on clinical practice.

Self-administered questionnaires which were designed in relation to the stated aims of the research were given out in the group educational sessions to ensure a good response rate and also to ensure that nurses did not confer with each other and bias the answers given. The use of questionnaires before training offered the nurses the opportunity to identify their knowledge deficits in keeping with the premise of adult learning theory (Knowles 1984), which was the theoretical framework used in developing the educational programme. Open and closed ended questions were used to allow for collection of both quantitative and qualitative data. The questionnaire (Appendix 8) consisted of sixteen questions. Questions one to four were intended to

collect data in relation to wound healing, factors that delayed healing and how a wound affects a patient's quality of life. Questions five and six were designed to investigate nurse's knowledge and understanding of the concept of WBP and the TIME framework and consisted of open ended questions. The remaining questions focused on each element of TIME. Question eight and nine on tissue management, question ten, eleven and twelve on infection control and question fifteen and sixteen on edge/evaluation. Wound pictures were used to obtain information on how nurses diagnosed and treated wounds in relation to tissue problems and wound edge problems.

#### **4.3.7 Observation schedule**

Observing and recording practice is fraught with difficulty. In order to ensure accurate and consistent documentation of the observed behaviour, with relevance to the study aims a structured observation schedule (Appendix 9) was designed. The categories in the observation schedule focused specifically on WBP and TIME. The WBP 'Care cycle' (Dowsett 2004, Dowsett and Newton 2005) was used to influence the layout and sequence of the schedule categories. The schedule was used to record the nurses and patient codes as well as the wound type, duration and frequency of visits. The first recorded observation focused on assessment and aimed to record the detail at which the following information was recorded: past medical history, current history, pain, mobility, nutrition, medication and effects of the wound on daily living. Due to the various levels that these details can be recorded, a scoring system from 1-5, was recommended and developed, with 1 being the most basic level recorded and 5 where the documentation showed evidence of monitoring and evaluation. The nurses' assessment and re-assessment of the patient was observed, and their interaction with the patient recorded for example how they responded to pain at dressing change or reports of health issues that were significant for that patient.

The second focus of observation was on wound diagnosis. In order to treat wounds successfully it is necessary to treat the underlying cause (Dealey 2001, Schultz et al 2003). A Doppler assessment is recommended for patients with leg ulcers (RCN 1989) and risk assessment for patients with pressure ulcers (NICE 2003). The type of wound was noted and the availability of a relevant and specific assessment. The researcher observed the type of treatment in use for evidence that the underlying

cause had been addressed, so if a patient had a diagnosis of venous leg ulceration, the expectation was that the patient would have or have been offered compression therapy. Where a patient had an existing pressure ulcer, evidence of provision of pressure relief equipment both on the patient's bed and their chair was noted and re-positioning change was recorded. The patient's notes were also checked for evidence of assessment in relation to disease factors that delay wound healing, and any communication between the patient and nurse in relation to these was recorded.

The observation schedule was designed to then record details of the patients wound assessment. The Trust recommends use of a wound assessment form (Appendix 3) to record data. All nurses have had training on the wound assessment form as part of their induction and wound care updates and it is available on the Trust intranet. The form also asks for a record of the wound dimensions or some form of measurement. If a formal record was taken of the wound size during the visit this was also recorded, including the technique used. The frequency of dressing change and re-assessment of the wound was also recorded. For those patients who did not have a wound assessment form available, time was spent going through the recorded clinical updates.

The remaining focus of observation was in relation to the wound bed and the TIME framework, with observation of the wound for non viable tissue, evidence of clinical infection, evidence of a moisture balance problem and problems with the edge of the wound such as undermining or raised edges. The nurses discussions with the patient and descriptions used to discuss the wound type were noted, as was the treatment and dressing that the nurse provided for the patient. The type of debridement in use, the treatment of infection if appropriate were all observed and recorded. The notes were also checked for a record of edge advancement or reduction in the wound size. The type of wound measurement was observed and recorded. Finally the type of referrals and the rationale for these were noted, including referral to tissue viability services.

To prevent disruption to the patient's wound care routine route, visits were planned to coincide with the patient's usual plan of care, so that they took place on the day and time that had been agreed by the patient. To avoid role conflict the researcher contacted the nurse prior to the visit to remind them of the purpose of the visit.

Following introductions to the patient, the researcher again explained the reason for the visit. Where nurses required specialist advice, a referral was made to the tissue viability team and a colleague went to see the patient at a later date. However problems were encountered with some visits when nurses were asking for specialist advice and this will be discussed in section 4.5.

The researcher was aware of the potential to observe practice that was unsafe or of a poor standard. It was agreed that where practice was unsafe the researcher would intervene in the interest of patient safety, but fortunately this was not necessitated during the course of the research. Where practice was deemed to be safe, but of a poor standard, this was discussed with the student's second supervisor who is an expert in the field of practice, in order to develop an action plan. In one instance it was necessary to provide further support and training for an individual participant in relation to pain at wound dressing change. The participant was receptive to recommended changes for practice improvements.

The results of the observation schedule and questionnaire were compared to determine if what respondents said they did was what actually took place in clinical practice. The findings of these comparisons will be discussed in section 4.5.13.

#### **4.3.8 Reliability and validity**

To improve reliability in the questionnaire, closed-ended multiple-choice questions were predominately used (Oppenheim 2001). To increase reliability and validity of the questionnaire and observation schedule, they were peer reviewed by a group of wound care experts who currently make up the International Advisory Board for Wound Bed Preparation to check for ambiguity, imprecision or assumptions, and amended in light of any recommendations made by the group.

To ensure content and construct validity the questionnaire and the observation schedule were piloted. The questionnaire was piloted in a neighbouring primary care trust on a sample of ten community nurses, with a similar caseload to the host trust and of similar nursing grades. Following completion of the questionnaire the researcher set up a focus group of those nurses in the pilot study to discuss the questionnaire pilot and ensured the necessary suggested recommendations were made.

The observation schedule was piloted by two independent experts, one a Nurse Consultant in tissue viability in another trust where the TIME framework was not being used and a Clinical Nurse Specialist in tissue viability within the host trust who was familiar with the framework. Each of them collected data on ten patient visits. To reduce the Hawthorne effect and behaviour change during the observation visits, each participant was given clarification with respect to anonymity and confidentiality prior to the visit. They were also given the opportunity for questions or to raise any concerns about the research visit. However the potential for effect could not be completely overruled due to the nature of conducting real life research, in the patient's home care setting. To ensure reliability of information and reduce bias in recording, some information was recorded during the visit. More detailed recording took place immediately after the observation visit, once the participants had been debriefed, to ensure facts were recalled as soon after the event as possible.

#### **4.3.9 Control of variables**

To control extraneous variables and enhance the study's interpretability, consistency of conditions were maintained throughout the study. The researcher ensured that the data were collected in the same format from all participants, and that the educational programme was delivered consistently. Observation of practice was restricted to a single setting e.g., the patient's home and information was collected using a structured format. Statistical analyses using both parametric and non parametric statistical tests were also used to control the variables and ensure that the results were less likely to be due to chance. No other wound care training was delivered during the course of the research to reduce the likelihood of other educational influences on nurse's knowledge and practice.

Internal validity was ensured by using the same sample throughout for comparison, before and after the delivery of the educational programme. Consistency of conditions was also maintained to ensure internal validity. External validity was achieved by ensuring the sample size was adequate by analysis of covariance using statistical analysis, and that the sample was representative of nurses who undertake wound care in the community setting. The environment was also controlled by ensuring that all training took place in the nurse's bases for the sample time allocation and that visits to observe practice all took place in the nurses usual environment which was the patients

home. Data were also collected over a set period after the educational programme to reduce the likelihood that changes in knowledge and practice were due to external factors such as wound care company updates.

#### **4.3.10 Educational programme**

The educational programme consisted of two modules that were delivered over a series of two half-study days. Module 1 consisted of an introduction to the concept of Wound Bed Preparation, the 'care cycle' and the TIME framework. Module 2 Covered the TIME framework in detail, drawing on the most up to date evidence for clinical practice, in terms of tissue debridement, infection control, moisture balance and monitoring and managing the wound edge. Case study examples were utilized to demonstrate key concepts such as local and systemic infection and wound edge problems. The photographs used for the questionnaire were used as examples when discussing the T and E of TIME. A demonstration of the wound measurement device (visitrak) also took place, and a practical workshop followed that allowed the nurses to practice using the device. Presentation handouts as well as two published papers on the concept of Wound Bed preparation (Dowsett and Ayello 2004, EWMA 2005), were given to each nurse. To support use of the TIME framework when assessing and treating patients, a laminated A4 card with the 'care cycle on one side and the TIME table on the other was distributed. On completion of the training programme each locality base was issued with two Visitrak measurement devices and measurement grids and probes. These were purchased with the support of the locality nurse managers.

#### **4.3.11 Procedures**

The researcher/tissue viability Nurse Consultant works closely with the community nurses providing regular in-house training and undertaking joint visits to give expert advice on patient care, so the opportunity to discuss potential improvements to care and research are always available and utilized. A well established tissue viability link nurse system has also been developed and this forum was used as an opportunity to first introduce the research project. The link nurses were keen to be involved and agreed to disseminate the information back in their clinical areas.



#### **4.3.12 Ethical considerations**

This was a single site research study as part of a PhD in Professional Practice at City University. The proposal for the research was subject to peer review by City University. Ethical approval was obtained (Appendix 10) from the East London and the City Research Ethics Committee, under the operational procedures for NHS RECs, from the Central Office for Research Ethics Committees (COREC). The researcher was aware of her responsibilities to the individual patients and nurses in the proposed study, and that responsibility involved ensuring that there was no interference with their physical, social or mental well being. Informed consent was obtained from nurses and their patients who took part in the study.

The study participants were made aware that they could withdraw from the study at any time should they so wish, without any negative impact. Anonymity was guaranteed by coding the observation schedules and the questionnaires and this was explained to the nurses who agreed to take part. Careful consideration was given to the vocabulary used and question type in the data collection tools, to ensure that they were politically correct and not offensive to individuals. A comfortable and non-threatening environment was promoted during field work observations. Information was fed back to participants on completion of the research in a series of workshops, with the necessary recommendations for practice included. It was made explicit that the results would be reported and would be submitted for publication at a later date

#### **4.3.13 Indemnity**

The research was registered with City University under the research governance guidelines and a letter of indemnity was obtained from City University and the hosting Primary Care Trust.

#### **4.3.14 Consent**

Consent was obtained from the Primary Care Trust, who acted as sponsor for the research. The proposal was also submitted for Trust research and development management approval and consent obtained (Appendix 11). The research proposal was presented to the primary care and community nurse managers and approved (Appendix 12). A presentation and discussion took place at the tissue viability link nurses meeting and dates were arranged for presenting the research project to the

wider community nurse groups. A series of presentations took place in each of the four community nurse localities to explain the research and to invite participation. An information sheet and a consent form (Appendix 13) were given to each of the nurses and they were asked to return this in the internal post if they were happy to participate. It was made implicit that participation was voluntary and that those nurses who did not want to take part could attend the educational sessions. Any new members of staff who joined the trust once the research was underway were also invited to the training sessions, as they would be working in teams who would be implementing new approaches to care. It was seen as advantageous in recruiting to the study that the researcher did not manage the community nurses and works in a different directorate. This reduced potential pressure to participate in the research.

In order to gain patient consent for the non participant observation visits, a letter (Appendix 14) explaining the research and the purpose of the researcher visiting was given to the patient by the nurse and consent obtained prior to the visit. The patient was assured that the research visit would not impact on their usual wound care treatment and that if specialist nursing input was required, it would be available to them at a later date. To ensure that the patients General Practitioner was aware of the research, an explanatory letter was sent to those GP's who had patients taking part in the research.

#### **4.3.15 Administering the instruments**

Those nurses who agreed to take part were entered onto a data base and allocated a number for the purpose of ensuring anonymity. Each nurse was contacted to arrange for an observation visit and also given a list of dates and venues for the training. Observation visits were conducted over an eight month period. The pre training observation visits took place over a period of four months from September to December 2005, and the post training visits from May to August 2006. The nurses were phoned the day before the visit to remind them of the purpose of the visit, and differentiate it from the usual specialist advice visit. When the observation visit was completed the nurse was then given a list of training dates and venues for module one and two. A record of attendance at training was maintained and evaluation forms completed on completion of both modules. Before the delivery of training the nurses were given the questionnaire to complete in an allocated time. The nurses were not

allowed to confer with colleagues at this time. Following the second module all nurses were re-issued the questionnaire, and again given an allocated time to complete without the opportunity to discuss with colleagues. The questionnaires and observation schedules were coded by the nurses allocated number. To ensure patient confidentiality the patients who agreed to home visits were also allocated a number. A record of the corresponding nurses names and patient names was kept in a confidential file.

#### **4.3.16 Data analysis**

Advice on coding the data was sought from a senior lecturer/practitioner in the field of tissue viability that had previous experience of coding data for analysis with SPSS. The data were coded and entered into SPSS. It was then checked for accuracy by a statistician at City University. Quantitative data was analysed using the computer software package Statistical Package for Social Sciences (SPSS) version 14.0. Parametric and non-parametric statistical tests were used to analyse the data, based on the distribution and the level of significance of the findings reported. Descriptive statistics were used as well as themes and categories to further analyse the data. The themes and categories were predetermined based on the literature, section 4.2 and as follows;

- Patient assessment knowledge and practice
- Wound assessment knowledge and practice
- Use of the TIME framework
- Nursing interventions and treatment.

#### **4.3.17 Statistical analysis**

The distribution of the data were checked for normality using the Kolmogorov-Smirnov test, and the data was also plotted on a histogram. Where the data was normally distributed parametric statistical analysis was used in the form of a related t test. For data that were not normally distributed the Wilcoxon signed-rank test was used. For those questions containing ordinal data the McNemar test was used to measure differences in knowledge and practice before and after the educational intervention.

#### **4.3.18 Statistical tests used**

##### **4.3.18.1 Kolmogorov-Smirnov test (KS test)**

This test compares the scores in the sample to a normally distributed set of scores with the same mean and standard deviation. If the test is non-significant ( $p > .050$ ) it tells us that the distribution of the sample is not significantly different from a normal distribution, that is that it is probably normal. If, however the test is significant ( $p < .05$ ) then the distribution in question is significantly different from a normal distribution. However as it can be easy to get a significant result from small deviations from normality, which can bias the statistical procedure, the data was also plotted on a histogram.

##### **4.3.18.2 Related t test**

This test also referred to as paired-samples t test, is used for repeated measures or matched pairs, with an interval/ratio level of data. The test looks at the actual size of the difference between each subject's scores in the two conditions. To determine the likelihood that the differences between the two conditions were due to chance, the test takes into account the mean differences for the group as a whole and the variation in the size of the differences for individual subjects (Field 2005).

##### **4.3.18.3 Wilcoxon signed-rank test**

This test is a non-parametric test that is used for repeated measures or matched pairs, where the level of data is ordinal. The test examines the difference between subjects's scores in each of the conditions. It looks at the direction of the differences and also ranks them to compare the relative size of those differences where subjects do best in condition A and those where performance in condition B is best (Field 2005).

##### **4.3.18.4 McNemar test**

This tests the differences between two related groups when you have nominal data. It is typically used when you are looking for changes in people's scores and it compares the proportion of people who changed their response in one direction to those who changed in the opposite direction. It is used when you have two related dichotomous variables (Field 2005).

#### **4.3.19 Limitations of the study methodology**

There is the potential for re-activity whilst carrying out practice observations in patients own home due to the close nature of researcher and participants. There is also potential for bias as the researcher was undertaking the observations, and may have had expectations of what to expect in terms of wound care practice. This could have been reduced by having an independent observer. However this was not possible due to funding and availability of a suitable person. These potential limitations were identified and an observation schedule with a category system developed to try to overcome them. Additionally by taking retrospectively documented information from the patient's notes, this was more likely to be an accurate representation of events that had been taking place prior to the observation visit.

The study could be criticised for not using a control group as recommended in experimental design studies, but this method would not have been consistent with the philosophy of implementing evidence based practice and there was also the potential for cross contamination of knowledge due to the frequent re-allocation of community nurses across the geographical area, as previously discussed in section 4.3.3.

The study was limited to a set follow up timescale and it would have been interesting to investigate the sustainability of the knowledge and practice improvements, by following up the participants twelve months later. However evidence from recent audits, for example, the use of the TIME based wound care formulary suggest that the TIME framework has been imbedded in clinical practice (section 4.5.16) and continues to make a difference to the patients of Newham.

4.4 Results

4.4.1 Characteristics of the sample

A total sample of n=48 community nurses were invited to take part in the study. Forty seven nurses responded agreeing to take part, and completed written consent forms. The nurses were based in four geographic localities and their clinical grades varied between band 7 and band 5 (Figure 1). A total number of 79 patient visits took place to observe clinical practice, 47 before the educational programme and 32 after. Fifteen were lost to follow up after the training programme, for the reasons as shown (Table 1). Forty nurses attended the educational programme and all 40 (100%) completed the questionnaire before and after the training.

Figure 1 Clinical banding of nurse participants

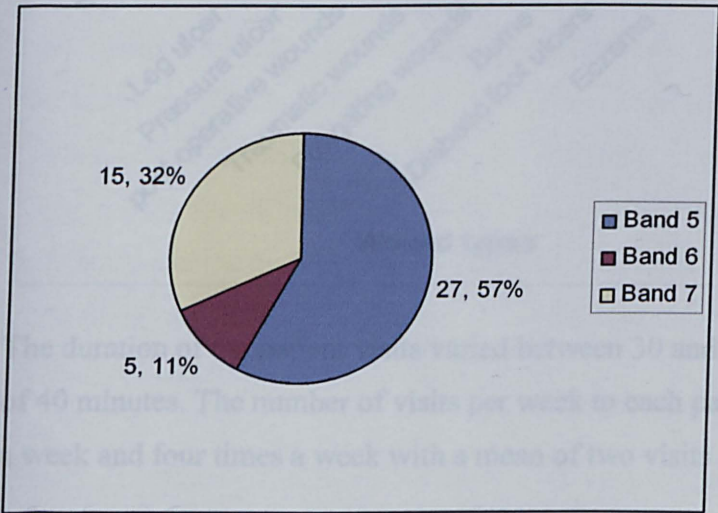


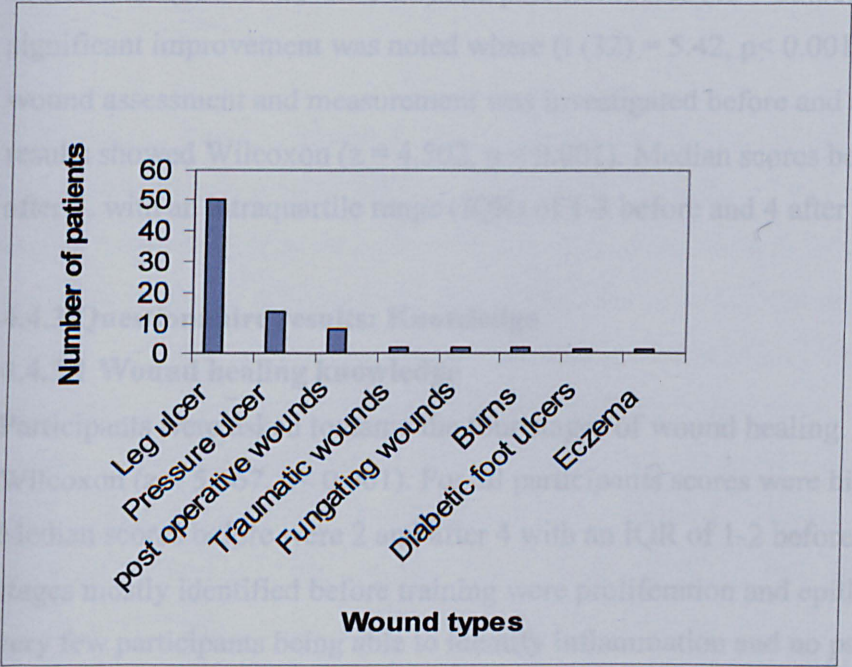
Table 1 Reason for participant withdrawal

Reasons for withdrawal	No. of participants
Left the trust	5
Sick leave	3
Withdrew from the study	2
Changed roles	2
Maternity leave	1
Study leave	1
Annual leave	1



A number of different wound types were observed during the observation visits (figure 2). However the most common wound type observed was leg ulceration, which accounted for 80% of the visits.

**Figure 2 Wound types observed**



The duration of the patient visits varied between 30 and 90 minutes with a mean time of 40 minutes. The number of visits per week to each patient also varied between once a week and four times a week with a mean of two visits a week to each patient.

**4.4.2 General findings:**

The questionnaire results were analysed before and after the educational intervention to compare mean ( $\bar{X}$ ) scores, and standard deviation (SD). Pre-test scores of ( $\bar{X}$  = 25.35, SD 7.19) and post test scores of ( $\bar{X}$  = 42.08, SD 3.63). A significant improvement was noted ( $t(39) = 17.37, p<0.001$ ). Individual question scores were analysed and they also showed an improvement in knowledge, and will be discussed in more detail in section 4.4.3.

The results from observation visits were analysed for changes in nurse’s practice, in patient assessment and wound assessment, using the TIME framework, before and after the educational intervention. Pre-test scores ( $\bar{X}$  = 21.77, SD3.94) and post test



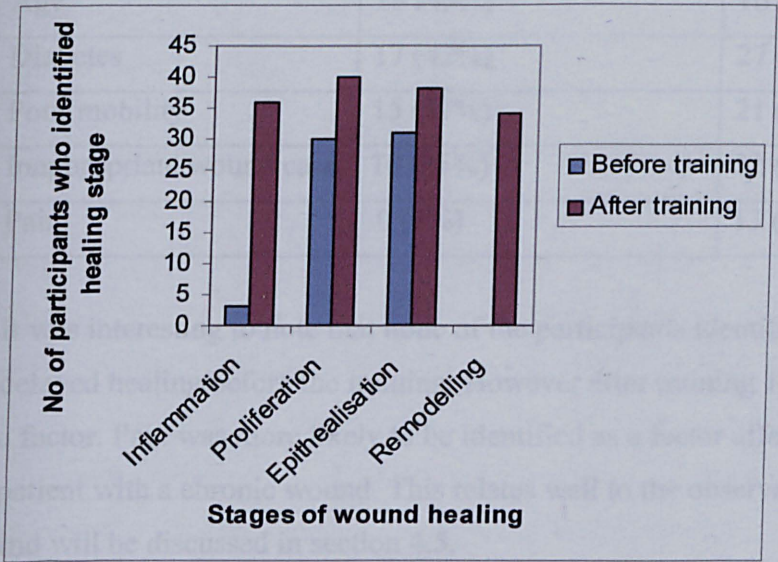
scores of ( $\bar{X} = 28.91$ ,  $SD 3.65$ ). A significant improvement was noted where ( $t(32) = 7.12$ ,  $p < 0.001$ ). Scores for patient assessment and wound assessment were analysed independently and the following results were found. Using the seven category assessment details, the following results were found for patient assessment. Pre-test scores were ( $\bar{X} = 19.5$ ,  $SD 3.36$ ) and post test scores ( $\bar{X} = 25.06$ ,  $SD 3.57$ ). A significant improvement was noted where ( $t(32) = 5.42$ ,  $p < 0.001$ ). Nurses practice in wound assessment and measurement was investigated before and after training. The results showed Wilcoxon ( $z = 4.502$ ,  $p < 0.001$ ). Median scores before were 2 and after 4, with an intraquartile range (IQR) of 1-3 before and 4 after training.

### 4.4.3 Questionnaire results: Knowledge

#### 4.4.3.1 Wound healing knowledge

Participants were asked to name the four stages of wound healing. The results showed Wilcoxon ( $z = 5.667$ ,  $p < 0.001$ ). For all participants scores were higher after training. Median scores before were 2 and after 4 with an IQR of 1-2 before and 3-4 after. The stages mostly identified before training were proliferation and epithealisation, with very few participants being able to identify inflammation and no participant identifying remodelling/maturation. After training this had improved significantly with all four factors being identified (Figure 3).

**Figure 3: Number of nurses who correctly identified the stages of wound healing before and after training**





It is important that clinicians recognise inflammation as a normal process in wound healing and are aware that prolonged inflammation can occur in chronic wounds, causing delayed healing. Underlying inflammatory process can also be the underlying cause of a wound for example pyoderma gangrenosum and therefore improved knowledge in this area can improve diagnosis and treatment. This will be discussed further in section 4.5.

Knowledge of wound healing closure was explored where participants were asked if a venous leg ulcer healed by primary or secondary intention. Twenty five (62%) of nurses responded correctly by identifying secondary intention before training. This had improved after training to 36 (90%) of nurses. The McNemar test showed ( $p = 0.007$ ). Four participants still had an incorrect answer despite being given this information as part of the training programme. Participants were then asked to identify six factors that delayed wound healing . The Wilcoxon signed-rank test was used to analyse the results. The results (Table 2) showed an increase in the number of factors identified after training where Wilcoxon ( $z = 4.339, p<0.001$ ). Median scores before were 5 and after 6, with an IQR of 4-5 before and 5-6 after.

**Table 2    Most common factors identified that delay wound healing**

Factor identified	No. of nurse (before)	No. nurses (after)
Poor nutrition	34 (85%)	35 (87%)
Infection	30 (75%)	13 (32%)
Age	18 (45%)	16 (40%)
Diabetes	17 (42%)	27 (67%)
Poor mobility	15 (37%)	21 (52%)
Inappropriate wound care	10 (25%)	32 (80%)
Pain	0 (0%)	13 (32%)

It was interesting to note that none of the participants identified pain as a factor in delayed healing before the training. However after training 13 (32%) identified this as a factor. Pain was more likely to be identified as a factor affecting quality of life for a patient with a chronic wound. This relates well to the observation findings and will be discussed in section 4.5.

Knowledge of quality of life issues were also investigated in relation to wound healing. Participants were asked to list four effects that a wound has on a patient’s quality of life. The results (Table 3) showed that knowledge had improved significantly in this area after training where, Wilcoxon ( $z = 4.714$ ,  $p < 0.001$ ). Median score before were 3 and after 4, with an IQR of 2-3 before training and 3-4 after training. The most common factors listed are outlined in Table 4.

**Table 3    Most common quality of life issues identified by nurse**

Factors	Before	After
Social isolation	25 (62%)	35 (87%)
Pain	15 (37%)	32 (80%)
Reduced mobility	21 (52%)	24 (60%)
Depression	9 (22%)	21 (52%)
Inability to carry out activities of daily living	9 (22%)	10 (25%)

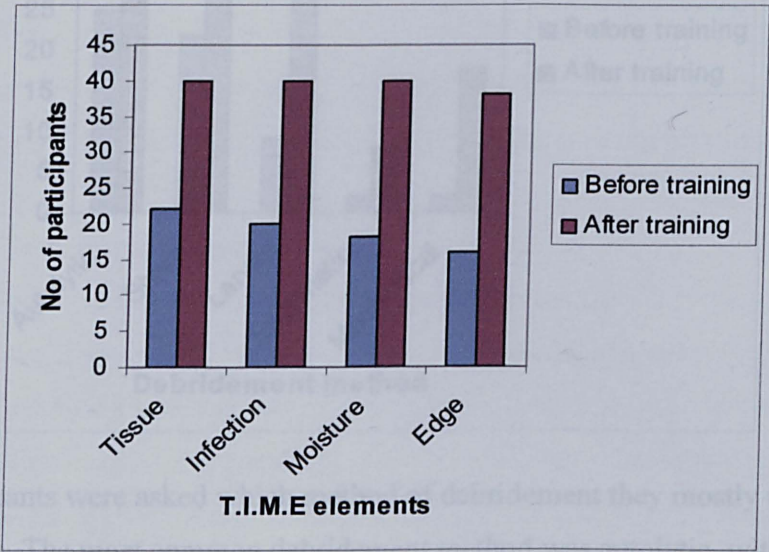
Chronic wounds can have a significant impact on a patient’s quality of life and on healing. These effects are often not recognised or addressed by the clinician. Improving quality of life should be seen as an important end outcome when managing these patients, particularly when healing may not be achievable as in palliative wound care. This will be discussed further in section 4.5.2.

**4.4.3.2 Wound Bed Preparation and TIME**

Participants were asked to define the term ‘Wound Bed Preparation’. Their answers were compared to the definition of WBP as ‘Preparation of the wound to facilitate healing’ or ‘Preparing the wound for healing’. The number of participants who correctly answered before training was 18 (45%), and after training 35 (88%). Using the McNemar test the results were found to be statistically significant ( $P = 0.001$ ). To explore knowledge and understanding of the TIME framework participants were asked what the letters T.I.M.E stood for in relation to wound healing. The Wilcoxon signed-rank test was used to analyse the results. Scores were significantly

higher Wilcoxon ( $z = 4.47, p < 0.001$ ). Median scores before were 2 and after 4, with an IQR of 0-4 before and 4 after (Figure 4).

**Figure 4** Number of participants who were able to define T.I.M.E



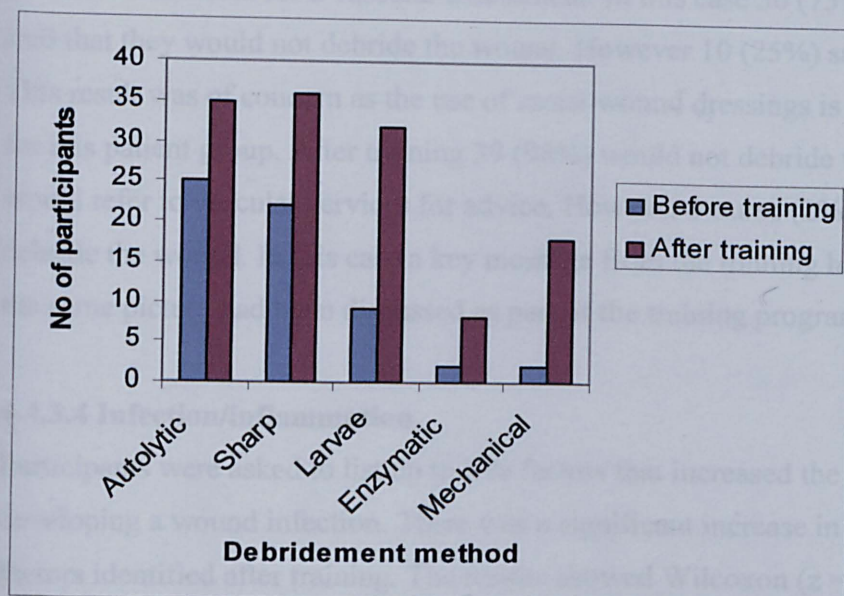
Follow up evaluation of the training programme showed that participants found the TIME framework easy to understand and more importantly easy to use in practice.

**4.4.3.3 Tissue**

Participants were asked to list five methods of wound debridement. Again knowledge of debridement methods increased after training (Figure 5). The results showed Wilcoxon ( $z = 4.833, p < 0.001$ ). Median scores before we 2 and after 4, with an IQR of 0-4 before and 4 after training. Only 1(2%) of participants were able to identify all five debridement methods before training. This increased to 14 (35%) after training.



**Figure 5 Number of participants identifying debridement methods**



Participants were asked which method of debridement they mostly used in clinical practice. The most common debridement method was autolytic, with 21 (52%) using this method before training and 34 (85%) after training. It is worth noting a non-response rate to this question before training 16 (40%), which may show lack of understanding of debridement methods. No respondent identified sharp or larvae before or after training. However there was an increase in the number of patients referred to the tissue viability service for sharp debridement and larvae therapy after the training and this will be discussed further in the next chapter.

Participants were shown two photographs of necrotic wounds and asked if they would debride these wounds, and if yes which method they would use. Picture a. was a necrotic sacral pressure ulcer, which should be debrided to remove necrotic tissue and promote healing. Before training 36 (90%) of respondents said that they would debride the wound, with 4 (10%) not debriding. After training this had increased to 40 (100%) said that they would debride the wound, which is the correct treatment for the wound type. The method most likely to be used was autolytic with the following dressings; hydrogels with foam and hydrocolloids. Following training 5 (12%) nurses said that they would refer the patient to tissue viability services for

sharp debridement. The training highlighted alternative debridement methods to nurses in practice, and the use of the tissue viability service as a referral pathway. Picture b. was a necrotic toe on a patient, which should be left dry and a referral made to vascular services for a vascular assessment. In this case 30 (75%) of respondents said that they would not debride the wound. However 10 (25%) said that they would. This result was of concern as the use of moist wound dressings is not recommended for this patient group. After training 39 (98%) would not debride the wound, and would refer to vascular services for advice. However 1 nurse (2%) said they would debride the wound. In this case a key message from the training had not been lost, as the same picture had been discussed as part of the training programme.

#### 4.4.3.4 Infection/inflammation

Participants were asked to list up to five factors that increased the risk of a patient developing a wound infection. There was a significant increase in the number of risk factors identified after training. The results showed Wilcoxon ( $z = 4.627, p < 0.001$ ). The median scores before training were 1.5 and after training 4.0, with an IQR of 1-2 before and 2-4 after training. Before training most participants could identify 1-2 factors. One factor 17 (42%) and two factors 11 (27%). After training most participants were able to identify 4 factors 16 (40%) with 6 (15%) able to identify five factors. The most common factors identified are outlined in Table 4 and 5.

**Table 4 Factors identified that increase the risk of wound infection before training**

Factors	Before training
Poor dressing technique	20 (50%)
Environment	16 (15%)
Malnutrition	13 (32%)
Diabetes	8 (20%)
Smoking	2 (5%)



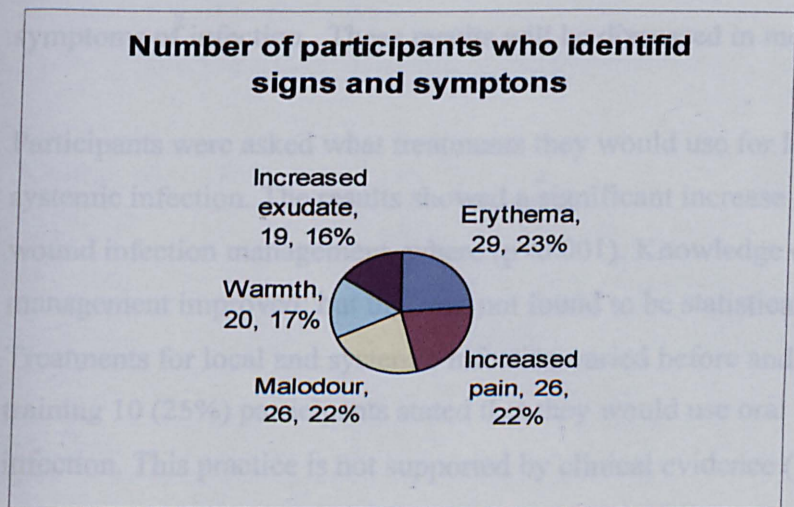
**Table 5 Factors identified that increase the risk of wound infection after training**

Factors	After training
Malnutrition	23 (57%)
Diabetes	22 (55%)
Immunosupression	18 (45%)
Poor dressing technique	17 (42%)
Smoking	17 (42%)

Pre training participants were more focused on extrinsic factors such as environment and poor dressing change. The focus changed to intrinsic factors such as diabetes and malnutrition after the training programme.

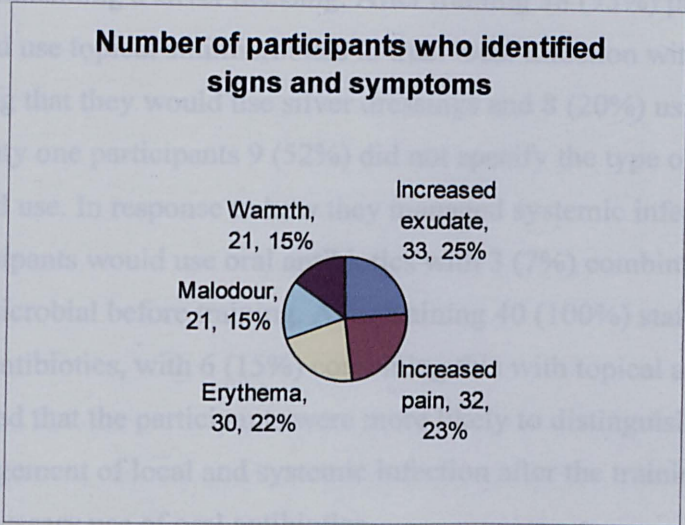
Participants were then asked to list up to five signs and symptoms that wound indicate that a patient had a wound infection. The results were compared to the list identified from the literature . Again the results showed that knowledge in this area had improved following the educational intervention, where Wilcoxon ( $z = 4.332$ ,  $p<0.001$ ). Median scores before training were 4.0 and after training 5.0, with and IQR of 3-5 before training and 4-5 after training. The most common signs and symptoms listed before (Figure 6) and after (Figure 7) training are shown.

**Figure 6 Number of participants who identified most common signs and symptoms before training**





**Figure 7 Number of participants who identified most common signs and symptoms after training**



The six most common factors listed before and after training are consistent with the criteria for identification of a wound infection as identified by Cutting and White (2005). However some important criteria were not identified as suggested by EWMA position document (2005). These included cellulitis which was not mentioned by any of the participants before training and only 6 (15%) after training, and wound breakdown which was identified by 1 (2%) before training and 2 (5%) after training. Cellulitis is defined as a ‘spreading infection of the skin and subcutaneous tissues, characterised by local pain, tenderness, oedema and erythema’ (EWMA 2005 p15). This is a controversial indicator, as redness and swelling may often appear around the wound for other reasons. Nurses did however identify pain and erythema as signs and symptoms of infection. These results will be discussed in more details in section 4.5.

Participants were asked what treatments they would use for local infection and for systemic infection. The results showed a significant increase in knowledge of local wound infection management, where ( $p < 0.001$ ). Knowledge of systemic infection management improved, but this was not found to be statistically significant ( $p = .250$ ) Treatments for local and systemic infection varied before and after training. Before training 10 (25%) participants stated that they would use oral antibiotics to treat local infection. This practice is not supported by clinical evidence (Bowler 2001, Schultz et

al 2003) as previously discussed. After training no participant recommended the use of oral antibiotics. Seventeen (42%) participants responded that they would use a topical antimicrobial for local infection before training with 4(10%) specifically recommending a silver dressing. After training 38 (95%) participants stated that they would use topical antimicrobials to treat local infection with 13 (32%) specifically stating that they would use silver dressings and 8 (20%) using cadexomer iodine. Twenty one participants 9 (52%) did not specify the type of antimicrobial that they would use. In response to how they managed systemic infection 33 (82%) of participants would use oral antibiotics with 3 (7%) combining these with a topical antimicrobial before training. After training 40 (100%) stated that they would use oral antibiotics, with 6 (15%) combining this with topical antimicrobials. The research showed that the participants were more likely to distinguish differences in the management of local and systemic infection after the training, with a reduction in the unnecessary use of oral antibiotics.

#### 4.4.3.5 Moisture

The focus of this question was on moisture balance and participants were asked to list up to four interventions that they used to manage excess wound exudate. The results showed that knowledge in this area had improved significantly after training Wilcoxon ( $z = 4.672, p < 0.001$ ). Median scores before training were 2.0 and after 3.0, with an IQR of 1-2 before training and 3-4 after. None of the participants were able to give four answers before training. After training 20 (44%) were able to identify three interventions and 14 (31%) were able to identify four interventions. The most common interventions listed to manage excess exudate before (Table 6) and after (Table 7) training are shown.

**Table 6 Interventions identified to manage excess exudate before training**

Number of nurses	Intervention
29 (72%)	Absorbent dressing
12 (30%)	Increase dressing change
11 (27%)	Absorbent pad
7 (17%)	Compression therapy
6 (15%)	VAC



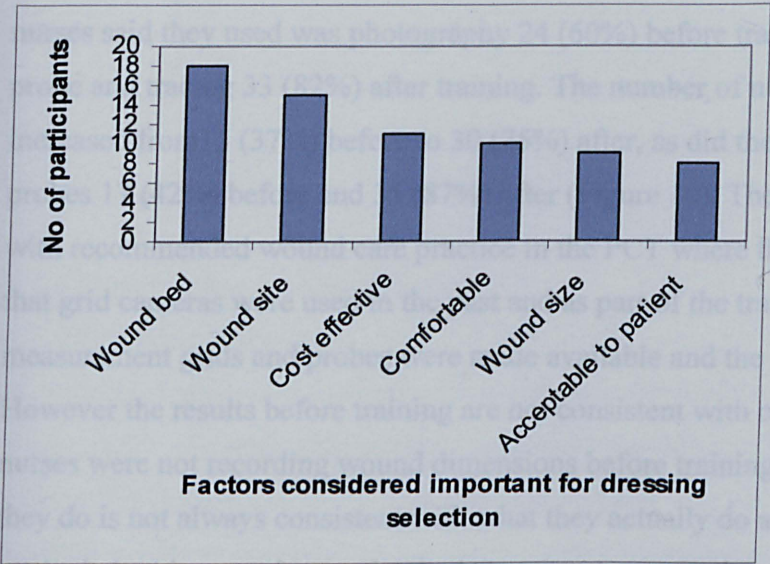
**Table 7 Interventions identified to manage excess exudate after training**

<b>Number of nurses</b>	<b>Intervention</b>
33 (82%)	Absorbent dressing
30 (75%)	Compression therapy
18 (45%)	VAC
14 (10%)	Increase dressing change
14 (10%)	Treat infection

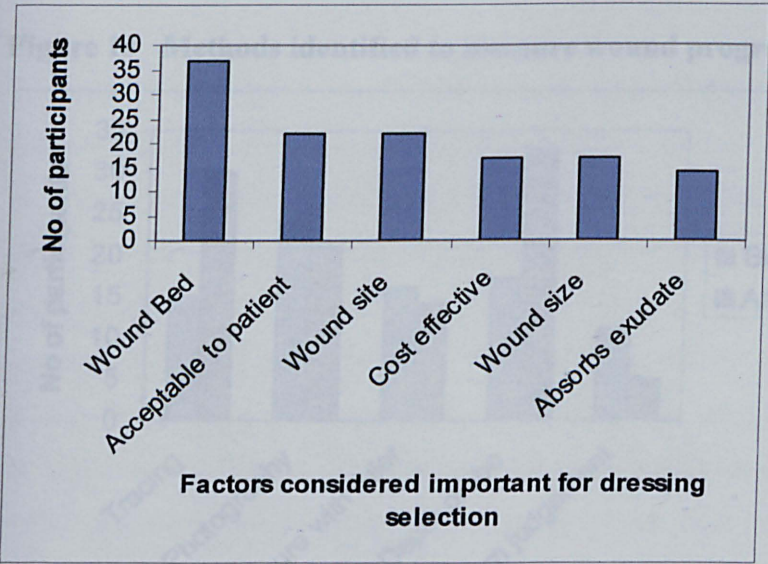
The results showed an increase in recognition of treating the underlying cause when managing wound exudate, for example using compression therapy and treating infection. This was a key message in the educational programme. Participants were also more aware of using topical negative pressure therapy (TNPT) as a means of managing exudate in chronic wounds. The significance of these results will be discussed in more detail in section 4.5.

To explore knowledge in relation to wound dressing selection, participants were asked to list up to 6 factors that were important when selecting a wound dressing for a patient. The answers given were compared to the criteria for an ideal moisture balance wound dressing identified in the literature. Factors identified as important when selecting a dressing before training (Figure 8) and after training (Figure 9) are shown. The nurse's knowledge of the factors that are important when choosing a dressing improved significantly after training. The results showed Wilcoxon ( $z = 4.971$ ,  $p < 0.001$ ). Median scores before training were 3 before and 5 after training, with an IQR of 2-4 before and 3-5 after training.

**Figure 8 Factors identified as important when selecting a dressing before training**



**Figure 9 Factors identified as important when selecting a dressing after training**



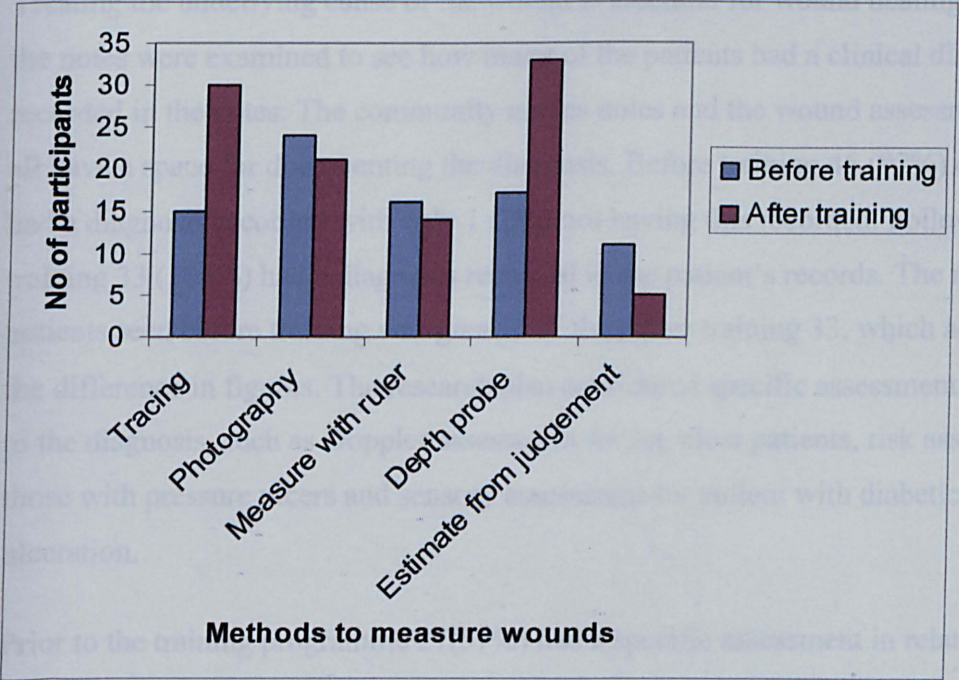
The type of wound bed was seen as an important factor for dressing selection by participants, 9(22%) before training and 37 (92%) after training. What was also encouraging was the focus on patient acceptability and comfort. Clearly these factors are important to ensure patient choice and involvement with treatment. With increased dressing costs and reduced NHS budgets it was interesting that participants highlighted cost effectiveness as a factor.



4.4.3.6 Edge/evaluation

Participants were asked which methods they most frequently use to measure wound progress. The results showed that the most frequent means of measurement that the nurses said they used was photography 24 (60%) before training and use of depth probe and tracing 33 (82%) after training. The number of nurses using tracing increased from 15 (37%) before to 30 (75%) after, as did the use of measurement probes 17 (42%) before and 35 (87%) after (Figure 10). These results are consistent with recommended wound care practice in the PCT where the research took place, in that grid cameras were used in the past and as part of the training programme Visitrak measurement grids and probes were made available and the nurses trained in their use. However the results before training are not consistent with observed practice as many nurses were not recording wound dimensions before training. What participants say they do is not always consistent with what they actually do and therefore using multi-methods in this case observation had the advantage of being able to see what happens in clinical practice.

Figure 10 Methods identified to measure wound progress



To investigate knowledge of wound edge problems, two photographs of wounds with edge problems were incorporated into the questionnaire and the training programme. Participants were asked to indicate the reason why these wounds may not be healing. Picture a. showed a chest wound with raised edges and picture b. showed a wound that was undermining at the wound edges (appendix 8). The results showed a significant improvement in knowledge after training Wilcoxon ( $z = 4.97, p < 0.001$ ). Before training 4 (10%) participants were able to identify that the wound had a raised edge, increasing to 31 (77%) after training.

#### **4.4.4 Observation results: practice**

##### **4.4.4.1 Patient assessment**

A comprehensive wound assessment is recommended when treating patients who present with a wound. That wound assessment should include a number of patients factors (previously outlined). A paired sample t-test was used to compare nurse's practice in patient assessing using seven categories before and after training. Pre-test scores ( $\bar{X} = 19.5, SD 3.36$ ) and post test scores ( $\bar{X} = 25.06, SD 3.57$ ). A significant improvement was noted where ( $t(32) = 5.42, p < 0.001$ ).

Treating the underlying cause of the wound is essential for wound healing; therefore the notes were examined to see how many of the patients had a clinical diagnosis recorded in the notes. The community nurses notes and the wound assessment forms all have a space for documenting the diagnosis. Before training 46 (97%) of patients had a diagnosis recorded with only 1 (2%) not having this recorded. Following training 33 (100%) had a diagnosis recorded in the patient's records. The number of patients seen before training was greater 47 than after training 33, which accounts for the difference in figures. The research also considered specific assessment in relation to the diagnosis, such as Doppler assessment for leg ulcer patients, risk assessment for those with pressure ulcers and sensory assessment for patient with diabetic foot ulceration.

Prior to the training programme 27(57%) had a specific assessment in relation to their wound and 9 (19%) did not. For some patients it was not appropriate to have a specific assessment  $N = 11$ . After training this had improved with 24 (72%) out of the

33 patients seen having had a specific assessment and only 2 (6%) did not. Treatment of a patient with a wound relies on identifying the underlying cause so making a diagnosis is an essential part of the care programme. This will be discussed further in the next chapter. The researcher also observed for evidence that the underlying cause had been addressed, using the criteria outlined in table 8. Wound factors such as infection and tissue type were not included in this section as these were addressed under the TIME categories. For some wounds this was not applicable.

**Table 8    Intervention in relation to diagnosis**

Diagnosis	Intervention
Pressure ulcer	Pressure relief/redistribution methods or equipment in place
Venous leg ulcer	Compression therapy
Diabetic foot ulcer	Diabetic control addressed/pressure offload

Before training 37 (78%) of patients had an intervention to address the underlying cause of the wound and 7 (14%) did not. After training this had improved in terms of the sample size with 30 (95%) having the underlying cause addressed and only 1 (3%) patient who did not. Good wound assessment and wound care alone does not heal wounds. It is essential to treat the underlying cause of the wound in order to achieve healing.

The researcher sought to investigate if the participants had identified disease factors that delay wound healing, and their treatments, using the following criteria (Table 9).

**Table 9   Disease factors that delayed wound healing**

Diabetes
Rheumatoid arthritis
Peripheral vascular disease
Anaemia
Autoimmune disease
Use of immunosuppressive drugs
Use of steroids
(Schultz et al 2003)

The most common related disease factors identified were diabetes and peripheral vascular disease. A total of 22 disease related factors were identified before training. This had increased to 52 after training. It is not known if this was because the patient group after training had more disease factors or if the nurses were more aware of the need to identify and record these, due to the nature of the training or observation visits.

**4.4.4.2 Wound assessment**

The patients notes were reviewed for evidence of a wound assessment and some form of wound measurement. The PCT recommends the use of a wound assessment form which also includes measurement of the wound, record of dressings used and frequency of reassessment. The results showed a significant increase in the use of wound assessment forms and wound measurement ( $z = 4.502, p < 0.001$ ). Median scores before were 2 and after 4, with an IQR of 1-3 before and 4 after training.

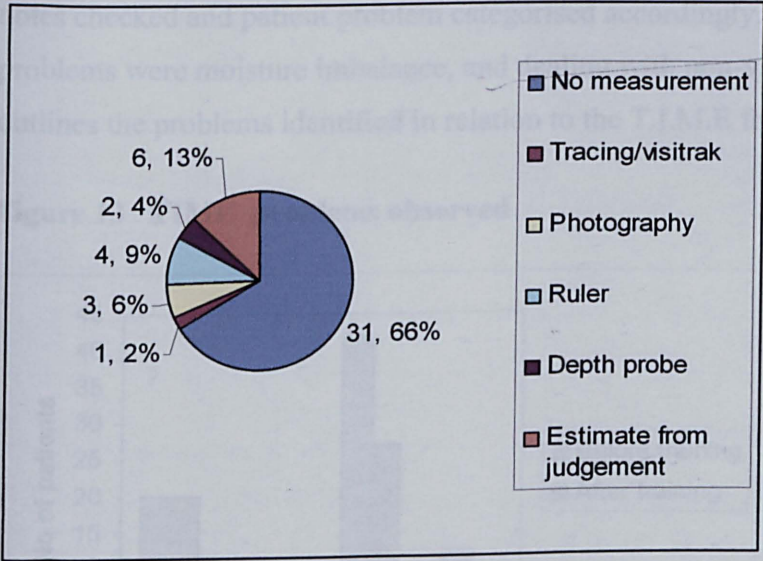
Forty two percent (20) of patients had a wound assessment form completed before the training. Two of these were completed on initial assessment and had no further entries to evaluate progress. Only 16 (34%) had some form of wound measurement. For most patients a record of the dressing change was documented in the main notes using descriptive terms such as ‘Dressing change’, ‘Wound improving’, ‘Reduced in size’ and ‘no change’. Many patients had over time had a variety of different treatments



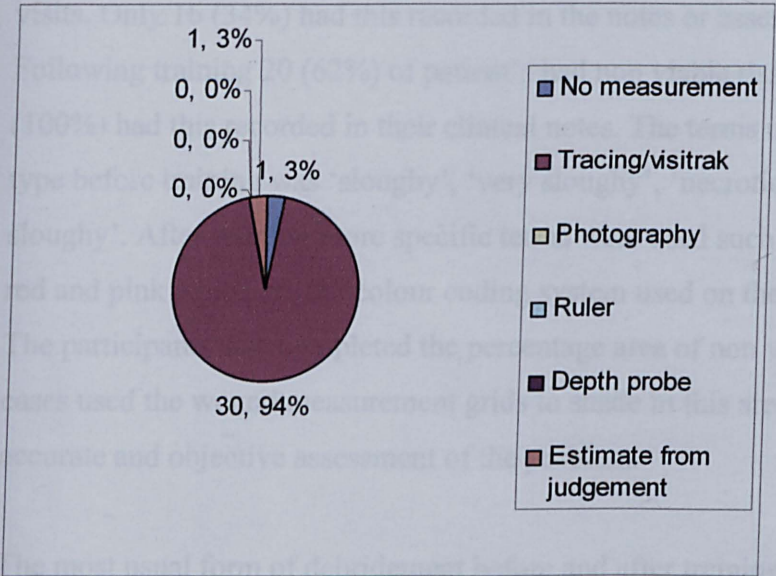
and large stocks of dressings were available in the patient's home. This has both patient and financial implications which will be discussed in section 4.5.

Following training a significant improvement was noted in the way in which wounds were assessed and measured. Thirty one (97%) patients had a wound assessment form completed and updated at regular intervals. Only 1 (3%) patients did not have a completed assessment form, with the wound assessment documented to some extent in the patients' notes. Descriptive terms such as 'sloughy' and 'large wound' were used. In terms of measurement 31(97%) of patients had had their wounds measured. For 30 (94%) this was in the form of a wound tracing using the visitrak tracing grids which had been provided for the nurses as part of the educational programme. Two patients did not have a measurement taken of their wound. The wound measurement methods used by the nurses before and after training are shown (Figure 11 and 12).

**Figure 11    Wound measurement method before training**

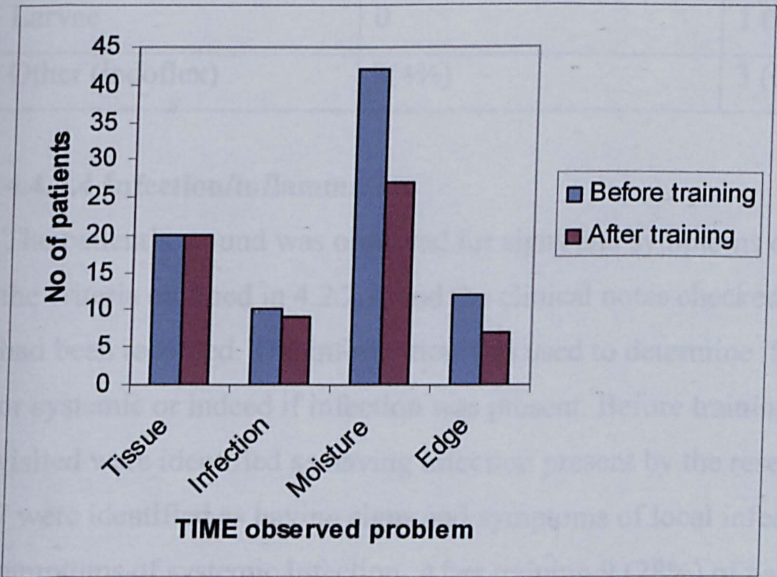


**Figure 12 Wound measurement method after training**



The type of wound in relation to the T.I.M.E framework was observed and the clinical notes checked and patient problem categorised accordingly. The most significant problems were moisture imbalance, and dealing with non-viable tissue. Figure 15 outlines the problems identified in relation to the T.I.M.E framework.

**Figure 13 TIME problems observed**





#### 4.4.4.3 Tissue

Twenty patients (42%) were identified as having non viable tissue in the pre training visits. Only 16 (34%) had this recorded in the notes or assessment form as a problem. Following training 20 (62%) of patient's had non viable tissue present and they all (100%) had this recorded in their clinical notes. The terms used to describe the tissue type before training was 'sloughy', 'very sloughy', 'necrotic areas' and 'loose sloughy'. After training more specific terms were used such as black, green, yellow, red and pink which are the colour coding system used on the wound assessment form. The participants also completed the percentage area of non viable tissue, and in some cases used the wound measurement grids to shade in this area therefore giving a more accurate and objective assessment of the problem.

The most usual form of debridement before and after training was autolytic debridement, with a small percentage of nurses using Iodoflex dressings to debride the wound. The methods of debridement participants were using before and after training are shown (Table 10).

**Table 10 Methods of debridement used**

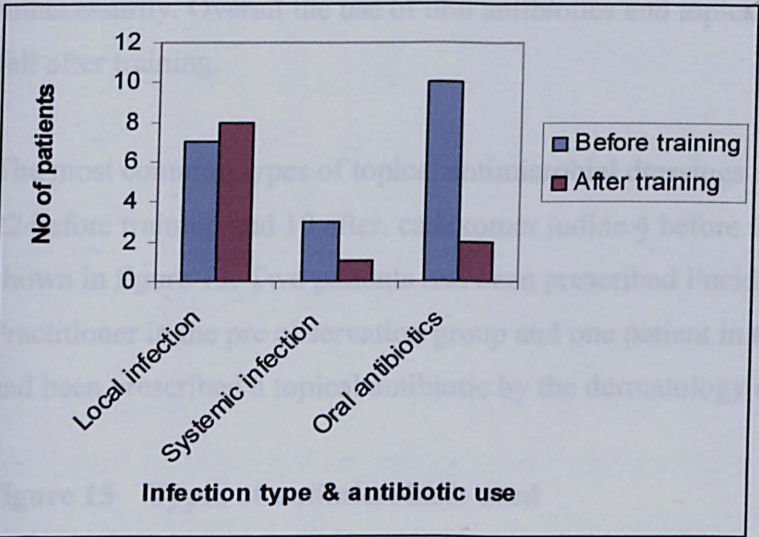
Debridement method	Before training	After training
Autolytic	18 (37%)	16(33%)
Larvae	0	1 (2%)
Other (iodoflex)	2(4%)	3 (6%)

#### 4.4.4.4 Infection/inflammation

The patient's wound was observed for signs and symptoms of clinical infection, using the criteria outlined in 4.2.2.2, and the clinical notes checked to see what had been recorded. The information was used to determine if the infection was local or systemic or indeed if infection was present. Before training 10 (21%) of patients visited were identified as having infection present by the researcher. From this group 7 were identified as having signs and symptoms of local infection and 3 signs and symptoms of systemic infection. After training 9 (28%) of patients visited were

identified as having an infection, of which 8 (25%) was local infection and 1 (3%) systemic. All 19 patients had infection recorded as a problem in their notes, but no differentiation was made between local and systemic. Consequently 7 (15%) patients had been prescribed oral antibiotics before training with 4 (8%) of these being inappropriately and unnecessarily prescribed. The use of oral antibiotics reduced after training, with only 1 (3%) patient receiving antibiotic therapy unnecessarily (Figure 14).

**Figure 14    Infection and antibiotic use**



The practice of wound swabbing was also observed and recorded. Current best practice suggests that diagnosis of a wound infection should be based on clinical assessment. When there is evidence of infection of the surrounding or deeper structures then wound swabs may be useful. Bacterial culture can help to determine antimicrobial sensitivities for selection of appropriate oral or parental antimicrobial treatment and to identify colonization with resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) (Sibbald et al 2006). In practice it can take many days to get the results of a wound swab and treatment may need to start before the results become available.

Before training 12 (25%) patients had had a wound swab taken. Given that only 3 (6%) were considered to have evidence of clinical infection, this practice is both inappropriate and costly with wound swabs costing approximately £25 each to

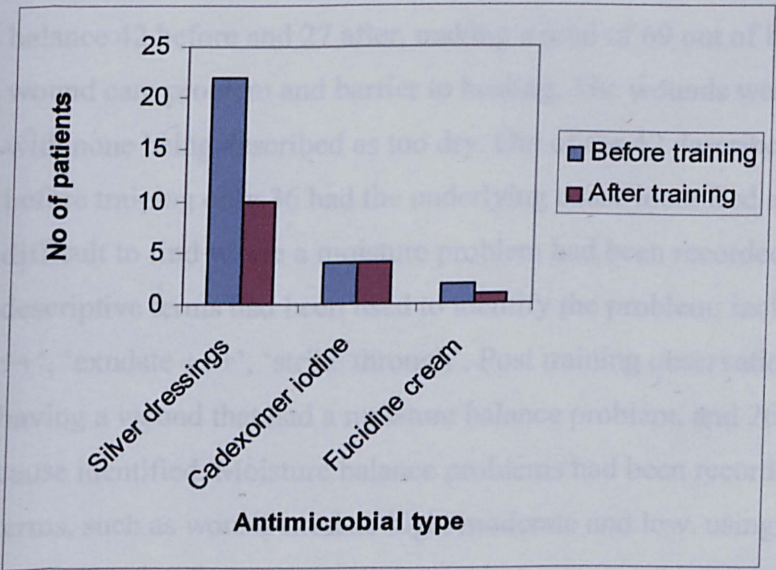


process. None of the patients visited following training had had a wound swab taken, although one patient was receiving antibiotics.

In terms of treatment choice for this patient group, 28 (60%) were prescribed topical antimicrobial dressings before training. After training this had reduced to 14 (43%) patients. Given that the total number of patients identified as having an infection before training was 10 (21%), then 18 (38%) patients had been prescribed topical antimicrobial dressings inappropriately. After training this problem continued to exist, but not on as large a scale with 5 (15%) patients having topical antimicrobials used unnecessarily. Overall the use of oral antibiotics and topical antimicrobial dressings fell after training.

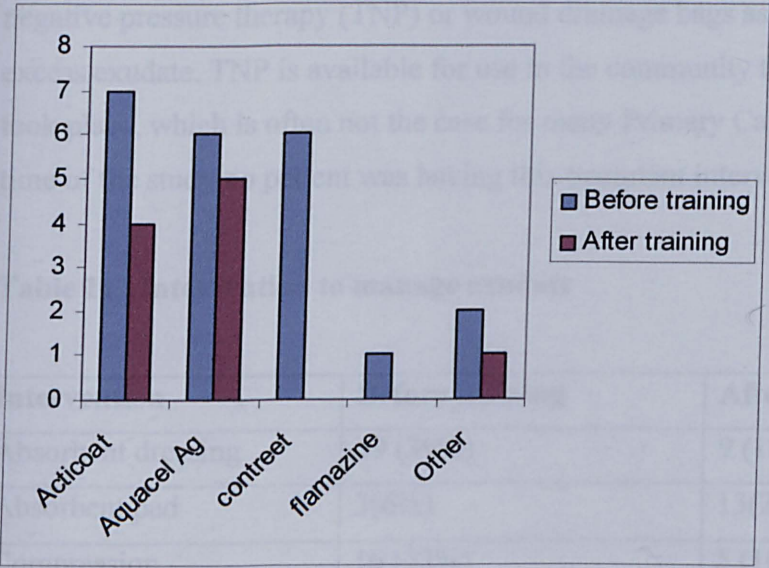
The most common types of topical antimicrobial dressings used were silver dressings 22 before training and 10 after, cadexomer iodine 4 before training and 4 after as shown in figure 13. Two patients had been prescribed Fucidin cream by their General Practitioner in the pre observation group and one patient in the post observation group had been prescribed a topical antibiotic by the dermatology department (Figure 15).

**Figure 15    Types of antimicrobials used**



The type of silver dressing used was also analysed, and a variety of silver dressings were in use (Figure 16). The overall use of silver dressings fell after training.

**Figure 16 Silver dressings used**



**4.4.4.5 Moisture**

The wound was observed and clinical records checked for evidence of a moisture balance problem. A significant number of patients had a problem with moisture balance 42 before and 27 after, making a total of 69 out of 81 patients having this as a wound care problem and barrier to healing. The wounds were all described as too wet, with none being described as too dry. Out of the 42 described as having wet wounds before training only 36 had the underlying cause identified as a problem. It was difficult to find where a moisture problem had been recorded in the notes and various descriptive terms had been used to identify the problem; including ‘leaking’ ‘exudate ++’, ‘exudate +++’, ‘strike through’. Post training observations identified 27 as having a wound that had a moisture balance problem, and 26 having the underlying cause identified. Moisture balance problems had been recorded using more objective terms, such as wound exudate high, moderate and low, using the wound assessment and evaluation form.



The type of intervention and dressings used were also observed and recorded from the clinical notes before and after training (Table 11). No participant was using Topical negative pressure therapy (TNP) or wound drainage bags as a means of managing excess exudate. TNP is available for use in the community trust where the research took place, which is often not the case for many Primary Care Trusts. However at the time of the study no patient was having this treatment intervention.

**Table 11    Intervention to manage exudate**

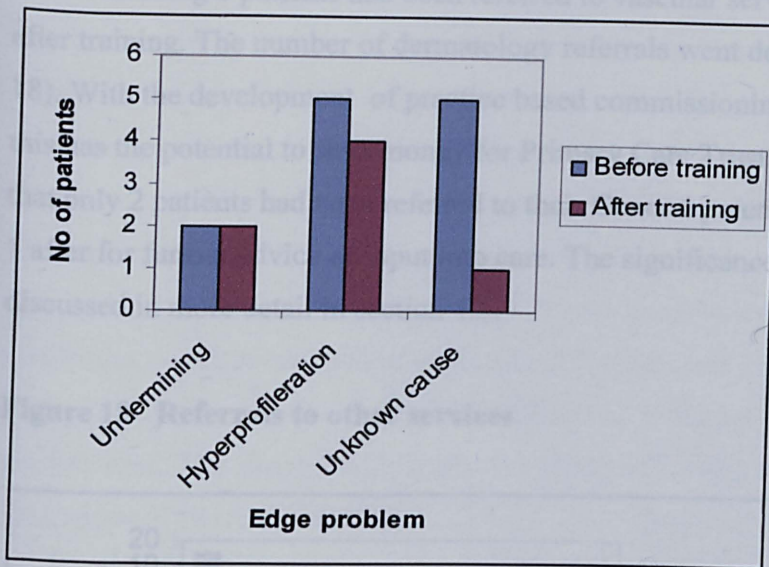
Intervention	Before training	After training
Absorbent dressing	19 (39%)	9 (18%)
Absorbent pad	3(6%)	13(27%)
Compression	16 (33%)	5 (10%)
Treatment of infection	4(8%)	6 (12%)

**4.4.4.6 Edge/Evaluation**

In order to report on this aspect of TIME, the wound was observed and the clinical records checked for evidence of edge advancement. A reduction in the first four weeks of treatment is an indication of how the wound will progress to healing (Flanagan 2005) as previously discussed, and therefore this was also noted. Any wound abnormalities such as undermining or hyper-proliferation were also noted. Case studies that included photographs of both these edge problems had been used for the training and had been included in the questionnaire.

Thirty 30 (63%) patients had a record of edge advancement, and 17 (36%) were described as non- healing before training. After training 25 (78%) patients were recorded as having edge advancement and 8 (25%) as non- healing. Before the training programme only 5 (29%) patients had this recorded as a problem, with 12 (70%) patients having wounds that were not reducing in size not identified or recorded as a problem. The type of edge problems identified are shown (Figure 17).

**Figure 17 Type of wound edge problem**



Only 3 (17%) of participants had recorded some type of action to deal with the problem and this was usually in the form of a referral for specialist advice.

After training 8 (25%) patients had wounds that were failing to heal and all of these had the problem identified and recorded with specialist referrals in place. Assessment of reduction in wound size was usually subjective or in many cases not done at all before training. After training 30 (94%) participants were using Visitrak wound measurement grids to measure the wound surface area and compare progress at four weekly intervals.

#### **4.4.4.7 Referrals**

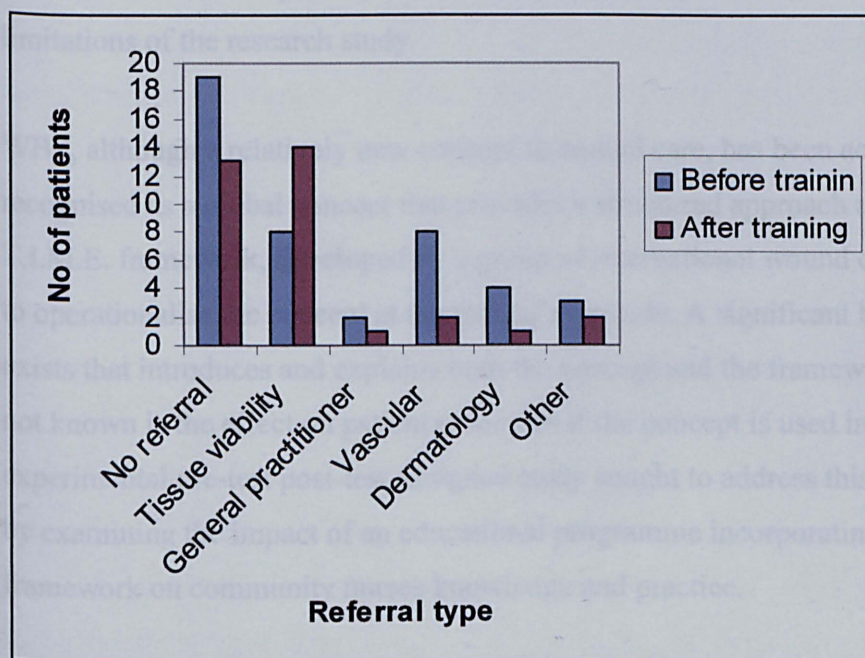
Many patients with chronic wounds will need input from the multi-disciplinary team, especially when wounds are failing to heal, or the patient needs an intervention such as a wound biopsy or vascular surgery. Twenty five (53%) patients had been referred to other services before training and this increased to 62% after training, with an increase in the number referred to tissue viability services. Before training 19 (40%) patients had not been referred to any other service, and out of this 13 (28%) were identified by the researcher as patients who would potentially benefit from specialist advice. After training there was an increase in the number of patients referred to the tissue viability team from 8 to 14.



## 4.5 Discussion

Hospital in-patient referrals for dermatology and vascular services were also reduced. Before training 8 patients had been referred to vascular services and this reduced to 2 after training. The number of dermatology referrals went down from 4 to 1 (Figure 18). With the development of practice based commissioning and payment by results this has the potential to save money for Primary Care Trusts. Other findings showed that only 2 patients had been referred to their General practitioner before training and 1 after for further advice or input into care. The significance of these findings will be discussed in more detail in section 4.5.

**Figure 18 Referrals to other services**



In summary the results showed that community nurses wound care knowledge and practice improved after the delivery of an education programme based on the concept of WBP and the associated TIME framework. Improvements were noted in all aspects of the TIME framework; tissue management, infection control and management, moisture balance and management of the wound edge. The results were found to be statistically significant ( $p=0.001$ ).

## 4.5 Discussion

This chapter is concerned with a discussion of the results of this study and how they relate to the study hypothesis and to subject literature identified within this thesis. The implications of the results for practice, research, education and policy will also be highlighted. The results of the questionnaire, which focused on nurse's knowledge of wound care, will be discussed first, followed by a discussion of the results of the observation visits, focusing on nursing practice. Associations between the two findings will be made. This discussion will be followed by an overview of the process of delivering an educational programme to community nurses, including the challenges and actions taken to overcome these. Practice development issues and changing nursing practice through the utilisation of change management theory will be discussed. The chapter will conclude by discussing and acknowledging the limitations of the research study.

WBP, although a relatively new concept in wound care, has been accepted and recognised as a global concept that provides a structured approach to wound care. The T.I.M.E. framework, developed by a group of international wound care experts, aims to operationalise the concept at the patient's bedside. A significant body of literature exists that introduces and explains both the concept and the framework, but what is not known is the effect on patient outcomes if the concept is used in practice. This experimental pre-test post-test designed study sought to address this gap in knowledge by examining the impact of an educational programme incorporating the TIME framework on community nurses knowledge and practice.

The ultimate goal of educating healthcare professionals must be to improve patient outcomes. It is therefore important to evaluate what impact if any, education has on not just knowledge, but the application of that knowledge to practice. Previous studies described in the literature review focused specifically on nurses' knowledge, and those that focused on both knowledge and practice measured practice through knowledge evaluation. This study is unique in that it has taken a newly developed framework (TIME) developed by the International Advisory Board, and examined the impact of this framework on clinical practice through the use of an education programme. The study not only examined knowledge but the effect of that improved knowledge on practice. Practice changes were measured by direct observation in the



patient's home environment. The study is also unique in that an experimental approach was used to examine clinical practice by controlling the variations that exist in the real life setting. The changes to practice as a result of the study have also been sustained as demonstrated by more recent clinical audit data.

The results of this experimental study demonstrated an improvement in community nurse's knowledge and practice, following the delivery of an educational programme on the concept of WBP and the T.I.M.E framework. The improved knowledge and practice was found to be statistically significant using both parametric and non-parametric statistical analysis.

#### **4.5.1 Questionnaire results: Knowledge**

A response rate of 100% was achieved for the questionnaire; by ensuring that community nurses were given allocated time to complete this before and after the training programme. It would have been useful to have sent the questionnaire out six months after the training had taken place to ascertain if the knowledge acquired had been retained. However, this was not feasible due to the timescale of the research project. Subsequent audits of practice have demonstrated that the improvements to practice have been sustained and will be discussed later in the chapter.

Nurses' knowledge of the wound healing process was poor before training which is supported by the literature suggesting that there is widespread ignorance of basic wound healing processes (Flanagan 1992, Bell 1994). Only 6% of nurses identified inflammation as part of the wound healing process before training. This has implications for practice in that there is the potential for the nurse to incorrectly diagnose the wound aetiology or indeed to misinterpret normal inflammation for infection. Following training 75% of nurses were able to identify inflammation as part of the normal wound healing process. None of the nurses in the study were able to identify all four stages of wound healing before the educational intervention. After training 85% of nurses could identify all four stages of wound healing. The types of wounds that participants were caring for were mostly chronic wounds (Figure 2.), with 80% of these being leg ulceration. All chronic wounds heal by secondary intention, but again fifteen participants (37%) identified primary intention as the wound closure method for these wound types before training, and four (10%) were

incorrect in their response after training. These findings show that nurse's knowledge of the physiology of wound healing was poor before the educational intervention, but had improved significantly after. It also may suggest that nurses do not always consider the relevance of this theoretical knowledge to practice, when managing chronic wounds in the community setting. The TIME framework focuses the clinician on the barriers to healing at the wound bed, taking the underlying pathophysiology into consideration and therefore increases awareness of abnormalities in the wound healing process.

#### **4.5.2 Assessment**

Question three in the questionnaire asked the nurses to identify factors that delayed healing. There are many reasons why wounds fail to heal, as previously identified in the literature. Most nurses were able to list two to three factors before training. This had increased to three to four after training. Nine 9(22%) nurses identified 6 factors before training and this increased to twenty five (62%) nurses identifying 6 factors after training. The responses before training were patient focused for example, poor nutrition, age, diabetes. After training the nurses were focused on both patient factors and wound care factors with 32 (80%) of nurses listing inappropriate wound care as a factor. Recognition of our potential to contribute to delayed healing by poor standards of practice is an important part of practice development, and therefore this improvement in knowledge was seen as important in this study. Respondents placed emphasis on infection as an important factor in delayed healing, with 66% identifying this as a factor before training. What was interesting from the results is that only 28% identified this after training. Given that a large percentage of the training was given over to the 'I' infection in the training programme this result was unexpected. No respondent identified pain as a factor in delayed wound healing although this was identified as a clinical sign and symptom of infection which is associated with delayed wound healing. Pain was also highlighted as a quality of life issue for patients. A number of nurses listed the home environment as a factor that would delay wound healing, 8 (17%) before training and 13 (28%) after. This would suggest that nurses had moved their focus, following training, from the patient alone to the wound and the environment of care as important in determining wound healing.

Question four sought to measure nurses knowledge of the impact of their wound on quality of life. This is often a neglected and under recognised aspect of wound care practice. The majority of work in this area relates to leg ulcer patients, with reports of negative psychological impact, depression and anxiety (Phillips et al 1994) and pain, emotional reaction and physical immobility (Franks et al 1994). Patients with chronic wounds are more likely to suffer health related quality of life problems that continue for much longer, than those with acute wounds (Harding and Price 2000).

Knowledge of quality of life issues in relation to wound care patients was poor before the training programme. Some respondents were only able to identify two patients quality of life issues before training, but this increased to three to four factors after training, with 13 (32%) identifying 3, and 27 (67%) identifying 4. Before training few nurses had considered the mental health needs of patients with chronic wounds, clearly placing social issues as more important. Social isolation was the most common factor identified by nurses before and after training, 25 (62%) before and 35 (87%) after training. Depression as a quality of life factor was identified by only 9 (22%) of nurses before training. After training, this had increased with 21 (52%) of nurses identifying it as a factor. The recognition of pain as a quality of life issue for these patients was also poor with only 15 (37%) of nurses recognising this as a possible problem before training. This improved to 32 (80%) identifying this as a factor after training. Clearly the nurses took on board a key message in the training programme on the effects of a chronic wound on the patient's quality of life. For those patients who do not go on to healing, such as palliative wound care patients, measuring the impact of care in relation to improvements in quality of life is crucial as an end outcome.

Question five and six of the questionnaire focused on the concept of WBP and the TIME framework. The concept of WBP and the TIME framework were not well known to the nurses before the training programme. This was interesting as a substantial body of literature exists on the subject since 2003. However it was useful for the purpose of the research as previous exposure to the ideas may have influenced the nurse's responses. It would then have been difficult to attribute the improved knowledge responses to the educational intervention in this situation. Less than 50% of those who attended had heard of WBP and none of the nurses were able to identify

all four elements of the TIME framework. Following training 100% of nurses were able to identify the T.I.M of the framework and 95% were able to identify all four elements. In the follow up evaluations all the nurses stated that they considered the TIME framework useful for practice. Evaluations from the training programme suggested that nurses found the framework easy to understand, relevant to their daily practice and likely to facilitate identification of the problems that may delay healing. Some nurses stated that the TIME framework would help them to make appropriate wound care treatment choices for their patients. The aim of the International Advisory Board was to develop a tool that would introduce the concept of WBP into clinical practice and therefore this feedback provides valuable information to the international advisory board members, and to the wider International wound care community.

#### **4.5.3 Tissue**

In terms of tissue management, the pre-training results showed that autolytic debridement was the most common debridement method in use. Not all nurses however were clear about definition of terms before training, with some describing the use of hydrogels as enzymatic debridement when in fact they are classified as autolytic. A non response rate of 35% pre-training may also suggest lack of knowledge of debridement methods, or failure to understand the categorisation of the treatments they use to debride wounds. Only one respondent was clearly able to articulate all five debridement methods before training. There was a significant increase in knowledge of all five debridement methods after training, with 14 (35%) able to list all five methods and 20 (50%) able to identify four. This increased knowledge of methods available also impacted on practice with an increase in the number of patients referred to the tissue viability team for sharp debridement post training. There was also an increase in the number of requests for larvae therapy. These changes support the current drive in the NHS to offer patient choices in the type of care and treatments they receive (DOH 2006).

The use of wound photographs as case examples, both for the questionnaire and for the training programme, were considered useful by clinicians as this allowed them to draw on their experiences of managing these types of wounds. This was in keeping with the literature that supports the use of practice based knowledge as an influence on clinical decision making in wound management (Luker and Kenrick 1995). Most

responses were appropriate in terms of the action to be taken to manage the necrotic pressure ulcer and the toe. However it raised concern when 10 (25%) of respondents stated that they would debride the necrotic toe with moist interactive wound dressings. The recommended treatment would be to keep the wound dry and refer the patient to vascular services. Following training 39 (98%) of nurses said that they would not debride the toe, but refer the patient to vascular services. The participant that responded incorrectly after training was followed up informally in clinical practice to reinforce this key message, due to the potential risk to the patient. To reduce the risk of this problem for the future the guidelines for referral to vascular services need to be reviewed, as do the wound debridement guidelines and all non-healing wounds referred to tissue viability specialist service.

#### **4.5.4 Infection**

Nurse's knowledge of risk factors in the development of a wound infection was poor prior to training. Only 17 (37%) were able to identify one factor and 11 (24%) two factors before training. Given that community nurses are undertaking wound assessments on a daily basis this finding was surprising. Although 20 (50%) recognised poor dressing technique as a factor before training, the main focus was on the patient's environment as a risk factor, with 10 (25%) identifying patient non concordance as a factor. Some nurses mentioned a 'dirty house' and 'poor personal hygiene' as risk factors. The identification of patient factors such as malnutrition and diabetes as risk factors for infection increased after training. Few respondents were focused on the wound bed as a factor with only 2 (4%) identifying the chronicity of the wound and none identifying the size or site of the wound before or after training. Given the focus of the training on the wound bed this was a surprising finding.

There was a significant increase in the number of signs and symptoms of a wound infection that nurses were able to identify. Only 10 (25%) nurses were able to correctly identify five signs and symptoms before training, but this improved to 31 (77%) after training. Given that the diagnosis of infection is a clinical decision (EWMA 2005), the pre training knowledge raises some concerns. It was also interesting that whilst nurses were able to identify the traditional criteria for identification of infection (Cutting and Harding 1994), few identified additional criteria such as wound breakdown and delayed healing, as outlined in the training

programme and in the most up to date evidence (EWMA 2005). These findings were also supported in clinical practice with nurses demonstrating an inability to differentiate between local and systemic infection. This will be discussed in section 4.5.10.

Again the responses to question twelve showed that the nurses were confused in determining treatments for local and systemic infection. In fact the responses showed that nurses did not appear to differentiate between the two when making clinical decisions about treatment. A considerable proportion 10 (25%) stated that they would use oral antibiotics to treat local infection. Given the concerns about overuse of antibiotic therapy and the potential for resistance, combined with the evidence from the literature suggesting that oral antibiotics should not be used to treat local infection (Bowler 2001, Schultz et al 2003), this raises concerns about practice. Clear messages were delivered in the training programme about the management of local infection and no nurse stated that they would use oral antibiotics to treat local infection after training. Participants had a good understanding of the need to use oral antibiotics for systemic infection with 33 (82%) recommending them before training and 40 (100%) after training. The focus of knowledge improvement was on managing local infection, with a statistically significant improvement in knowledge after training. The number of nurses who stated that they would use a topical antimicrobial, in particular a silver dressing increased. In observed practice the use of silver dressings fell after training, which will be discussed further in section 4.5.8.

#### **4.5.5 Moisture**

Community nurses knowledge in how they managed excess wound exudate improved after training. This is a challenging area of practice, as the research evidence supports a moist interactive wound healing environment (Winter 1962, Winter and Scales 1963, Cutting and Tong 2004), and yet chronic wound fluid has been shown to be detrimental to wound healing (Parks et al 1998). Achieving the correct balance is often difficult in clinical practice, and correct treatment of the underlying cause is essential (Fletcher 2003). The results showed that only 1 (2%) nurse considered this when treating the problem before training and 6 (13%) after training. However there was a significant number of nurses who recognised the importance of compression therapy as a means of managing exudate from 7 (17%) to 30 (75%).

Fourteen (35%) nurses were able to make an association between the M and the I of the TIME framework after training, by identifying infection as a possible cause of increased exudate. Although the focus was mainly on the use of absorbent dressings and pads, the number of nurses who identified topical negative pressure therapy (TNPT) increased from 6 (15%) to 18 (45%). Topical negative pressure therapy has now become available for use in the PCT and at the time of writing this up, there were four patients receiving this therapy supported by the community nurses. It is important that when nurses are educated in the use of advanced therapies such as TNPT for managing excess moisture at the wound bed, that these are then made available to them for patient use. Ensuring the community nurses are skilled in using advanced therapies such as TNPT also reduces the number of bed days in hospital for patients, thus reducing costs. It also ensures that care is delivered closer to the patient's home, in line with the White Paper 'Our health, our care, our say' (DOH 2006).

Community nurses knowledge of factors that are important in wound dressing selection again improved significantly after training. Before training only 1 (2%) participant was able to identify six factors that are important and 7 (17%) were not able to identify any factors. After training the minimum score was three factors with 15 (38%) identifying five factors and 8 (20%) identifying all six. The focus of the answers on wound bed issues improved after training, with 9 (22%) identifying this as an important factor before and 37 (92%) after training. Nurses also recognised the importance of patient acceptability, evidence base and cost effectiveness, and responses in all these categories increased after training. Very few nurses identified pain as important in relation to dressing selection, 2 (4%) before and 8 (20%) after. However comfort was identified as important by 10 (25%) before and 13 (32%) after, and could be said to be related to pain management. The lack of community nurses focus on pain, in relation to wound assessment and management appears to be a theme running through the research finding, and will be highlighted as an area for future practice development as a recommendation of the study (see section 4.7.1).

#### **4.5.6 Edge/evaluation**

Two issues were considered in terms of nursing knowledge in relation to the E in the TIME framework. The first was the method used to determine if the edge of the

wound was progressing to healing. The second was to determine their knowledge in relation to wound edge problems using wound photography. The same wound photographs were used in the questionnaire and in the educational programme to ensure consistency. Nurses identified more than one method both before and after training. The most common method the nurses said they used before training was photography 24 (60%) and use of a depth probe 17 (42%). These findings were not consistent with what was observed in practice before training, and will be discussed in the next section. After training the nurses stated that the most common wound measurement method used was tracing 30 (75%) and use of depth probe 33 (82%) and these findings were consistent with practice observed after training. Many patients did not have their wounds measured before training and those who had dimensions given were usually estimated from judgement. Given the evidence in the literature supporting the importance of wound measurement, in terms of evaluating the treatment and predicting healing time, this change in practice was considered to be a significant advance in practice.

Nurses' knowledge in relation to wound edge problems was poor before training. Only 3 (7%) nurses were able to identify a raised wound edge in picture one, and 4 (10%) undermining of the wound in picture two. Six nurses (15%) did not respond to the question. This improved significantly after training, with 33 (82%) able to identify the raised wound edge, and 34 (85%) able to identify undermining. Only 1 (2%) nurse was able to identify both problems before training, but this increased to 30 (75%) after training. The E of the TIME framework is perhaps not as well understood as the other elements, but the use of case study examples as part of the educational programme was clearly beneficial in terms of creating a better understanding of edge related wound problems.

#### **4.5.7 Observation results: Practice**

A total of 79 visits took place to observe practice, 47 before the delivery of the educational programme and 32 after the programme.

#### **4.5.8 Assessment**

Accurate assessment and diagnosis of a patient with a wound is essential for good wound care practice. Evidence from the literature shows that assessment is poor, as is the documentation of that assessment (Coulliet 2001), Huynh and Forget-Falcicchio



2005). This view is supported by previous work undertaken by the researcher, who described limitations in community nurses knowledge associated with the assessment and treatment of chronic wounds such as leg ulcers (Dowsett 1997).

Community nurses' practice was observed before and after the educational intervention, in terms of the detail and level of assessment as previously discussed. In general the detail of assessment was good, with most nurses documenting some evidence of assessment of past medical history, current history, pain, mobility, nutritional status and medication. This was possibly attributed to the community nurses' assessment notes that include these details in the patient assessment records. However many nurses did not make any comment of the effects of the wound on the patients daily living, although this was also a category of assessment in the notes. Before training only 13 (27%) nurses had evidence of assessment, or discussions with patients in relation to this aspect of care. This improved after training, with 16 (48%) recording some aspect of quality of life in the notes, or talking to the patient about this during the observed visit. Exploring quality of life related issues with patients is time consuming and may be emotionally challenging for nurses. Increased workloads and a reduction in the number of community nurses (currently fifteen vacancies), can mean that this important element of care is neglected. Overall scores for the level of assessment did however improve from 2-3 before training to 3-4 after training, which showed that the nurses had moved from merely documenting the problem to action planning and addressing the issues identified in the assessment.

There were inconsistencies between what was documented in the notes and what was observed in practice, for a number of patient visits. One patient was sat in a wheelchair and clearly indicated that they could not stand, yet the nurse had recorded walks independently in the notes. Another patient reported to the nurse during the visit that she was taking morphine for pain control, yet no pain was documented in the notes. Another patient had 'no pain' recorded in the notes, yet during the observed visit expressed pain and discomfort, which was not confined to the dressing change. One patient reported pain to the nurse during the visit and self administered analgesia, but this was not recorded in the notes or explored in any great detail in conversations between the nurse and the patient. Many patients had a problem identified as part of

their assessment for example, poor nutrition or pain, but no follow up action plan in the care plan, or observed intervention to address the problem.

However there was evidence of good practice in relation to patient assessment. One nurse scored five for pain and quality of life and had a very detailed discussion with the patient about her pain control, ability to go out to get her shopping and to maintain her independence. This patient also had a detailed wound assessment form, recording pain levels, interventions and outcomes. Two other nurses expressed concern for the patient when they reported pain during dressing change, and stopped the procedure until the patient was happy for them to proceed.

The number of patients who had the wound type such as leg ulcer and pressure ulcer documented was high before and after training, 97% and 100% respectively. Those patients who had leg ulcers also had the type of leg ulcer documented for example, venous, arterial or other. The literature clearly states that treatment of the underlying cause of the wound is essential for optimum healing, so this aspect of care was very good, and nurses were not at all reluctant to determine the cause of the problem. The tissue viability service delivers an annual in-house training programme on wound assessment and diagnosis with a focus of treating the underlying cause, and this may account for these results.

There was an increase in the number of patients who had evidence of a specific assessment in relation to their wound type after training. This included a leg ulcer assessment with Doppler reading for those patients presenting with a leg ulcer and a pressure ulcer risk assessment with grading, for those presenting with a pressure ulcer. Practice was observed to ascertain if the treatment plan or treatment given to the patient during the visit addressed the underlying cause of the wound. For most patients the treatment plan or care given was appropriate in treating the cause, 37 (78%) of visits before training, and 30 (90%) after training.

Determining the number of patients with disease factors that impacted on wound healing was difficult and the results may not necessarily reflect the picture accurately. This is in part due to poor record keeping, but also the ability of the researcher to identify these problems during the visit, unless discussed by the nurse or patient at the

time of the visit. Some patients also had disease factors that were not identified in the schedule for example sickle cell disorder, and therefore these had to be recorded separately. Although the findings are interesting they are not as relevant as the rest of the results in determining the impact of training on community nurses practice.

One of the most notable improvements to practice following the training programme was the improvement in wound assessment. Wound care assessment and evaluation forms have been available in the PCT since 1997, when the tissue viability service was first set up. They are recommended for use in the wound management guidelines and policies, yet only 20 (42%) patients had a wound assessment form in their notes before the training, and many of these were not fully completed. This improved to 31 (97%) after training, demonstrating a significant ( $p<0.001$ ) improvement in practice in this area. It was very difficult as an observer to determine the progress of the wound over the treatment time, where no assessment forms were available. Entries in the notes were not always useful for example, 'wound improving' or 'wound no better'. In many instances the only documentation stated 'dressing renewed'. These subjective comments on patients progress are not useful when evaluating treatment and monitoring progression to wound healing. The literature suggests that monitoring and evaluation of wound care interventions improves when nurses are using assessment tools (Morrison 1989) and can lead to more appropriate and cost effective care (Moffatt et al 1992).

Only 16 (34%) patients in the pre training observation visits had had their wound measured. Given the literature that supports wound measurement as an objective way of monitoring and evaluating wound progress and treatment decisions, this result was poor. Subjective terms such as 'reduced in size' and 'no change' were used to describe the wound progress for most of the observed visits. Some nurses appeared to be relying on the patient's opinion to determine the wound progress, asking the patient questions like 'do you think it has got smaller'. Determining the percentage reduction in wound size in the first four weeks of treatment is a good indicator of wound healing (Flanagan 2003), and this key message was incorporated into the educational programme, along with training and access to wound measurement grids and measuring device (Visitrak). Following training and availability of the tool, the

number of patients who had their wound measured increased significantly to 31 (97%), with 30 (94%) having a grid measurement available in the clinical notes.

#### **4.5.9 Tissue**

The type of tissue at the wound bed plays a very important role in wound healing, and therefore the ability to accurately describe the tissue type and take appropriate action when it is contributing to delayed healing is essential. Various descriptors are identified in the literature to describe tissue type, and not all areas used standardised terms. Community nurses in the pre observation visits used descriptive terms such as 'necrotic tissue' and 'slough', but were more likely after training to use colour codes as outlined on the wound assessment form. This method is of course not totally reliable, as red does not always mean healthy tissue, and red friable granulation tissue can indicate the presence of infection (Cutting and White 2005).

What was evident from observing the patients wound and tissue type was a lack of documentation of the tissue type in the patient's notes. Although 42% of patients had non-viable tissue present at the wound bed, only 16 (34%) had this recorded in their notes. In the post training patient group, 20 (62%) had evidence of non-viable tissue and they all had this recorded. The wound measurement grids were also being used to show the percentage area of non-viable tissue, as demonstrated during the training programme. The use of the wound assessment forms together with the tracing grids were shown to be a more objective way of identifying the tissue type and determining the impact of interventions to move from non-viable to viable tissue.

Debridement is seen as an important element of wound care practice where devitalised tissue is present (National Institute of Clinical Excellence 2000). All 40 patients identified in the visits as having non-viable tissue were having some treatment aimed at debridement. Autolytic debridement with the use of moist interactive dressings was the most favoured method, 18 (90%) before and 16 (80%) after. This is a safe and easy to use method of debridement, but is not always the quickest way to debride the wound. After training 1(5%) patient had larvae therapy being used, and there were a number of referrals to the tissue viability team for sharp debridement. In general community nurses recognised non-viable tissue and took

appropriate action to debride this, before and after training. Their documentation of the problem and evaluation of interventions improved after training, as did the uptake or use of more debridement methods, although this was not significant. The use of oral antibiotics decreased after training with only four patients having them prescribed for local infection. This is of course four patients too many and given the concerns about over use of oral antibiotics is an area of practice that continues to need addressing for the future. Community nurses are not allowed to prescribe oral antibiotics unless they have undertaken a course of extended prescribing, and therefore in these cases it was the patient's General practitioner (GPs) who prescribed these.

#### **4.5.10 Infection**

The researcher observed the patients wounds for evidence of clinical infection using the wound infection criteria for specific wound types identified by the European Wound Management Association (2005), and the work of Sibbald et al (2000) further differentiating between superficial and deep infection. A total of 19 (23%) patients were identified as having a wound infection, 10 in the pre training visits and 9 in the post training visits. All of these patients had infection as a problem documented in their notes, but no differentiation was made between local (superficial) or systemic (deep) infection, in the pre training group, which had a direct impact on the way in which they were managed. Seven out of the ten patients in the pre training visits had been prescribed oral antibiotics unnecessarily. The use of oral antibiotic therapy for local infection is not recommended (Bowler et al 2001, EWMA 2006).

#### **4.5.11 Moisture**

A total of 69 patients were observed to have a moisture balance problem, 42 before the training programme and 27 after. Eighty seven percent of these were due to excess exudate, with wounds being described as 'too wet' or 'highly exuding', in the patient's records before training. After training the descriptors used were; high, moderate and low exudate, as outlined in the wound assessment and evaluation forms. It was clear from the observed visits that nurses were focused on the use of absorbent dressings and pads before training, with 39% using absorbent dressings. After training the focus shifted to treatment of the underlying cause with 27% using some form of

compression therapy and the use of absorbent dressings fell to 18%. A number of patients were also referred to the tissue viability team for topical negative pressure therapy after training.

#### **4.5.12 Edge**

Pre training observations showed that this was a neglected area of practice.

Community nurses were not assessing or identifying wound edge problems although a number of patients were found to have undermining and hyper-granulation present when observed. The nurses were also not in a position to comment on edge advancement, as they were not recording wound measurements objectively on assessment or at regular intervals. As a consequence of this some nurses were describing wounds as non-healing when they were in fact healing slowly. There was a reduction in the number of wounds described as non-healing after training from 36% to 25%. This may have been due to more accurate and objective wound measurement using the Visitrak wound measurement grids and devices, where even the smallest improvement can be detected.

#### **4.5.13 Knowledge and practice associations**

#### **4.5.14 Assessment**

Generally patient assessments were of a comprehensive nature and most patients had a specific assessment relevant to their wound diagnosis for example, Doppler ultrasound. Knowledge and practice was identified as poor in their assessment of the impact of the wound on the patient's quality of life, and this element of assessment improved after training. Wound assessment knowledge and practice was poor and there were variations in what nurses said they did and what was observed in practice. Few nurses were using the PCT recommended and already available wound assessment forms and their understanding to the barriers to healing in terms of the TIME framework was poor. There was a significant increase in the number of nurses using wound assessment forms post training although these forms were not introduced as part of the research project. These forms prompted assessment of TIME related issues at the wound bed, so this could have contributed to some of the improvements in this study. Improved knowledge was associated with improved practice, but other interventions such as the availability of wound measurement tools were also necessary to improve patient care. This demonstrates that changing wound care

practice is not solely about delivering education, but provision of the tools to ensure the changes are supported in practice, such as wound measurement devices and wound assessment forms.

#### **4.5.15 TIME**

The delivery of the educational programme based on the TIME framework led to an increase in community nurses knowledge and changes in practice with respect to the four elements of the framework. The results of the questionnaire matched the observations in practice for the T of the framework. Most nurses said that they used autolytic debridement, with hydrogels as the choice of wound care product. This was supported in observed clinical practice. Following training knowledge of debridement methods increased, as did the range of debridement methods that were offered to patients. There was an increase in the number of patients having larvae therapy and a request for sharp debridement.

Community nurses' knowledge of signs and symptoms of infection and the ability to distinguish between local and systemic infection improved. Knowledge in this area was poor before training and this was reflected in practice, where diagnosis of infection was not always accurate and the nurses were not differentiating between local and systemic infection. Following training there was a reduction in the number of wound swabs taken, the use of oral antibiotics and the use of silver dressings. The researcher does acknowledge that there may have been other variables that may have influenced practice, such as the number of patients presenting with signs and symptoms of infection.

There was consistency in findings between nurse's knowledge and observed practice in this area. Evidence from the literature, clearly shows that treatment of moisture balance should aim to address the underlying cause, and yet only 1 (2%) nurse who completed the questionnaire identified this as a treatment objective before training. The focus before training was on absorption of exudate using dressings and pads, but after training nurses were more focused on treating the underlying cause. There was also an increased awareness of the association between excess exudate and infection, linking the elements of the TIME framework together. The increased use of the wound assessment and evaluation forms standardised the way in which the nurses

described and measured the type and amount of wound exudate, and it was easier to monitor progress from highly exuding to low, linking this progression to the intervention.

Knowledge of edge problems was poor and few nurses could identify undermining and a raised wound edge as potential barriers to healing before the training programme. This was also picked up during the observation visits with a number of patients having edge problems which were delaying healing and yet had not been referred for specialist advice. Because the nurses were not objectively measuring wounds before the training intervention, it was difficult for them to determine what was non-healing. Healing is slow for some patients and using objective measurements is not only useful for the clinician to evaluate progress, but also beneficial to the patient in giving them some hope that their wound is actually healing.

#### **4.5.16 Practice development**

This research project was successful in improving community nurses knowledge and in developing their practice, through the use of an educational programme. The development and delivery of wound care education to meet the changing needs of community nurses and the ever changing advances in wound care technologies is challenging. What was clear from undertaking this research project is that education needs to be relevant to practice, delivered locally and presented in a manner that takes existing knowledge and practice into consideration. The process of changing practice is a challenge and requires engagement of not only clinicians, but their managers and the wider organisation. This research project was successful in part, due to the ability of the researcher to engage all of these stakeholders. This is one of the advantages of being a practitioner researcher, who is not seen as someone who is coming in from outside for the sole purpose of undertaking research. The added advantage of being a practitioner researcher is the continued support of the change and the ability to integrate the change into existing practices. It can however be difficult to play two roles, that of researcher and practitioner. The nurses in this study identified the researcher as someone who normally provided a specialist service and they needed continuous reminding that the patient visits were being undertaken as part of a research project. Some nurses had also failed to deliver this message to patients and



therefore there was the added expectations from some of the patients visited that wound care advice was to be given. A small number of nurses failed to turn up for visits or turned up late for visits as they did not perceive the research to be as important as a specialist service visit, and this necessitated re-scheduling of the visits.

Getting evidence into practice can be difficult. Rogers (1995) argues that the adoption of new ideas, practices, and artefacts is influenced by the interaction among the innovation, adopter and the environment. Change in practice is more likely to be successful where the change is compatible with existing structures, can be seen to have an advantage and can improve outcomes. As wound care makes up a significant proportion of the community nurses' workload, with the need for wound assessment and correct management, this research project and recommended changes to practice were well received. For knowledge to lead to a behaviour change it has to be actively related to what individuals already know, including what they know through experience (Fitzgerald et al 2005). Nurses in the project could clearly see first hand that using a structured approach as outlined in the TIME framework was useful to address the practical problems they face day to day when caring for patients with wounds. This was also identified in the evaluation of the TIME based educational programme. If we want to create effective health services and quality improvements for patients, then evidence based practice needs to be disseminated to clinicians so that they can incorporate it into the daily delivery of patient care.

It is important to consider all types of evidence when attempting to change practice. In wound care there is a lack of randomised controlled trials (RCTs) in some areas of practice, in particular comparison of like for like treatments, but a wealth of clinical data, epidemiological studies and observational data (Dowsett and Claxton 2006). Most patients with chronic wounds are excluded from RCTs due to their age and other co morbidities, and therefore other methods of study may be more appropriate. It is important that this lack of RCT evidence should not be used as a reason for not applying the concept of WBP and does not mean that the evidence available is not relevant and valuable for practice (Thompson 2003). The results of this study clearly demonstrate that there is a wealth of evidence in relation to each element of the TIME framework and that utilizing this structured approach does improve patient outcomes.

The role of the wider organisation in creating a climate that fosters good practice is recognised in the literature (Damanpour 1991). A key factor is organisational stability and harmony, which unfortunately is not a feature of the current NHS climate. Many changes are taking place in a response to Department of Health reports such as 'Our health, our care, our say' (DOH 2006), local integration of health and social care and practice based commissioning. The last twelve months have been financially difficult for many organisations. These financial constraints have also had an impact on commissioning of education with cuts to the education budgets. In the researchers trust, the education and training budget was cut from 34.00 ftw in 2006/07 to 19.00 in 2007/08. This will clearly have implications for practice and for patient care. On a more positive note the National Health Service Knowledge and Skills framework (NHS KSF) has been introduced as part of the Agenda for Change Reforms, and was implemented in the host trust during the period of this research project. This framework defines and describes the knowledge and skills which NHS staff need to apply in their work in order to deliver quality services. The framework supports the effective learning and development of individuals and their teams, and application of this knowledge in practice (Department of Health 2004). The launch of the KSF in the organisation may have lead to a perceived need for education and changes in practice by those nurses who took part in the study.

Education is one approach that can provide a change in practitioner knowledge and behaviour as demonstrated by this research project. For education to be successful in changing practice it needs to be relevant to practitioners and delivered in a way that is appropriate for their learning needs. To achieve this educationalists and practitioners need to work collaboratively to develop education programmes that meet local healthcare needs and can be delivered locally. The wider organisation and those who commission education also need to facilitate the implementation of this new knowledge (Closs and Chealer 1994), and ensure the information is incorporated into local guidelines and protocols (Richens et al 2004).

Changing practice is challenging, but sustaining change can be difficult and involves integration of the changes into everyday practice. In an attempt to ensure continued use of the TIME framework and appropriate selection of treatments based on the identified barriers to healing, the tissue viability service developed a wound dressing's

formulary for use across primary and secondary care, based on the TIME framework. The formulary lists the type of dressings and treatments in relation to the TIM and E, with a prompt to refer the patient if wound healing is not taking place. This wound care formulary has been disseminated nationally as part of the work and is available at [www.wounds-uk.com](http://www.wounds-uk.com). The TIME wound care formulary was developed and launched during the course of the research project, as the post training observation visits were near completion. A Trust audit of the wound care formulary in 2007 and analysis of the nurse prescribing data showed that the TIME formulary was being used successfully. This audit of wound dressings used by community nurses in practice, showed 80% concordance with the wound care dressing on the formulary. The 20% non formulary product exceptions were advanced wound care products which had been prescribed by the tissue viability specialist nurses for non healing wounds. This indicates continued use of the TIME framework and appropriate use of wound care products to type of wound bed problem. In terms of patient assessment and wound assessment, an audit undertaken by the researcher in 2007, of the four nurse led community leg ulcer clinics showed that 100% of patients had a wound assessment and evaluation form available and 80% had had their wound measured using the Visitrak wound measurement grids. Given that the educational programme on the TIME framework was delivered in January and February of 2006, these more recent findings demonstrate that the TIME framework and the improved wound care practices have been sustained.

Other initiatives have taken place to ensure wider dissemination nationally of the benefits of the TIME framework for practice, education and research. The UK TIME Advisory Board was set up in 2005, to support the dissemination of WBP and TIME nationally. The group which is chaired by the researcher is made up of eight key clinicians in the field of tissue viability, who have an interest in generating and developing ideas for how the TIME framework can be utilized for the benefit of patients, clinicians, educationalists and researchers. The aim of the board is to improve clinician knowledge, patient experience and outcomes in the speciality of wound care. Outcomes from the group include the development of a wound assessment and evaluation form using the TIME framework, which is available at [www.wounds-uk.com/woundcare/downloads/TIMEassessment](http://www.wounds-uk.com/woundcare/downloads/TIMEassessment), and patient information leaflet to engage patients in the care of their wound using TIME.

## 4.6 Conclusion

Wound care accounts for 3% of the annual National Health Service expenditure budget, which is estimated at £2.3 - £3.1 billion per year (Drew et al 2007). The majority of patients with wounds are cared for in primary care, many by community nurses. It is therefore important that the knowledge and practice of these nurses is based on the most up to date evidence, utilising the potential that new concepts in wound care can bring to the patients care setting. Wound Bed Preparation as a concept has gained international acceptance and recognition as a structured approach that can potentially improve the way in which we deliver wound care, and improve patient outcomes.

This experimental design study sought to examine the effect of implementing an educational programme based on the concept of WBP, utilizing the TIME framework, on community nurses wound care knowledge and practice. The results of the study showed that community nurses knowledge improved significantly ( $t(39) = 17.37$ ,  $p < 0.001$ ), particularly in relation to wound healing and identification and management of the elements of the TIME framework. There was also a significant improvement noted in observed and reported practice, where ( $t(32) = 7.12$ ,  $p < 0.001$ ). Community nurses assessment of the patient and of the wound improved and this directly impacted on how they managed the barriers to healing within the context of the TIME framework. There was a shift from treating the problem alone to identification and management of the underlying cause, and increased awareness of those patients with delayed wound healing who needed to be referred for specialist intervention.

The research findings support the evidence from the literature in terms of the variability of practice in wound assessment and management (Forget-Falcicchio 2005). The findings also support evidence of poor practice in documentation of wound care (Tapp 1990) and the importance of using wound assessment and evaluation forms as a means of improving wound care monitoring and evaluation (Dealey 1999).

Knowledge improvements following the educational intervention were similar to the result of other studies identified in the literature (Luker and Kenrick 1995, Nelson 1997, Wong 2003). This research however was unique in that it examined how this improved knowledge impacted on practice, by observing practice in the clinical setting. It was difficult to apply an experimental approach to this aspect of the project, as there are many variables in the real life setting of clinical practice, however the use of a structured approach using the TIME framework allowed for the collection of more robust data.

The healthcare environment is changing and all these changes call for new knowledge and skills among practitioners. The fact that practice is a locus of change means that learning and researching practice are essential for practitioners. Where no theory exists about new practice situations then practice must precede theory for theory to be relevant for practice. Nurse Consultants and Advanced Nurse Practitioners are ideally placed to research their own practice. The Nurse Consultant role has an allocation of 20% of their time to research and Nurse Consultants need to be protecting and utilizing this time in order to develop their roles, contribute to evidence based practice and improve the lives of our patients.

## **4.7 Recommendations for practice, education and future research**

TIME is a useful framework that can be applied to practice, education and research in the field of wound care and therefore the recommendations for the future are outlined in each of these areas.

### **4.7.1 Practice**

Utilizing the TIME framework has been shown to directly improve patient care and it is therefore recommended that this approach is considered for all practitioners involved in wound care.

The framework needs to be incorporated into patient care pathways that are currently being developed by practice based commissioners and other commissioners of services

There is a need to provide practical resources such as wound measurement devices and wound assessment forms in order to successfully implement the concept of WBP, using the TIME framework.

Two significant areas that have been highlighted for practice development include;

- To improve the identification of superficial vs. deep infection
- To improve issues around pain and dressing selection

It is recommended that the mnemonics NERDS and STONES (Sibbald et al 2006) with permission be incorporated into Newham wound management guidelines and into education programmes and material. To address issues in relation to pain it is recommended that the wound assessment forms currently used are reviewed to include a dedicated section on pain assessment and management and that this is audited annually until improvements are noted. Additionally recommendations from the WUWHS (2004) and the Wound Pain Model (Woo et al 2008) is introduced into practice for the future.

#### **4.7.2 Education**

Wound care educational programmes need to incorporate and support the use of the TIME framework in practice, both at an academic level and practice level.

Practitioners need to be involved more in the commissioning of education that is relevant and meaningful for practice, through patient and clinician feedback, surveys and monitoring of outcomes in practice. Additionally the Trust should undertake a training needs analysis annually and this should inform the educational contract commissioned.

The development of an inter professional model of wound care education needs to be explored that brings together key practitioners involved in wound care, and this could be delivered at development levels from novice to expert.

Service providers need to consider this research evidence and other evidence in the literature supporting the links between education and improved patient outcomes and reconsider their investments in local educational contracts in light of this.

#### **4.7.3 Research**

There is a need to develop more practice focused research projects that can clearly demonstrate improved patient outcomes.

Nurse consultants and advanced practitioners need to be supported by academic institutes and their organisations to develop and deliver on their research capacity.

There is a need for further research to explore other benefits that the concept of WBP and the TIME framework might bring to practice, in relation to further improvements to patient care and reduction in wound care costs.

Possible research topics for the future should include; The impact on wound healing and quality of life using the TIME framework, and the potential for savings if the concept is used in practice.

#### **4.8 Limitations of the study**

The results of this study are limited to community nurses in the practice of wound care. There are many other clinicians involved in wound care such as General Practitioners and physicians and it may have been useful to examine the impact of the concept of WBP and TIME from a multi-disciplinary perspective.

The participants of the study were followed up within the first six months following the delivery of the educational programme and it would have been useful to follow them up again at twelve months to see if the improved knowledge and practice had been sustained. This was not possible due to the timescale of the project. Evidence does however show that the improvements to practice have been sustained as discussed in section 4.5.16.

Applying an experimental design to the practice setting is difficult due to the number of variables that need to be controlled. Whilst this research project made every effort to control these variables by using structured tools that had been peer reviewed and piloted, it was not always possible to control all the variables. Although the time interval between pre-test and post-test was short, it is possible that some changes in practice may have taken place without the impact of the experimental variable.



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## **5.0 DISSEMINATION ARTEFACT**

### **5.1 Main dissemination artefacts**

**A Paper** has been submitted to **The International Wounds Journal** for publication.

**Title: Utilizing the TIME framework to improve community nurses wound care knowledge and practice: An experimental study. (attached)**

**A Poster** was accepted and presented at World Union of Wound Healing Societies Conference in Toronto June 2008

### **5.2 Additional dissemination artefacts**

#### **5.2.1 Case Study**

##### **Publications**

Dowsett C (2005) Managing leg ulceration in patients with sickle cell disorder.  
**Nursing Times 101:16: 48-51 (attached)**

##### **Conference presentations**

**'Managing sickle cell ulceration in the community': Oral presentation. Wounds UK Conference. Harrogate. November 2003**

**'Managing sickle cell ulceration in the community': Poster presentation. Community and Primary Care Nursing conference. London. April 2005.**

### **5.2.2 Critical review of the literature**

#### **Publications**

Dowsett C (2003) An overview of Acticoat dressing in wound management. **British Journal of Nursing (tissue viability supp)**, 12,19, S44-49. (attached)

Dowsett C (2004) The use of silver-based dressing in wound care. **Nursing Standard**, 19,7: 56-60 (attached)

### **5.2.3 Research Report**

#### **Publications**

##### **Book chapter:**

Dowsett C., Ayello E (2006) TIME principles of chronic wound bed preparation and treatment in; **Trends in Wound Care Volume IV. Cutting KF (ed). Quay books, London. Chapter 11, 120 – 137.**

##### **Papers:**

Dowsett C, Ayello E (2004) TIME principles of chronic wound bed preparation and treatment. **British Journal of Nursing (Tissue Viability Supplement)**, 13, 5: S16-23. (attached)

Dowsett C, Edwards-Jones V, Davies S (2004) Infection control for wound bed preparation. A journey through TIME Wound bed preparation in practice. **British Journal of Nursing (supp)** 13, 18: 12-17.

Dowsett C, Newton H (2005) Wound Bed Preparation: TIME in practice. **Wounds UK, vol 1, issue 3: 48-70.** (attached)

Dowsett C, Claxton K (2006) Reviewing the evidence for wound bed preparation.

**Journal of Wound Care, 15,10:439-442.** (attached)

### **Conference presentations**

**Royal College of Nursing wound care conference 2005 London:** Oral presentation on wound bed preparation, which included research methodology.

**European Pressure Ulcer Advisory Panel (EPUAP) conference 2005 Aberdeen**

Oral presentation on wound bed preparation 'Care cycle'.

**Wounds UK conference 2005 Harrogate:** Presentation on Infection management.

**Wounds UK conference 2007 Harrogate:** Presentation 'TIME for improved clinical outcomes', including overview of research results

Televised panel discussion on the TIME framework sent to all NHS Trust in the UK

available from <http://www.healthexec.tv/cgi-ails.pl?action=pre&id=395>

### **5.2.4 Awards**

The Research project was winner of **Wounds UK award 2007**, in the category;

Wounds System Award, 'Improving Clinical Outcomes by Adopting a Systematic Approach'.

I also received a '**Queen Elizabeth the Queen Mother's Award for Outstanding Service**' in June 2008 for my significant contribution to community nursing.



## **DISSEMINATION ARTEFACT**



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# Utilizing the TIME framework to improve community nurses wound care knowledge and practice: an experimental study

## Introduction

This research study examined the impact of delivering an educational programme utilising the concept of Wound bed preparation and the associated TIME framework on community nurses wound care knowledge and practice. Wound bed preparation (WBP) has gained international recognition as a concept that can provide a structured approach to wound management. The concept links treatment to the underlying cause of the wound and focuses on removal of the barriers to healing (Schultz et al 2003). The TIME framework was developed in 2002 by the International Advisory Board for WBP, as a practical tool for use at the patient's bedside when implementing the concept of WBP. TIME is an acronym summarising the four main components of WBP: tissue, infection/inflammation, moisture imbalance and edge advancement of the wound.

T: Tissue - non-viable  
I: Infection/Inflammation  
M: Moisture imbalance  
E: Edge of wound

## Methods

### Design:

This study utilized an experimental pretest-posttest design using repeat measures. The study hypothesised that a structured educational intervention based on the concept of Wound Bed Preparation and the TIME framework would positively impact on community nurses wound care knowledge and practice.

### Sample:

A sample of  $n=46$  community nurses were invited to take part in the study from one Primary Care Trust in London. Full participation was defined as taking part in a non-participant observation visit, to a patient requiring wound care before and after attending an educational programme, and completing a questionnaire before and after the event. Statistical power analysis was used to estimate the sample size required to adequately test the hypothesis.

### Intervention:

The intervention consisted of an educational programme utilizing adult learning theory (Knowles et al 2005) and evidence based practice based on WBP and TIME.

### Instruments:

Multi-methods of data collection were used for the study. Non-participant observation, questionnaires and retrieval of information from the patients' clinical notes, were used to gather data, on community nurses knowledge and practice before and after the introduction of the educational programme. The data was triangulated to test one source of information against another and to increase the reliability of the findings.

### Data analysis:

Data was analysed using the computer software package Statistical Package for Social Sciences (SPSS) version 14.0. Parametric and non-parametric statistical tests were used to analyse the data, based on the distribution and the level of significance of the findings reported.

### Ethics:

Ethical approval was obtained for the study and informed consent obtained from the nurses and their patients who took part.

## Results

A total of 47 nurses took part in the study. However 15 were lost to follow up, making the final sample size 33, which fulfilled the sample size requirements for statistical analysis. Their clinical banding varied between bands five and seven as outlined in figure 1.

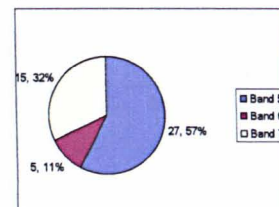


Figure 1: Clinical banding of nurse participants

A total of 79 visits to patients took place to observe the type of wounds being treated, the TIME elements and treatment. A number of different wound types were observed, but the most common wound type observed was leg ulcers, which accounted for 60% of the visits.

Community nurses wound care knowledge and practice improved significantly after the delivery of the TIME based educational programme. Knowledge: Pre-test scores of ( $\bar{x}=25.35$ , SD 7.19) and post test scores of ( $\bar{x}=42.08$ , SD 3.63). A significant improvement was noted ( $t(39)=17.37$ ,  $p<0.001$ ). Practice: Pre-test scores ( $\bar{x}=21.77$ , SD 3.94) and post test scores of ( $\bar{x}=28.91$ , SD 3.65). A significant improvement was noted where ( $t(32)=7.12$ ,  $p<0.001$ ). Scores for patient assessment and wound assessment were analysed independently. Patient assessment improved significantly ( $t(32)=5.42$ ,  $p<0.001$ ), and wound assessment also improved significantly ( $z=4.502$ ,  $p<0.001$ ).

## Assessment

All patients had had a general assessment, but the level of that assessment improved after training, with more emphasis on identification and treatment of the underlying wound aetiology. Wound assessment improved significantly after training. 42% (20) patients had a wound assessment form completed before the training. Two of these were completed on initial assessment and had no further entries to evaluate progress. Only 16 (34%) had some form of wound measurement. Post training a significant improvement was noted in the way in which wounds were assessed utilizing the TIME framework and measured. Thirty one (97%) of patients had a wound assessment form completed and updated at regular intervals and 31 (97%) of patients had had their wounds measured. 94% of these were in the form of a wound tracing using the visitrak tracing grids which had been provided for the nurses as part of the educational programme.

## TIME

The concept of Wound Bed Preparation was poorly understood and knowledge of the TIME framework was limited before the training programme. This improved significantly after training as shown in figure 3.

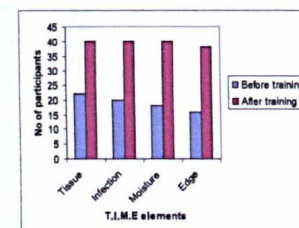


Figure 2: Number of participants who were able to define T.I.M.E.

## Tissue

Knowledge of debridement methods increased after training as outlined in figure 4, and there was an increase in the number of patients referred to the tissue viability service for sharp debridement and larvae therapy after training.

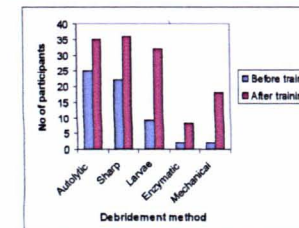


Figure 3: Number of participants identifying debridement methods

Twenty patients (42%) were identified as having non viable tissue in the pre training visits. Only 16 (34%) had this recorded in the notes or assessment form as a problem. Following training 20 (62%) of patients had non viable tissue present and they all (100%) had this recorded in their clinical notes. The terms used to describe the tissue type before training was 'sloughy', 'very sloughy', 'necrotic areas' and 'loose sloughy'. After training more specific terms were used such as black, green, yellow, red and pink which are the colour coding system used on the wound assessment form. The participants also completed the percentage area of non viable tissue, and in some cases used the wound measurement grids to shade in this area therefore giving a more accurate and objective assessment of the problem.

## Infection/inflammation

Knowledge of risk factors for the development of a wound infection increased after training ( $z=4.627$ ,  $p<0.001$ ), as did the nurses knowledge of clinical signs and symptoms of infection. ( $z=4.332$ ,  $p<0.001$ ). Community nurses knowledge of local wound infection management increased significantly ( $p<0.001$ ). Their knowledge of management of systemic infection also improved but this was not found to be significant ( $p=250$ ). Pre training 10 (21%) of patients visited were identified as having infection present by the researcher. From this group 7 were identified as having signs and symptoms of local infection and 3 signs and symptoms of systemic infection. After training 9 (28%) of patients visited were identified as having an infection, of which 8 (25%) was local infection and 1 (3%) systemic. All 19 patients had infection recorded as a problem in their notes, but no differentiation was made between local and systemic. Consequently 7 (15%) of patients had been prescribed oral antibiotics before training with 4 (8%) of these being inappropriately and unnecessary. The use of oral antibiotics reduced after training as did the use of topical antimicrobial dressings as outlined in figure 4.

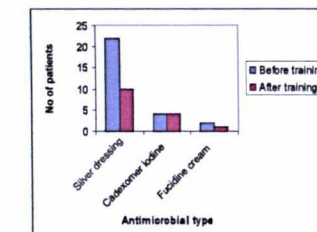


Figure 4: Types of antimicrobials used

## Moisture imbalance

Community nurses knowledge of interventions to manage moisture imbalance improved significantly after training. ( $z=4.672$ ,  $p<0.001$ ). They also placed more emphasis on treating the underlying cause of the problems. Knowledge of factors to consider when choosing a dressing to manage excess exudate also improved ( $z=4.971$ ,  $p<0.001$ ). A significant number of patients observed had a moisture balance problem, 42 pre training and 27 post training. All these wounds had excess moisture at the wound bed. Pre training descriptive terms were used to document the problem including 'leaking' 'exudate ++', 'exudate +++', 'strike through'. Post training moisture balance problems had been recorded using more objective terms, such as wound exudate high, moderate and low, using the wound assessment and evaluation form.

## Edge

Knowledge of this aspect of the TIME framework was poor before training. Nurses were unable to identify problems such as undermining and hyper-proliferation at the wound edge, using case study examples. Only 4 (10%) identified a non healing wound edge, but this increased to 31 (77%) after training. Edge advancement in terms of wound measurement also improved. The number of nurses using tracing increased from 15 (37%) before to 30 (75%) after, as did the use of measurement probes 17 (42%) before and 35 (87%) after, as outlined in figure 5.

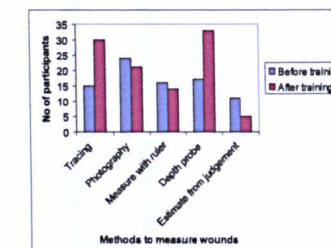


Figure 5: Methods identified to measure wound progress

## Conclusion

This experimental study has shown that the delivery of an educational programme on the concept of wound bed preparation and the TIME framework improved community nurses wound care knowledge and more importantly their wound care practice. The results have implications for how wound care is delivered in the community setting and has the potential to ensure more appropriate treatment decisions based on the identified barrier to healing and more cost effective care.

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**Title: Utilizing the TIME framework to improve community nurses wound care knowledge and practice: An experimental study.**

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## **Abstract:**

This research study examined the impact of delivering an educational programme utilising the concept of Wound Bed Preparation (WBP) and the associated TIME framework on community nurses wound care knowledge and practice. The TIME framework was developed by the International Advisory Board for Wound Bed Preparation (Schultz et al 2003), as a practical tool for use in the clinical setting and summarises the four main components of Wound Bed Preparation:

- Tissue
- Infection/inflammation
- Moisture
- Edge

An experimental pretest-posttest design using repeat measures was used to test the hypothesis that a structured educational intervention based on the TIME framework would positively impact on community nurses wound care knowledge and practice. Data was collected using questionnaires, non participant observation and collection of data from patient's clinical records. Community nurses wound care knowledge and practice improved significantly after training. Knowledge improved significantly ( $t(39) = 17.37, P < 0.001$ ) as did wound care practice ( $t(32) = 7.12, p < 0.001$ ). It was concluded from the study that the TIME framework is a useful tool for delivering wound care education and can make significant improvements to wound care practice.

## **Key words:**

Community nurses  
Knowledge and practice  
TIME framework  
Wound care

## **Introduction**

Caring for people with wounds is costly, both financially and in terms of the impact on the patient's quality of life. The cost of wound care in the United Kingdom accounts for 3% of the annual National Health Service expenditure. This has been estimated at £2.3-£3.1 billion per year (Drew et al 2007). This does not reflect litigation cost that result from complications or indeed the hidden cost to the patient, such as pain, depression and social isolation. The majority of these wounds are chronic in nature such as leg ulcers and pressure ulcers, and are cared for in the community setting by General Practitioners and community nurses. Evidence from the literature shows that there are variations in wound care practice (Harding 2000), leading to inequalities in the care provided to patients. There are also variations in the way in which wound management is documented (Tapp 1990). The concept of WBP was developed as a structured approach to the management of chronic wounds, and has the potential to offer a solution in terms of addressing these inequalities.

WBP has been defined as 'the management of a wound in order to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures' (Falanga 2000). The concept of WBP focuses the clinician on optimising conditions at the wound bed so as to encourage normal endogenous healing. It is an approach

that should be considered for all wounds that are not progressing to normal wound healing. WBP should be considered within the context of total patient care and should include a comprehensive assessment of the patient and an appreciation of their concerns and priorities (Sibbald et al 2000). Four main components are proposed as the mainstay of treatment using WBP. These have been abbreviated using the acronym TIME and include regular debridement of the wound to remove sloughy and necrotic tissue, the control of bacteria and infection prevention and management, maintenance of a moisture balance and epidermal advancement (Schultz et al 2003). The TIME framework was developed by the International Advisory Board for WBP (Schultz et al 2003). A body of literature describes the components of the TIME framework and case study examples of its practical implementation. However to date there is no research to demonstrate the impact of the concept on the wound care knowledge and practice of clinicians following introduction of the concept in an educational programme.

## **Methods**

The study utilized an experimental pretest-posttest design using repeat measures. The study hypothesised that a structured educational intervention based on the concept of wound bed preparation and the TIME framework would positively impact on community nurses' knowledge and practice in wound care. The dependent variable was defined as the level of change in wound care knowledge and practice as demonstrated by community nurses. The independent variable was defined as the educational intervention, the presumed cause of changes in knowledge and practice. The dependent variable was measured by the use of questionnaires and non-participant observation of clinical practice in wound care, before and after the introduction of an educational programme. The independent variable was operationalised by delivering an educational programme on the TIME framework to community nurses over a series of two half day modules. Adult learning theory (Knowles 2005) and evidence based practice provided the underpinning for the development of the training programme. An overview of the content of the educational programme is provided in Table 1.

A sample of n=47 community nurses took part in the study from one Primary Care Trust. Full participation was defined as taking part in a non-participant observation visit to a patient requiring wound care before and after attendance at the educational programme, and completing a questionnaire before and after the event. Seventy nine patient visits were observed, 47 before and 32 after the educational intervention. Statistical power analysis was used to estimate the sample size required to adequately test the hypothesis. To detect a medium effect size, with 85% power at the 5% level, allowing for attrition, a minimum sample of 31 participants was required. All community nurses were however invited to take part to ensure an inclusive approach.

Community nurses knowledge was examined using a questionnaire in relation to the following key areas:

- Physiology of wound healing
- Knowledge of Wound Bed Preparation and the TIME framework
- Patient assessment
- Wound assessment
- Identification and management of the elements of TIME

Wound care practice was examined by non-participant observation and recording of information from the patient's clinical records, in relation to the following key areas

- Patient assessment: general and specific to wound type
- Identification and treatment of the underlying cause
- Wound assessment
- Identification, recording and treatment of TIME related problems
- Referral pathways

The questionnaire and observation schedule were peer reviewed by the International Advisory Board for Wound Bed Preparation to increase reliability and validity and piloted in another local Primary Care Trust. The results were analysed using the computer software Statistical Package for Social Sciences (SPSS) version 14.0. This was a single site research study as part of a PhD in Professional Practice at City University and was peer reviewed. Ethical approval was obtained for the study and informed consent obtained from community nurses and their patients who took part in the study.

## Results

Forty seven community nurses clinical bands five to seven took part in the study; 32% band seven, 11% band six and 57% band five nurses. A total of 79 patient visits for wound care treatments were observed. The most common wound type seen was leg ulceration which accounted for 80% of the visits. The results showed that knowledge and practice improved significantly after the delivery of an educational programme based on the concept of Wound Bed Preparation and the TIME framework.

Pre-test knowledge scores of ( $\bar{X} = 25.35$ , SD 7.19) and post test scores of ( $\bar{X} = 42.08$ , SD 3.63) were shown. A significant improvement in knowledge was noted ( $t(39) = 17.37$ ,  $p < 0.001$ ). The results from observation visits were analysed for changes in nurse's practice, in patient assessment and wound assessment, using the TIME framework, before and after the educational intervention. Pre-test scores ( $\bar{X} = 21.77$ , SD 3.94) and post test scores of ( $\bar{X} = 28.91$ , SD 3.65). A significant improvement was noted in practice where ( $t(32) = 7.12$ ,  $p < 0.001$ ). Scores for patient assessment and wound assessment were analysed independently and the following results were found. Pre-test scores for patient assessment were ( $\bar{X} = 19.5$ , SD 3.36) and post test scores ( $\bar{X} = 25.06$ , SD 3.57). A significant improvement was noted in the way in which community nurses assessed patients ( $t(32) = 5.42$ ,  $p < 0.001$ ). Nurses practice in wound assessment and measurement also improved after training and this was found to be statistically significant ( $z = 4.502$ ,  $p < 0.001$ ).

## Knowledge

Nurse's knowledge of wound healing was poor and most nurses were only able to identify two stages of wound healing before training. This improved significantly after training ( $z = 5.667$ ,  $p < 0.001$ ), as shown in Figure 1. Before the educational intervention only 18(45%) of nurses were able to define the concept of 'Wound Bed Preparation' but this improved to 35(88%) after training. The TIME framework was poorly understood before the educational intervention but this improved significantly after training (see Figure 2). Community nurses knowledge in each element of the TIME framework improved.

**Tissue:** Nurses were able to identify and categorise more methods for wound debridement after training. Knowledge improvements in this area were found to be statistically significantly after the educational programme ( $z=4.833$ ,  $p<0.001$ ).

**Infection:** Nurses knowledge of the signs and symptoms of wound infection improved significantly ( $z=4.627$ ,  $p<0.001$ ). Nurses were also able to differentiate the differences between local and systemic infection, and appropriate treatments. Ten (25%) of nurses incorrectly stated that they would use oral antibiotics to treat local infection before the training with none recommending this practice after training.

**Moisture:** Community nurses understanding of the need to treat the underlying cause of the problem when managing wound exudate. There was an increase in the number of respondents who identified compression therapy as a treatment for the M in the TIME framework. Prior to training only 7(17%) of nurses identified this as a treatment for excess exudate, but this improved to 30(75%) after training. Given that 80% of the patients observed has leg ulceration this is an important outcome. Fourteen (35%) of nurses were able to make association between the M and the I of the TIME framework, by identifying infection as a possible cause of increased exudate. The main focus of treatment selection was on absorbent dressings, but the number of nurses who identified topical negative pressure therapy (TNP) as a treatment increased from 6(15%) to 18(45%). There was also an increase in nurses' knowledge of the importance of wound bed type in relation to dressing selection. Before the educational intervention only 9(22%) identified the wound bed as a factor in dressing selection, but this increased to 37(92%) after training.

**Edge:** Two issues were examined in relation to nurses' knowledge of the E in the TIME framework. The first was the method used to determine if the edge of the wound was progressing to healing, and the second was to determine their knowledge in relation to wound edge problems such as undermining using case study examples. The most common method nurses stated they used to monitor healing was wound photography 24(60%) and use of depth probes 17(42%), but this was not supported in observed practice, few patients having any form of wound measurement or an initial wound photograph. After training the methods stated were tracing 30(75%) and use of depth probe 33(82%) (see Figure 3), and these finding were consistent with observed practice. Community nurses knowledge in relation to wound edge problems was poor before training. Only 3(7%) of nurses were able to identify a raised wound edge and 4(10%) undermining in case study examples. This improved significantly after training with 33(83%) able to identify a raised wound edge, and 34(85%) able to identify undermining.

### **Practice**

Accurate assessment and diagnosis of a patient with a wound is essential for good wound care practice. Evidence from the literature shows that assessment is poor, as is the documentation of that assessment (Coulliet 2001). A total of 79 non-participation observation patient visits were undertaken, 47 before the educational intervention and 32 after. Comparisons were made between the assessment of patients by nurses before and after training. Pre-test scores ( $\bar{X}=19.5$ , SD 3.36) and post test scores ( $\bar{X}=25.06$ , SD 3.57). A significant improvement was noted where ( $t(32)=5.42$ ,  $p<0.001$ ). Generally the detail and level of assessment undertaken by the community nurses in this study was good, facilitated by the nursing notes which are of a detailed



nature. However assessment of quality of life issues was poor 13(27%) demonstrating evidence of assessment of QOL before training and 16(48%) after training. In particular assessment of pain, including pain on dressing change was poor. The number of patients who had a differential diagnosis was also high before and after training 97% and 100% respectively. The most notable improvements in practice were in relation to wound assessment and identification and management of related TIME problems. Only 20(42%) of patient had a wound assessment form completed before training but this improved to 31(97%) after training, demonstrating a statistically significant improvement ( $p < 0.001$ ). In terms of wound measurement, only 16(34%), (Figure 4). had some form of wound measurement taken, but again this improved after training to 31(97%), (Figure 5). The use of wound tracing using grids and measuring device became standard practice after the training programme.

**Tissue:** Identification, documentation and management of TIME related problems was poor before training. Twenty patients were identified as having non viable tissue in the pre-training observation group, yet only 16(34%) had this recorded in their notes as a problem. After training 20(62%) of patients seen had this problem and 100% had it identified and documented. The most used method for debridement was autolytic debridement before and after training, however, a number of patients were having larvae therapy and had been referral for sharp debridement after training.

**Infection:** Ten (21%) of patients in the pre-training observed group had clinical signs and symptoms of infection, as identified using the recommended criteria for infection (Cutting et al 2005). From this group seven patients were identified as having local infection and three as having systemic infection. Seven (15%) of these patients had been prescribed oral antibiotics. In the post-training patient group 9 (28%) of patients were identified as having clinical signs and symptoms of infection, of which 8 (25%) was local and 1(3%) systemic, with appropriate prescribing of oral antibiotic therapy, (Figure 6. There was also a reduction in the number of wound swabs taken for culture and sensitivity after training, with 12 (25%) of patients having had a swab taken before training and none having a wound swab taken after training. There was a reduction in the use of topical antimicrobial dressings from 28 (60%) in the pre training observed group to 14 (43%), in the post training group.

**Moisture:** A significant number of patients in the study had a moisture balance problem. A total of 69 patients presented with moderately to highly exuding wounds. Pre- training community nurses used descriptive terms such as 'exudate ++' and 'leaking' to describe the wounds. Post- training more objective terms were used such as high, moderate and low as used in the wound assessment and evaluation forms. Appropriate absorbent dressings and compression therapy were in use.

**Edge:** Thirty (63%) of patients had evidence of edge advancement and 17(36%) were observed or reported to have a non-healing wound in the pre-training observed patient group. After training 25(78%) had evidence of edge advancement and 8(25%) were non-healing. Again this element of practice was poorly identified and documented by the nurses, which made it difficult to assess progress. Only 5 (29%) had a non-healing wound recorded as a problem in the clinical notes, and only 3 (17%) had been referred for specialist advice. After training all 8 (25%) of those patients identified as non-healing had the problem recorded and specialist referral in place.

## **Discussion**

WBP although a relatively new concept in wound care, has been accepted and recognised as a global concept, which provides a structured approach to wound care. The TIME framework is a tool developed to operationalise the concept in clinical practice, and has been used in this study for the purpose of developing research, education and practice. As healthcare professional we need to be constantly seeking ways to improve care for patients and ensure positive outcomes through practice, research and education. The ultimate goal of educating health professional must be to improve patient outcomes. It is important therefore to evaluate what impact if any education has not just on knowledge, but the application of that knowledge to practice.

The study does acknowledge the difficulties of applying an experimental design to the practice setting due to the number of variables that need to be controlled. Whilst this research project made every effort to control these variables, by using structured tools that had been subject to peer review and piloted, and statistical analysis to analysis the data it was not always possible to control all the variables, due to the nature of real world research (Robson 1998).

Changing practice is challenging, but sustaining change can be difficult and involves integration of the changes into everyday practice. In an attempt to ensure continued use of the TIME framework and appropriate selection of treatments based on the identified barriers to healing, the tissue viability service developed a wound dressing's formulary for use across primary and secondary care, based on the TIME framework. The framework has also been incorporated into the tissue viability in-house educational programme. The results of this experimental study demonstrate the significant improvements that can be achieved in community nurses wound care knowledge and practice when the TIME framework is incorporated into an educational programme.

**Acknowledgements:** To Professor Rosmund Bryar, Public Health, Primary Care and Food Policy Department, City University, London who supervised this research project and to Newham Primary Care Trust, who supported and hosted the project.

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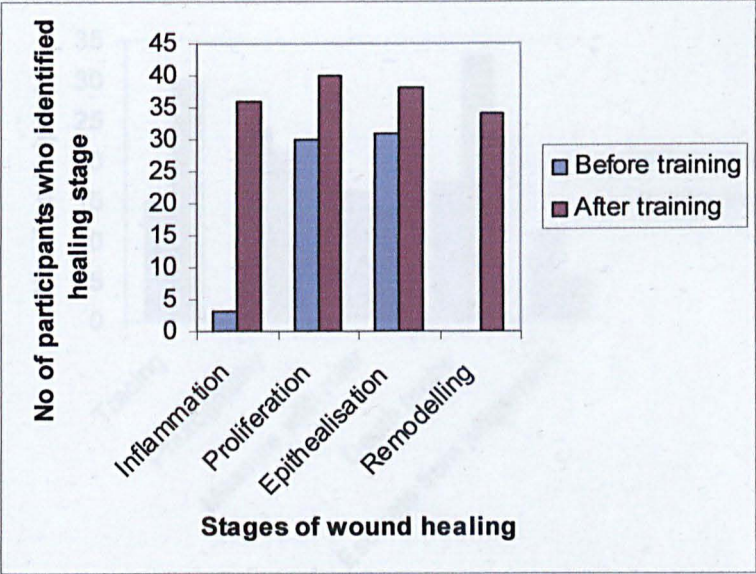
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**Tables and Figures.**

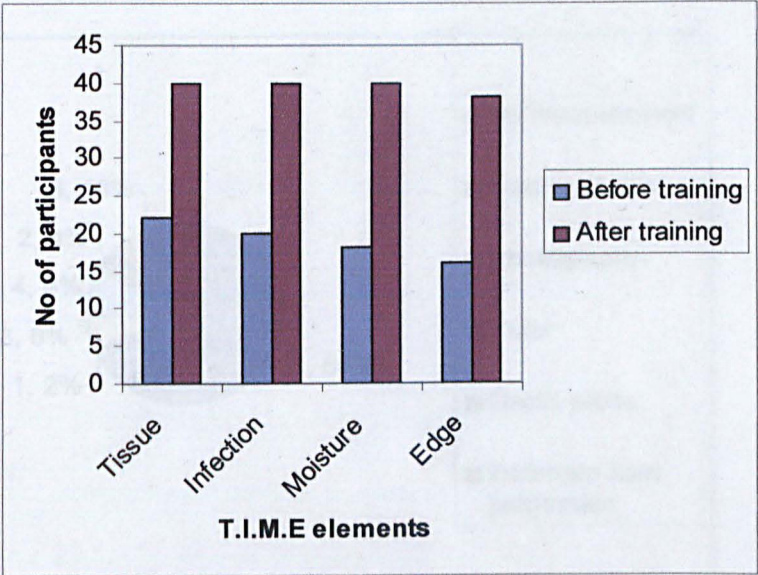
**Table 1. Overview of educational programme**

Module 1.	Module 2.
Physiology of wound healing Acute and chronic wound healing	Tissue management Assessment, treatment, outcomes
Patient and wound assessment Treatment of underlying cause	Infection/inflammation control Assessment, treatment, outcomes
Wound Bed Preparation Definition and development	Moisture balance Assessment, treatment, outcomes
Overview of the TIME framework Links between elements of TIME	Edge evaluation Assessment, treatment, outcomes

**Figure 1: Number of nurses who correctly identified the stages of wound healing before and after training**

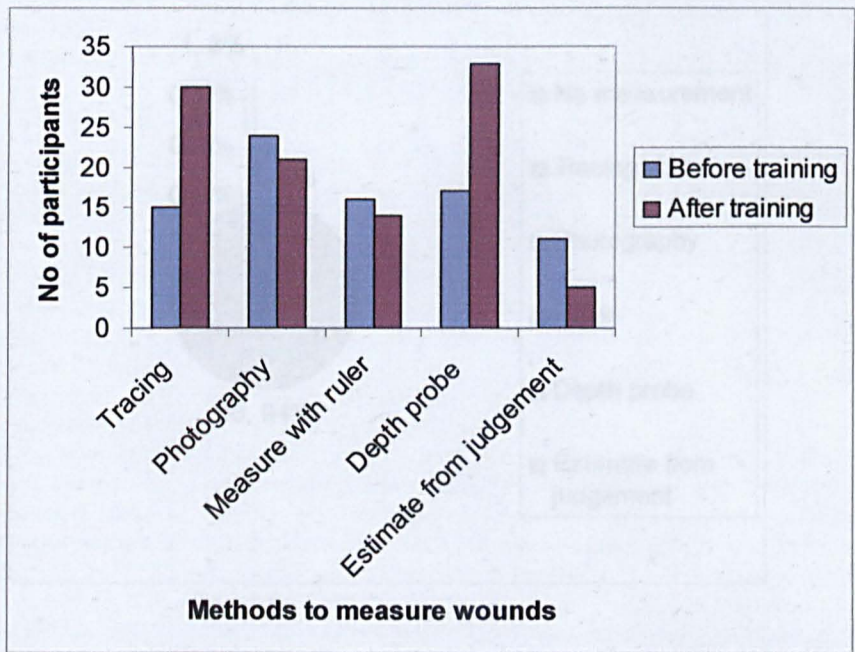


**Figure 2. Number of participants who were able to define T.I.M.E before and after training**





**Figure 3. Methods identified to measure wound progress**



**Figure 4. Wound measurement method before training**

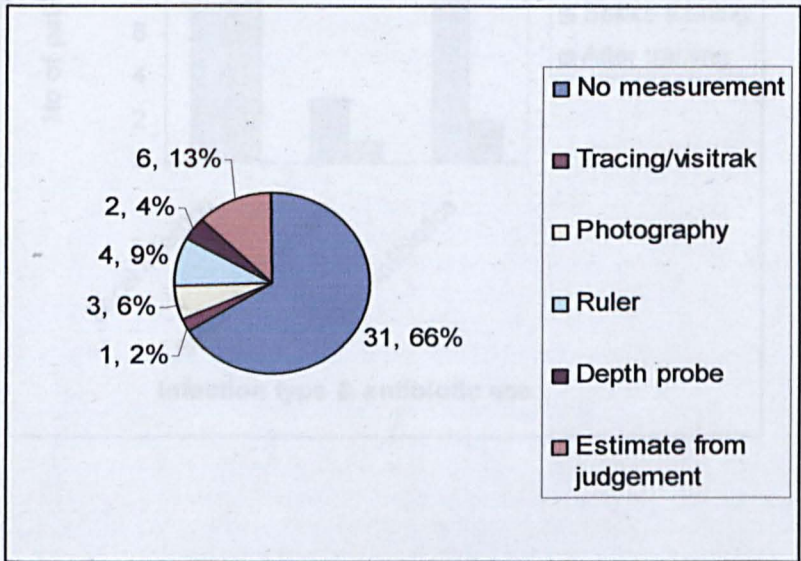


Figure 5. Wound measurement method after training

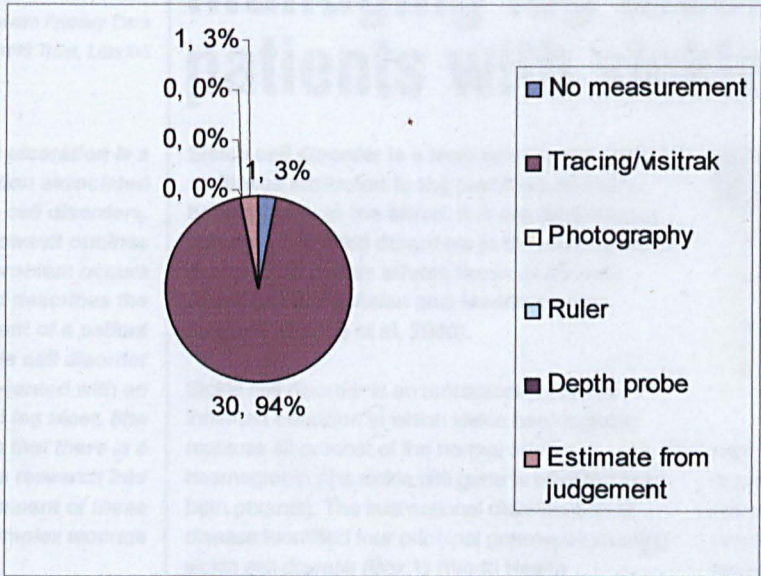
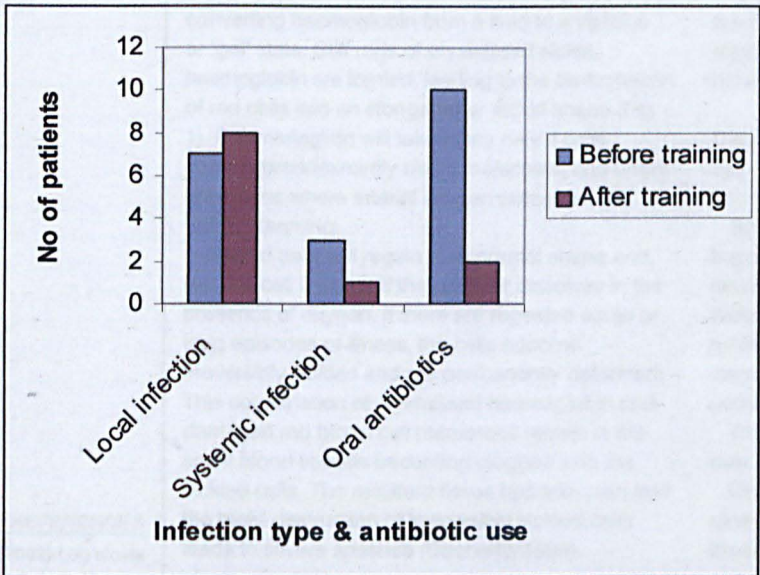


Figure 6 Infection and antibiotic use





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# Managing leg ulceration in patients with sickle cell disorder

**Leg ulceration is a complication associated with sickle cell disorders. Caroline Dowsett outlines why this problem occurs and describes the management of a patient with sickle cell disorder who presented with an infected leg ulcer. She concludes that there is a need for more research into the management of these complex wounds**

## KEY WORDS

Sickle cell disorder  
Leg ulceration  
Compression therapy

Sickle cell disorder is a term used to describe an illness attributed to the presence of sickle haemoglobin in the blood. It is one of the most common inherited disorders in the north west of Europe and mainly affects those of African, Afro-Caribbean, Asian and Mediterranean descent (Davies et al, 2000).

Sickle cell disorder is an autosomal recessive inherited condition in which sickle haemoglobin replaces all or most of the normal adult haemoglobin (the sickle cell gene is inherited from both parents). The international classification of disease identified four principal genotypes causing sickle cell disease (Box 1) (World Health Organization, 1992).

Sickle cell trait is the name given to the condition in which an individual has inherited the sickle cell gene from only one parent. It is not included as a disease in the haemoglobinopathies.

Sickle cell disorder can have a profound effect on a person's life. Under conditions of low oxygen tension, sickle haemoglobin molecules polymerise, converting haemoglobin from a fluid to a viscous or 'gel' state. Stiff rods of crystallised sickle haemoglobin are formed, leading to the de-formation of red cells into an elongated or sickle shape (Fig 1). Polymerisation will take place only if cells contain predominantly sickle molecules, and under conditions where arterial oxygen pressures fall below 40mmHg.

Sickled cells will regain their normal shape and resume cell function if the polymer dissolves in the presence of oxygen. If there are repeated acute or long episodes of illness, the cells become irreversibly sickled and are permanently deformed. This combination of crystallised haemoglobin and damaged red blood cell membrane results in the small blood vessels becoming clogged with the sickled cells. The resultant tissue hypoxia, pain and the rapid destruction of irreversibly sickled cells leads to severe anaemia (Docherty, 1999).

## Leg ulceration and sickle cell disorder

Leg ulcers are a well-recognised complication of sickle cell disorder. They are more common in people with homozygous sickle cell disease than with any other form of sickle cell disorder (Box 1), and males appear to be more commonly affected than females. Cackovic et al (1998) noted a 25–75 per cent incidence of leg ulcers in patients with sickle cell disorders, and suggest that 25–63 per

## BOX 1. THE FOUR PRINCIPAL GENOTYPES CAUSING SICKLE CELL DISEASE (WHO, 1992)

• Homozygous sickle cell disease	HbSS
• Sickle haemoglobin C disease	HbSC
• Sickle haemoglobin D disease	HbSD
• Sickle haemoglobin E disease	HbSE

cent of people with sickle cell disorder will develop leg ulcers during their lifetime. These ulcers usually occur in young people (10–35 years) and healing can take 16 times longer than leg ulcers from other causes (Anionwu, 2002).

Sickle cell ulceration usually begins as small, elevated, crusting sores on the lower leg, usually around the ankles or above the medial and lateral malleoli. They can be single or multiple and often have a punched out appearance with well-defined margins and a slightly raised edge. Sometimes multiple small ulcers develop and merge to form a larger lesion. These ulcers can be very painful and are often accompanied by reactive cellulitis and regional (inguinal) adenitis (inflammation of lymph nodes in the groin).

**Causes** Leg ulceration associated with sickle cell disorders can be described as spontaneous and traumatic.

Spontaneous ulcers begin as a painful area that becomes hyperpigmented and indurated. A necrotic lesion develops within the dermis and initially the overlying epidermis is intact. This subsequently breaks down, leaving a small, but deep, painful lesion that heals relatively quickly, usually within six to nine months (Serjeant, 1994).

Traumatic ulcers have a history of trauma, which may be minor, for example an insect bite.

One explanation for traumatic and spontaneous ulceration is that when injury occurs to cells in the lower leg or around the malleoli, proteins and other constituents of plasma in the blood vessels are lost into the surrounding tissue. This results in oedema of the leg or ankle, with resulting compression of tissue around the injury. Blood flow through the capillaries is thus reduced, and arterial pressure is increased, causing expansion of the pre-capillary arterioles. The supply of oxygen to the site of injury is also reduced, causing hyperpigmentation and roughening of the skin. This progresses to a nodular swelling associated with pruritis, pain and

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tenderness. The lesion fails to heal and develops into a large, infected ulcer that commonly heals and relapses over many years (Fig 2).

Other possible factors associated with the development of ulceration in this group of patients include venous incompetence and vasoconstriction on dependence (that is, standing for long periods of time) (Anionwu, 2002). Ulcers can develop from minor disruptions in the skin in the region of the ankles or lower half of the leg. Those associated with sickle cell disorders are difficult to heal, possibly because of the impediment in blood flow caused by the sickled red cells and reduced oxygenation to the area.

**Management** The management of patients with unusual causes of leg ulceration can be difficult, as there is a lack of good quality evidence to support any one treatment. A variety of different treatments for leg ulcers associated with sickle cell disorders has been reported. Serjeant (1994) suggests that the cornerstone of therapy is to keep the lesion clean and to provide firm supporting bandages to reduce haemostasis and lymphoedema if the patient is ambulant.

Some recommendations that have been made lack research evidence to support their use and some could be detrimental to patients. The sickle cell centre in Georgia, USA (National Institutes for Health Sickle Cell Information Centre, 1997), suggests using liquid household bleach to clean the ulcer and wet-to-dry gauze to debride the wound. However, the routine use of antiseptics is not recommended in wound management, and the National Institute for Clinical Excellence (2001) does not advocate using wet-to-dry gauze for the debridement of wounds as this causes pain and trauma for the patient and delays wound healing. Other recommendations in the literature for ulcer management include bed rest, blood transfusions, skin grafting and surgery, although these have not

been shown to improve healing rates or to prevent ulcer recurrence.

Given the lack of clinical evidence to support the management of patients with sickle cell leg ulceration, the nurse needs to combine good clinical judgement with clinical reasoning and be aware of the patient's perspective when making assessments and recommending treatments.

**Case study** Thirty-nine-year-old Chris Obek was referred to the tissue viability service by the haemoglobinopathy nurse specialist, with a non-healing leg ulcer. She was concerned that Chris was managing his own ulcer and that this was having a significant impact on his quality of life. Chris was born in the UK and is the oldest of three children. Both of his parents came from Nigeria. He is married and has a daughter aged two years. Chris works as an independent consultant, therefore any periods of absence from work because of his ulcer has an impact on his earnings, which is a source of great anxiety to him.

**Assessment** A general patient assessment and a more specific assessment of the leg ulcer, including Doppler ultrasound, were carried out. Chris's main complaint was that his ulcers were extremely painful and offensive smelling. He had had them intermittently since the age of 35, but usually they had healed with self-management, which included applying a variety of dressings that he had purchased from the local chemist. Chris could recall at least four episodes of ulceration in the past four years. He had recently been an inpatient for the management of a sickle cell crisis, and associated this with his current problem. He now felt tired and no longer able to cope with his ulcer.

Initial observations revealed ulceration of the lower medial and lateral aspects of the right leg. The lateral ulcer measured 6.5cm X 5cm and the medial one 5cm X 4cm.

The ulcers had started spontaneously as small lesions and had developed into one large lesion over the previous month. The wound bed was mainly sloughy (90 per cent), with some areas of granulating tissue (10 per cent) on the medial ulcer. There were large volumes of exudate from the wound and it was also malodorous. Chris was distressed by the pain associated with the removal of his dressing, despite having taken two codydramol tablets before attending the clinic. He reported that the ulcers were always very painful.

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FIG 1. SICKLE-SHAPED RED BLOOD CELL

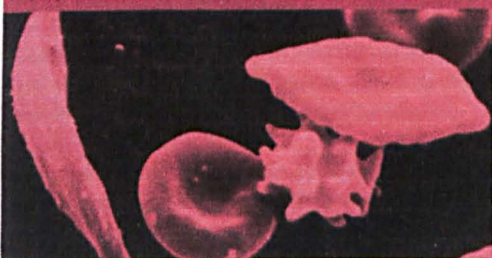




FIG 2. EXAMPLES OF SICKLE CELL ULCERATION



His past medical history included sickle cell disorder and four episodes of leg ulceration, but otherwise he was well. The Doppler readings showed an ankle brachial pressure index of 1.07 on the right leg and 1.05 on the left leg (normal range 1.0–1.3). (Measuring the ankle brachial pressure index is a method of identifying arterial insufficiency in a limb).

**Case management** Determining the best treatment for a patient means taking individual circumstances into consideration, applying evidence-based practice, using clinical judgement/reasoning, and taking into account the patient's preference (Byers and Brunell, 1998). In the absence of good clinical evidence for the management of patients with sickle cell leg ulceration, the nurse has to draw on clinical reasoning based on patient assessment, together with clinical risk management and patient consultation. Chris was made aware that sickle cell leg ulceration was not a common problem and that the research evidence and clinical expertise in this area were still growing.

The assessment process identified some factors that indicated venous hypertension: the location of the ulcer in the gaiter area, oedema, and skin staining around the ulcer. This, combined with normal Doppler readings, suggested that compression therapy might have a role to play in the management of Chris's ulcer. It was also noted that there were local signs of infection at the wound bed that needed to be addressed, including excess exudate and malodour. Management included taking the following actions:

- Reducing anxiety and pain by talking and explaining procedures and slowly and carefully carrying out the dressing change;
- Offering analgesia before changing dressings;

FIG 3. MULTI-LAYER BANDAGE TO HELP REDUCE OEDEMA



- Using an antimicrobial dressing (IodoFlex) as a primary dressing to reduce the bacterial burden and reduce excess exudate;
- Applying a multi-layer compression bandage to reduce oedema and promote venous return (Fig 3).

**Outcome** Chris's ulcers became less painful over the first month of treatment, and wound exudate levels reduced as his wound infection was eradicated with the use of topical antimicrobial therapy. As granulation tissue appeared in the wound bed the ulcers reduced in size. They took six months to heal.

Chris was measured and fitted for class-two below-knee compression hosiery in an effort to prevent recurrence of the ulcers, but unfortunately he has had two episodes of recurrence since his initial referral to the service. However, rapid referral to the tissue viability team has resulted in shorter courses of treatment. He is now under the care of the multidisciplinary team, which includes the vascular surgeon, the haemoglobinopathy services, his GP, the community nurse, and the tissue viability services. Chris now feels that he is no longer alone managing his ulcer, and this gives him hope for the future.

**Conclusion** Leg ulceration is a common complication of sickle cell disease. It causes pain and suffering and ulcers can take up to 16 times longer to heal than more common types of ulceration; venous leg ulcers, for example. There is a lack of research evidence to support practice in the management of this patient group. It is hoped that this case study will make some contribution to clinical practice, but future research is needed to evaluate the use of compression bandaging in the management of patients with sickle cell leg ulceration. ■



# An overview of Acticoat dressing in wound management

Caroline Dowsett

## Abstract

*This article reviews the in vitro and in vivo studies available on a new nanocrystalline silver dressing, Acticoat (Smith & Nephew), and discusses their relevance to the availability of this product on the Drug Tariff. The addition of nanocrystalline silver dressings will make a valuable contribution to wound care in the community, in terms of providing continuity of care for patients who are discharged from hospital and also in preventing admission to hospital with non-manageable wound infection.*

Most chronic wounds are treated in primary care with up to 80% of leg ulcers treated by community nurses and GPs (Callam et al, 1985). Treatment of these wounds is costly both for the patient in terms of reduced quality of life and financially. Modern wound dressings make a valuable contribution to improving healing rates and thus improving a patient's quality of life. One of the greatest concerns for wound care specialists is the increasing number of antibiotic-resistant species being isolated from wounds. Wound infection delays healing and can be life threatening for the patient.

Recent advances in biotechnology and original research have provided unique opportunities to develop dressings that are closely tailored to the type of wound to be treated. They are biocompatible and are proving to be of great benefit in advancing healing in difficult-to-heal wounds, while alleviating patient discomfort and impaired mobility.

Frequent dressing changes can increase the risk of nosocomial infection (Sheridan et al, 1997) and may increase patient pain, cost and the potential for delayed wound re-epithelialization. It is therefore advantageous to have a dressing that may be left on the wound for several days, while maintaining a bacterial barrier.

Silver is widely recognized as an effective broad-spectrum antimicrobial agent (Burrell et al, 1999; Thomas and McCubbin, 2003). There are currently a number of silver dressings available for use in the community that are available

on the Drug Tariff. This article discusses the benefits of a new unique nanocrystalline silver dressing, Acticoat (Smith & Nephew), in managing difficult-to-treat wounds.

## SILVER

Silver has been used for medicinal purposes for several thousand years (Goodman and Gilman, 1975) and has a wide spectrum of antimicrobial activity. It is effective against a broad range of aerobic, anaerobic, Gram-negative and Gram-positive bacteria, yeast, filamentous fungi and viruses (Lansdown, 2002b). Silver has also been shown to be effective against methicillin- and vancomycin-resistant strains and no resistant strains have been encountered (Lansdown, 2002a). In combination with its broad antimicrobial properties, silver also appears to have anti-inflammatory properties (Demling and DeSanti, 2001).

Before 1800 silver was used for a variety of conditions including epilepsy, venereal infections, acne and leg ulcers (White, 2001). Silver foil applied to surgical wounds improved healing and reduced postoperative infections (Halstead, 1985), while silver and 'lunar caustic' (pencil containing silver nitrate mitigated with potassium nitrate) were used for wart removal and ulcer debridement (Sollemann, 1942).

Before the introduction of systemic antibiotics in the 20th century, silver was regarded as an effective antimicrobial agent (Demling and DeSanti, 2001). In the early 20th century silver proteins and colloidal silver preparations became popular. Antimicrobials for the treatment of mucous membrane infection were highly effective, in contrast to other antimicrobial agents, with little recognized development of resistance (Pilcher and Sollemann, 1922–1923). However, their antimicrobial potency was closely related to the amount and rate of free silver released (Lansdown, 2002a).

The first silver antimicrobial agent for human use (approved by the US Food and Drug Administration (FDA) in the 1920s)

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was an electro-colloidal solution of pure silver in water (Demling and DeSanti, 2001). After the introduction of antibiotics in the 1940s, silver was used primarily as a topical rather than a systemic agent. The first silver salt used clinically was a topical solution of 0.5% silver nitrate, which represented the lowest concentration at which antibacterial action was obtained with no toxic effects on growing epidermal cells (Klasen, 2000).

Silver sulphadiazine cream was developed in the 1960s and is still used today. It has been widely accepted as a treatment for burns and chronic wounds; however, it requires frequent applications to maintain its antimicrobial control.

More recently, Acticoat, a new unique nanocrystalline silver dressing, has been developed allowing sustained release of silver over a prolonged period thereby reducing frequency of dressing changes required. Silver dressings are increasingly tailored as broad-spectrum antimicrobials and barriers to infection. They are designed to handle wound exudate, offensive odours and patient discomfort commonly associated with severe surgical wounds, graft and donor reactions, and chronic or delayed wounds including leg ulcers and diabetic foot wounds (White, 2001). Such dressings provide a highly commendable antimicrobial activity with barrier function against re-infection; their efficacy is closely related to the level of silver released and the duration of action (Lansdown, 2002a).

Research has shown that to be most effective at killing bacteria the silver has to be released to the wound bed at levels in excess of 20 mg/l (ppm) (Burrell, 2003).

## NANOCRYSTALLINE SILVER

Acticoat is a new silver dressing with nanocrystalline silver. Used in a number of wound types, including burns and chronic wounds, the dressing has a silver coating that is a unique physical structure consisting of silver nanocrystals organized in a coarse columnar structure. The extremely small size of the nanocrystals produces a very large surface area for antimicrobial activity. These tiny silver nanocrystals provide rapid yet sustained release of silver to the wound bed at 70 mg/l (ppm) making it a highly effective antimicrobial agent. The dressing core absorbs and retains moisture, thus helping to maintain a moist environment at the wound/dressing interface (Figure 1).

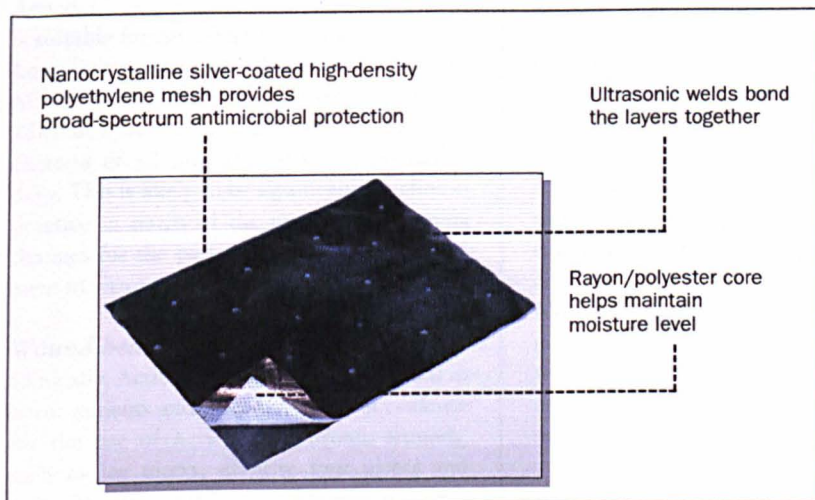
Acticoat has been evaluated in vitro where it was found to have minimal toxicity to mammalian tissue and prolonged sustained release of silver in an aqueous environment (Burrell et al, 1999). The antimicrobial barrier properties of nanocrystalline silver have been evaluated against a broad range of clinically relevant test organisms (Smith & Nephew, 2001a). In vitro data demonstrate that nanocrystalline silver effectively inhibits more than 150 organisms including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE), which represents a broad spectrum of bacteria (Smith & Nephew, 2001a).

## Antimicrobial properties

The antimicrobial barrier properties of Acticoat have been compared with two conventional topical antimicrobials containing silver, commonly used in wound care management: silver nitrate and silver sulphadiazine (Wright et al, 1998). All agents were tested against five clinically significant bacteria: *S. aureus*, *S. epidermidis*, *Escherichia coli*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*, in vitro. The results showed that Acticoat had the fastest rate of killing against all five bacteria tested. In most cases bacterial survival was below the level of detection after 30 minutes post-inoculation, while generally more than 2 hours was required for silver nitrate and silver sulphadiazine to reduce bacterial numbers to the same level.

Antibiotic-resistant bacteria, such as MRSA and VRE, represent an increasing concern in wound infection. An in vitro study compared the antimicrobial barrier properties of Acticoat with silver nitrate and silver

**Figure 1. Structure of Acticoat, the new silver dressing with nanocrystalline silver.**





sulphadiazine in logarithmic survival tests against 11 isolates of antibiotic-resistant bacteria (Smith & Nephew, 2001b). The results demonstrated that after 30 minutes the use of Acticoat resulted in bacteria being below the level of detection in all but one case.

In vitro studies comparing Acticoat to Arglaes demonstrated that Acticoat dressing maintained larger zones of inhibition, which provides a measure of the ability of a dressing to release antimicrobial agents from within its structures, against *P. aeruginosa* and *S. aureus* than Arglaes and had a longer lasting antimicrobial effect (Yin et al, 1999). Part of the explanation for the longevity and rapid action of the dressing is related to the equilibrium-driven release of silver ions from the dressing, i.e. as silver levels drop the dressing releases more silver to the wound bed (Thomas and McCubbin, 2003).

Burrell et al (1999) demonstrated that the dressing attains and maintains a silver concentration of 70–100 mg/l (ppm) in water, higher than many of the other available silver dressings. Thomas and McCubbin (2003) compared the antimicrobial activity in vitro of four silver-containing dressings — Acticoat (Smith & Nephew), Actisorb Silver 220 (Johnson & Johnson), Avance (SSL International) and Contreet-H (Coloplast) — some of which are available in the community setting on FP10.

The study concluded that Acticoat was more likely to produce the most rapid antimicrobial effect in vivo because of the rapid release of relatively large concentrations of highly active silver ions. Acticoat releases silver over a sustained period of 3 days and Acticoat 7 over 7 days, which means the latter is suitable for use under compression therapy. Long-term evaluation of Acticoat 7 against MRSA found that the Acticoat 7 dressing killed at least 99.9% of the antibiotic-resistant bacteria at all time intervals of 3, 5 and 7 days. This is likely to be significant for clinical practice in terms of the number of dressing changes for the patient and the cost of treatment in terms of dressings and clinicians' time.

### Wound healing

Clinically, Acticoat has been well evaluated in burns patients and there is increasing evidence for the use of Acticoat in chronic wounds, such as leg ulcers, diabetic foot ulcers and pressure ulcers (Sibbald et al, 2001). Tredget

et al (1998) described a randomized prospective clinical study involving 30 patients, each of whom had two burns comparable in size, depth and location. The wounds in each pair were treated with Acticoat or a fine mesh gauze soaked in 0.5% silver nitrate solution and remoistened every 2 hours. Frequency of burn wound sepsis was found to be less in wounds treated with Acticoat than in those treated with silver nitrate. Secondary bacteraemias arising from infected wounds were less frequent with Acticoat. The healing rates of the wounds were comparable.

The use of Acticoat as a dressing for donor sites has been investigated in a porcine model, where it was compared with petrolatum gauze (Olson et al, 2000), and in humans where it was compared with Allevyn (Smith & Nephew), an absorbent polyurethane foam (Innes et al, 2001). In the animal study, which involved 72 dermatome wounds, those dressed with Acticoat completely re-epithelialized in 70% of the time taken by wounds dressed with petrolatum gauze. In the human study there were no significant differences in the incidence of positive bacterial cultures between dressings at days 3, 6 and 9. However, the cohort size was small ( $n=15$ ), which could account for this result.

There is growing clinical material and evidence of the effective use of Acticoat dressings in chronic wounds. Sibbald et al (2001) conducted an uncontrolled prospective study to evaluate the use of Acticoat on a variety of chronic non-healing wounds, including diabetic foot ulcers, venous stasis ulcers and pressure ulcers in 29 patients. All patients showed a decrease in exudate levels and a reduction in the size of the wound at 2, 4 and 6 weeks. Semi-quantitative swabs in the study indicated a decrease in flora on the surface of the wound when using Acticoat. In a number of patients a dramatic decrease in pain was noted.

The study concluded that Acticoat has a beneficial effect of protecting the wound site from bacterial contamination. No emergence of resistance to MRSA was seen and there were no significant side-effects. Microbiologically, the bacterial load was determined via quantitative biopsies and semi-quantitative swabs. It successfully reduced the quantity of exudate, decreased abnormal granulation and in some patients greatly reduced their pain.

Acticoat's mode of action may include an anti-inflammatory effect whereby it not only

There is growing clinical material and evidence of the effective use of Acticoat dressings in chronic wounds...an uncontrolled prospective study [evaluated] the use of Acticoat on a variety of chronic non-healing wounds, including diabetic foot ulcers, venous stasis ulcers and pressure ulcers in 29 patients. All patients showed a decrease in exudate levels and a reduction in the size of the wound at 2, 4 and 6 weeks.



There is...growing evidence in the form of individual case studies on the use of Acticoat in chronic wounds...While it is hard to generalize from case studies, they do make a valuable contribution to the evidence base and are particularly good in terms of the "patient's story". A variety of case studies...showed improved healing rates, reduced wound exudate and reduced pain with the use of Acticoat dressing.

decreases matrix metalloproteinase (MMP) (which destroy or corrupt newly formed matrix) by removing the cause (bacteria), but may also actively suppress MMP levels as well (Mozingo et al, 2003).



**Figure 2.** Sloughy infected pressure ulcer on the hip.



**Figure 3.** Post-treatment with Acticoat and foam dressing. Complete healing in 5 weeks.



**Figure 4.** Infected venous leg ulcer.



**Figure 5.** Post-treatment with Acticoat and systemic antibiotics.

Mozingo et al (2003) conducted a pilot prospective clinical assessment of the impact of Acticoat on cytokines (growth factors) and MMPs in non-healing wounds. Ten patients with non-healing venous ulcers were randomly assigned to treatment with Acticoat or standard wound treatment. The results concluded that Acticoat dressing influenced the molecular composition of the wound, suppressing MMPs and tumour necrosis factor alpha (TNF-alpha) levels (pro-inflammatory cytokines) over the treatment period. This may further accelerate healing in previously static wounds. The study recommends further research in this area.

There is also growing evidence in the form of individual case studies on the use of Acticoat in chronic wounds totalling in excess of 20 case histories (Smith & Nephew, data on file). While it is hard to generalize from case studies, they do make a valuable contribution to the evidence base and are particularly good in terms of the 'patient's story'. A variety of case studies on file at Smith & Nephew were reviewed. All showed improved healing rates, reduced wound exudate and reduced pain with the use of Acticoat dressing. Most of the wounds were extremely challenging, which is often the case when using new products.

Some examples include:

- A patient treated at home with Acticoat for a non-healing leg ulcer complicated by diabetes. The ulcer had been present for over 2 months and healed in just 4 weeks with the use of Acticoat and foam.
- Acticoat used in an infected open thigh stump, again in a patient with diabetes, which was potentially life threatening. Systemic antibiotics were discontinued and Acticoat was introduced with a cavity dressing. The wound healed in 7 weeks.
- Acticoat and a foam were used in a grade 3 pressure ulcer on the hip, which had been present for 5 months. The wound was sloughy, infected and painful (Figure 2). Full healing was achieved in 5 weeks (Figure 3).
- Acticoat 7 was used in a diabetic foot ulcer which had been present for 1 year and measured 6 cm x 7 cm and 1 cm deep. The wound was infected and painful for the patient. Sharp debridement was used, along with a secondary foam dressing and pressure relief. There was a significant reduction in the wound size to 0.8 cm x 3.7 cm and 0.2 cm deep in



4 weeks. The patient also reported a significant reduction in pain.

- One case study combined Acticoat 7 with Intrasite Gel (Smith & Nephew), a hydrogel, to treat an infected non-healing venous leg ulcer (Figure 4). There was a significant reduction in ulcer size in just 2 weeks (Figure 5).

The case studies do not mention any adverse effects; however, some patients do experience stinging in the first few hours after dressing application. However, this is transient and will disappear on subsequent dressing applications. The patients in the case studies are typical of the types of patients with chronic wounds cared for in the community. Traditionally, patients were admitted to hospital if their ulcer was not healing or became infected, but this no longer needs to be the case. Many regions now have specialist community leg ulcer clinics and multidisciplinary diabetic foot clinics. The availability of advanced wound care products such as Acticoat and Acticoat 7 makes a valuable contribution to caring for patients in their own home environment and also avoids the use of repeat prescriptions for antibiotics.

The author's own experience of using Acticoat was confined to two patients, as it was not available on the Drug Tariff. Both of these patients had infected venous leg ulcers and had already been prescribed broad-spectrum antibiotics by their GP without effect. Acticoat 7 made a significant impact to the wound in both patients in terms of reducing inflammation, exudate levels and pain. Unfortunately, many primary care trusts do not have budgets to buy in these advanced products, thus limiting availability and disadvantaging patients. This is no longer an issue as Acticoat and Acticoat 7 were listed on the Drug Tariff on 1 August 2003.

## CONCLUSION

The nanocrystalline silver of Acticoat and Acticoat 7 is a unique form of silver that carries distinct properties that differentiate it from other more traditional silver dressings. Its use has been well evaluated in vitro and in vivo as outlined in this review. Further research such as a randomized controlled trial (RCT) would add great value to the available data.

An outcome tracking evaluation is complete on 50 patients using Acticoat and there are currently two RCTs underway comparing Acticoat

to other silver dressings. The available evidence was significant enough to warrant immediate availability of Acticoat and Acticoat 7 on the Drug Tariff from 1 August 2003 in a number of sizes: Acticoat in 10 x 10 cm and 10 x 20 cm; Acticoat 7 in 10 x 12.5 cm and 15 x 15 cm. This will widen the scope in terms of involving community patients in future research. **BJN**

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## KEY POINTS

- Silver is an effective broad-spectrum antimicrobial agent.
- Acticoat is a new silver dressing with nanocrystalline silver.
- The efficacy of silver dressings is closely related to the level of silver released and the duration of action.
- Acticoat releases appropriate levels of silver 70 ppm over a sustained period of 3 days or 7 days with Acticoat 7.
- Acticoat has been well evaluated in burns patients and there is increasing evidence for the use of Acticoat in chronic wounds such as leg ulcers, diabetic foot ulcers and pressure ulcers.



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# The use of silver-based dressings in wound care

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## summary

Chronic wounds such as leg ulcers and pressure ulcers are often slow to heal. One of the causes of delayed wound healing is the presence of micro-organisms in the wound. A strategy for the prevention and treatment of wound colonisation or infection, which is receiving renewed attention, is the use of silver-based dressings. Silver has been used as an antimicrobial agent for centuries. It is effective against a broad range of bacteria (including methicillin and vancomycin-resistant strains), yeast, fungi and viruses. A number of new silver-based dressings, some of which act by the sustained release of silver ions to the wound bed, have recently become available, but there are wide variations in the amount of data supporting the use of individual products. This article reviews the evidence base for silver-containing dressings to help practitioners select the most appropriate product for the type of wound being treated.

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## keywords

- Dressings
- Infection control
- Silver
- Wounds

These key words are based on subject headings from the British Nursing Index. This article has been subject to double-blind review.

MOST PEOPLE think of wound repair as an ordered set of events that proceeds quickly with few complications. Typically, the steps in the wound repair process include inflammation around the site of injury, angiogenesis and the development of granulation tissue, repair of the connective tissue and epithelium, and ultimately remodelling that leads to a healed wound (Schultz *et al* 2003).

However, this acute wound healing model does not apply well to chronic wounds. Many chronic wounds, such as leg ulcers and pressure ulcers, take months and sometimes years to heal, becoming stuck in the inflammatory and proliferative phases of wound healing (Ennis and Meneses 2000). There also appears to be an over-production of extracellular matrix molecules, which result from cellular dysfunction and dysregulation in the wound (Schultz *et al* 2003). Although there may be abundant growth factors in the

wound, these become trapped and are no longer available for the repair process.

Up to 80 per cent of chronic wounds, such as leg ulcers and pressure ulcers, are treated in primary care by community nurses and GPs (Callam *et al* 1985). Treatment of these wounds is costly, both for patients, in terms of reduced quality of life, and financially for healthcare providers. Good patient assessment and treatment of the underlying cause of the wound are essential if local wound care is to be successful. Patient factors, such as poor peripheral perfusion, diabetes, poor nutrition and smoking, as well as local factors at the wound bed such as the presence of necrotic tissue and infection, all delay wound healing (Dealey 2002).

Provision of the optimum wound healing environment is an important determinant of wound closure rate and is founded on the practitioner's ability to select the most appropriate dressing. That selection needs to be based on the most up-to-date evidence. This is an ongoing challenge for practitioners because new and varied dressings become available for use on a regular basis. Recent advances in biotechnology and original research have provided unique opportunities to develop dressings closely tailored to the type of wound to be treated. These dressings are biocompatible and are proving valuable in advancing wound healing in difficult to heal wounds, while alleviating patient discomfort (Lansdown 2004).

Recently a number of new silver dressings have become available for use by practitioners. They are recommended for the prevention and treatment of infection in surgical wounds, burns and chronic wounds such as leg ulcers (Lansdown 2004). However, there appears to be some confusion among practitioners about when to use a particular product and how long it should be used for.

## Wound infection

One of the events that impedes wound healing is micro-organisms colonising the wound bed. In



addition to producing a variety of toxins and proteases, these micro-organisms may also provoke a prolonged inflammatory response. The host inflammatory response is remarkably effective at eliminating the invading microbial population, but over time that same process may damage the surrounding skin (Wright *et al* 1998).

Chronic wounds are often heavily colonised by bacteria and/or fungi. This is partly because chronic wounds remain open for prolonged periods, but other factors, such as poor blood supply, hypoxia and underlying disease processes, also contribute (Hunt and Hopf 1997). The presence of bacteria in chronic wounds does not necessarily indicate that infection has occurred or that it will lead to impaired wound healing (Dow *et al* 1999, Kerstein 1997). Micro-organisms are present in all chronic wounds, and it has been suggested that low levels of certain bacteria can facilitate healing (De Hann *et al* 1974, Pollock 1984). Bacteria produce proteolytic enzymes such as hyaluronidase, which aids wound debridement and stimulates the release of proteases (Stone *et al* 1980).

Novel methods of managing wounds are being developed, partly in response to concerns about bacterial proliferation in moist wound beds and the rapid and steady increase in the number of antibiotic-resistant bacteria. One strategy for preventing and treating wound infection gaining renewed attention is the use of noble metal antimicrobial agents. The most prevalent noble metal being used in dressings to combat bacterial infection is silver.

## Silver

Silver has been used for medicinal purposes for several thousand years (Goodman and Gilman 1975). It is widely recognised as an effective broad-spectrum antimicrobial agent (Burrell *et al* 1999, Thomas and McCubbin 2003a). It is effective against a broad range of aerobic, anaerobic, Gram-negative and Gram-positive bacteria, yeast, filamentous fungi and viruses (Lansdown 2002). Silver has also been shown to be effective against methicillin and vancomycin-resistant strains of bacteria, and no resistant strains have been encountered (Lansdown 2002). As well as having broad antimicrobial activity, silver also appears to have anti-inflammatory properties (Demling and DeSanti 2001).

In the early twentieth century, silver proteins and colloidal silver preparations became popular as antimicrobials. In contrast to other antimicrobial agents, silver was highly effective for the treatment of mucous membrane infection, with little resistance found. However, the antimicrobial potency was closely related to the amount and rate of silver released (Lansdown 2002). The first silver salt used clinically was a topical solution of 0.5% silver nitrate, which represented the lowest concentration showing antibacterial action with no toxic effects on growing epidermal cells (Klasen 2000). Silver sulfadiazine cream was developed in the 1960s and is still used today. It has been widely accepted as a treatment for burns

and chronic wounds; however, frequent applications are required to maintain antimicrobial control (Dowsett 2003).

Silver is an inert metal and does not react with human tissues in its non-ionised form. In the presence of moisture, such as wound exudate, silver readily ionises to release silver ions ( $\text{Ag}^+$ ) or other biologically active ions, which bind with proteins on cell surfaces, including those of bacteria and fungi. Silver is present in wound dressings in a variety of forms, which vary in their capacity to liberate silver ions.

## Silver-based dressings

A variety of topical silver-based preparations have been evaluated on chronic wounds in controlled trials with favourable results (O'Meara *et al* 2000, 2001). More recently, a number of silver-based dressings have become available, including Acticoat®, Aquacel® Ag, Contreet®, Actisorb® Silver 220, Urgotul SSD® and Avance®.

**Acticoat®** is a low-adherent primary wound dressing, consisting of two layers of high-density polyethylene mesh coated with nanocrystalline silver, with a rayon-polyester core. The nanocrystals provide rapid yet sustained release of silver to the wound bed at 70mg/l (ppm), making it a highly effective antimicrobial agent. The dressing core absorbs and retains moisture, thereby helping to maintain a moist environment at the wound and dressing interface. It has been shown to be effective in inhibiting the growth of more than 150 organisms, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE) (Smith and Nephew 2001). Acticoat® is designed to stay in place for up to three days and Acticoat® 7 for seven days. The dressing is activated by moistening with water (sterile or tap) – the use of saline should be avoided because it deactivates the silver.

**Aquacel® Ag** is an absorbent antimicrobial dressing composed of Hydrofiber® impregnated with ionic silver. It is presented as a soft sterile, non-woven pad or ribbon. The dressing absorbs large amounts of wound fluid and bacteria to form a soft, cohesive gel that intimately conforms to the wound surface and maintains a moist environment, aiding autolytic debridement. It has been shown to provide broad-spectrum activity against a variety of micro-organisms, including antibiotic-resistant bacteria. Aquacel® Ag can be used on chronic wounds for up to seven days (ConvaTec 2004).

**Contreet®** is a polyurethane foam dressing containing antibacterial ionic silver complex dispersed homogeneously throughout the foam. Silver is released from the dressing into the wound bed when in contact with wound exudate. Contreet® foam dressing is effective against certain bacterial strains known to be detrimental to wound healing such as *Pseudomonas aeruginosa* and *S. aureus*, beta-haemolytic streptococcus, MRSA and VRE. Depending on the amount of exudate, the release of silver will continue for up to seven days or for the life of the dressing (Coloplast 2003).



**Actisorb® Silver 220** consists principally of activated carbon impregnated with metallic silver. The carbonised fabric is enclosed in a sleeve of spun-bonded, non-woven nylon, sealed along four edges. The dressing has an antibacterial action, with a broad spectrum of activity against bacteria and fungi (Russell and Hugo 1994), and reduces malodour by eliminating the bacteria that give rise to the problem, and absorption of the volatile amines and fatty acids responsible for the production of wound odour onto the activated charcoal layer. Actisorb® Silver 220 can remain in place for up to seven days, depending on the level of exudate, while the secondary dressing is changed as required. Initially, it may be necessary to change the Actisorb® Silver 220 dressing every 24 hours. The dressing should not be cut (Johnson and Johnson 2001).

**Urgotul SSD®** is a non-adhesive, non-occlusive hydrocolloid dressing, consisting of a polyester web impregnated with hydrocolloid particles (carboxymethylcellulose), Vaseline® and silver sulfadiazine. It is indicated for the local treatment of superficial or deep second-degree burns where there is a risk of infection. The presence of silver sulfadiazine, an antibacterial agent, confers on the Urgotul SSD® dressing the ability to act on the micro-organisms most frequently responsible for infecting wounds. Silver sulfadiazine has a wide spectrum of antimicrobial activity, covering the Gram-positive and Gram-negative bacteria and certain moulds and yeasts (Urgo 2003).

**Avance®** is an absorbent polyurethane foam dressing containing a silver complex. According to the manufacturer, Avance® decontaminates the exudate absorbed into the polyurethane foam, and can therefore be used to prevent cross and self-infection. Clinical data on the use of the dressing are limited.

#### Evidence to support use of silver-based dressings

There are wide variations in the

amount of *in vitro* and *in vivo* data available to support the use of these dressings. Evidence from *in vitro* studies needs to be balanced against clinical data (from prospective trials, outcome tracking and case studies, for example) and combined with expert opinion when making a decision about which product to use. Box 1 offers a checklist of what to consider when choosing a silver-based dressing.

Thomas and McCubbin (2003a) compared the antimicrobial effects of four silver-based dressings – Acticoat®, Actisorb® Silver 220, Avance® and Contreet® – on three micro-organisms in laboratory tests. The results showed that Acticoat® was likely to produce the most rapid antimicrobial effect *in vivo* because of the rapid release of relatively large concentrations of highly active silver ions. Contreet® had a broadly similar antimicrobial activity to Acticoat®, but a slower onset of action. Actisorb® Silver 220 appeared to offer fewer prospects of killing bacteria in the wound, but was capable of removing micro-organisms from wound exudate and sequestering them until they were inactivated by the silver in the charcoal fibres. Little convincing evidence of any antimicrobial activity for Avance® was found.

A further analysis by Thomas and McCubbin (2003b) of ten silver-containing dressings concluded that while the total amount of silver present in a dressing influenced its antimicrobial activity, the distribution of silver in the dressing (surface coating or dispersed through the structure), its chemical and physical form (metallic, bound or ionic state) and the dressing's affinity for moisture – a prerequisite for the release of active agents in an aqueous environment – all influenced a dressing's ability to kill micro-organisms. Products in which the silver content is concentrated on the dressing surface rather than 'locked' in its structure performed well, as did those in which silver was present in the ionic form. Although these results may be useful to clinicians, it is important to remember they are from laboratory-based studies, but in the clinical situation there are other factors that will determine a dressing's acceptability and clinical effectiveness.

Sustained silver-release dressings are mostly well tolerated without serious side effects (Karlsmark et al 2003, Lansdown 2004). The most common response seen to silver is argyria – grey colour of skin and conjunctiva – which results from the deposition of minute granules of silver sulphide in the dermis around the basement membrane and sweat ducts. These are easily removed from the skin with gentle cleansing.

Concerns have also been expressed about inducing bacterial resistance to silver. The available evidence suggests that most, if not all, of the sustained-release silver ion-containing dressings are effective against methicillin and vancomycin-resistant strains of bacteria, and that no resistant strains have been encountered. Li et al (1997) suggested that resistance could be induced when low concentrations of silver were used. This emphasises the importance of using products

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#### Box 1. Choosing a silver-based dressing

##### Indications

- Critically colonised wounds
- Infected wounds
- Delayed healing, which may suggest infection or critical colonisation
- Burn wounds

##### Guidance

- What is the evidence for the use of the dressing?
- Is it suitable for the type of wound?
- Is the wound critically colonised or infected?
- Does the dressing fulfil the objective of treatment?
- What is the patient's preference?
- Is the dressing cost-effective?



# TIME principles of chronic wound bed preparation and treatment

Caroline Dowsett, Elizabeth Ayello

## Abstract

Managing chronic wounds has progressed from merely assessing the wound to understanding the underlying cellular abnormalities and associated clinical problems. The concept of wound bed preparation offers a systematic approach to removing barriers to healing such as tissue (non-viable), infection/inflammation, moisture (imbalance) and edge (non-advancing or undermining). The principles of wound bed preparation as outlined in the tissue, infection, moisture, edge (TIME) table are explained in this article, with examples and recommended treatment interventions. The TIME table is recommended for use at the bedside when assessing patients with wounds.

**Key words:** Wounds ■ Clinical procedures

Wound bed preparation is a relatively new concept in wound care, although the elements that make up the concept are not. This article provides an overview of the concept as it relates to practice and introduces the principles of Tissue, Infection, Moisture, Edge (TIME). Wound bed preparation is the management of a wound to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures (Falanga, 2000; Schultz et al, 2003). Wound bed preparation allows healthcare professionals to define the steps involved in the management of chronic wounds through an understanding of the basic science underlying the problems. It is an approach that should be considered for all wounds that are not progressing to normal healing (Schultz et al, 2003).

Wound healing is a complex series of events that are interlinked and dependent on one another and can be defined as the physiological processes by which the body replaces and restores function to damaged tissue (Tortora and Grabowski, 2000). Acute wounds usually follow a well-defined process described as: coagulation; inflammation; cell proliferation and repair of the matrix; and epithelialization and remodelling of scar tissue (Schultz et al, 2003). These stages overlap and the entire wound-healing process can take several months.

In the past, the acute wound-healing model has been applied to chronic wounds, but it is now known that chronic wound

healing is different from acute wound healing. Chronic wounds become 'stuck' in the inflammatory and proliferative phases of healing (Ennis and Meneses, 2000) which delays healing. The epidermis fails to migrate across the wound tissue and there is hyperproliferation at the wound margins which interferes with normal cellular migration over the wound bed (Schultz et al, 2003).

In chronic wounds there appears to be an over production of matrix molecules resulting from underlying cellular dysfunction and dysregulation (Falanga et al, 1994). Fibrinogen and fibrin are also common in chronic wounds and it is thought that these and other macromolecules scavenge growth factors and other molecules involved in promoting wound repair (Falanga, 2000). So, while there may be a large number of growth factors within the wound, these can become trapped and therefore unavailable to the wound-



Figure 1. A necrotic wound.

repair process. Chronic wound fluid is also biochemically distinct from acute wound fluid; it slows down, or even blocks the proliferation of cells, such as keratinocytes, fibroblasts and endothelial cells, which are essential for the wound-healing process (Schultz et al, 2003).

## The principles of wound bed preparation

In a wound that fails to heal there is often a complex mix of local and host factors which need to be assessed and treated. A full and detailed patient assessment will highlight the underlying aetiology of the wound and other factors that may impede healing such as poor nutrition and pain (Dealey, 2002). The underlying cause will need to be addressed if wound bed preparation is to be successful. Wound bed preparation is a way of focusing systematically on all of the critical components of a non-healing wound to identify the possible cause of the problem. It is a concept that links treatment to the cause of the

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Table 1. The TIME principles of wound bed preparation (WBP)

CLINICAL OBSERVATIONS	PROPOSED PATHOPHYSIOLOGY	WBP CLINICAL ACTIONS	EFFECT OF WBP ACTIONS	CLINICAL OUTCOME
<b>TISSUE NON-VIABLE OR DEFICIENT</b>	Defective matrix and cell debris impair healing	Debridement (episodic or continuous) autolytic, sharp surgical, enzymatic, mechanical biological agents	Restoration of wound base and functional extracellular matrix proteins	Viable wound base
<b>INFECTION OR INFLAMMATION</b>	High bacterial counts or prolonged inflammation ↑ inflammatory cytokines ↑ protease activity ↓ growth factor activity	Remove infected foci Topical/systemic antimicrobials anti-inflammatories protease inhibition	Low bacterial counts or controlled inflammation: ↓ inflammatory cytokines ↓ protease activity ↑ growth factor activity	Bacterial balance and reduced inflammation
<b>MOISTURE IMBALANCE</b>	Desiccation slows epithelial cell migration  Excessive fluid causes maceration of wound margin	Apply moisture-balancing dressings  Compression, negative pressure or other methods of removing fluid	Restored epithelial cell migration, desiccation avoided Oedema, excessive fluid controlled, maceration avoided	Moisture balance
<b>EDGE OF WOUND NON ADVANCING OR UNDERMINED</b>	Non-migrating keratinocytes  Non-responsive wound cells and abnormalities in extracellular matrix or abnormal protease activity	Reassess cause or consider corrective therapies debridement skin grafts biological agents adjunctive therapies	Migrating keratinocytes and responsive wound cells. Restoration of appropriate protease profile	Advancing edge of wound

Source: Schultz et al (2003)

wound by focusing on the components of local wound care (Sibbald et al, 2000): debridement; bacterial balance; and moisture balance.

The TIME table (Table 1) illustrates in a simple way the link between clinical observations and underlying cellular abnormalities, and the effects of clinical interventions at a cellular level. A useful way of remembering the process of wound bed preparation is to use the acronym shown in this table, based on the observable characteristics of non-healing wounds (Schultz et al, 2003):

- T — for tissue which is non-viable or deficient
- I — for infection/inflammation
- M — for moisture imbalance, which must be corrected
- E — for edge, which is not advancing across the wound bed.

This table has been designed to help the wound care practitioner make a systematic interpretation of the observable characteristics of a wound and to decide on the most appropriate intervention. The first column lists the clinical signs of a non-healing wound. As growth factors, senescent cells or fibroblasts cannot be seen with the naked eye; the clinician needs clear, visible signs that can be assessed at the bedside. The second column highlights the proposed pathophysiology of that clinical observation. Column three and four suggest the clinical actions that need to be taken and the effects of these actions. The final column is for clinical outcomes, which are objective and measurable.

### T for tissue: dealing with non-viable tissue

Non-viable tissue, such as slough or necrosis, delays wound healing and is a focus for infection. The clinician needs to assess the wound and intervene using the TIME table:

- Clinical sign or symptom: non-viable, deficient tissue
- Underlying problem: impedes actions of growth factors; blocks cellular migration; provides a focus for continued infection and inflammation
- Intervention: debridement, repeated if necessary.

There are two important factors in considering tissue as a key element of wound bed preparation:

- To promote the growth of healthy tissue
- To clear away necrotic or non-viable tissue from the wound bed.

For the promotion of healthy tissue growth a well vascularized wound bed is essential (Schultz et al, 2003). Often this means both treatment of the wound bed and a consideration of the overall factors that have compromised the blood supply to the wound. It is also essential to clear away the non-viable tissue which is preventing good tissue growth (Steed et al, 1996).

Devascularized, necrotic tissue (Figure 1) provides a focus for infection, prolongs the inflammatory phase, mechanically obstructs contraction and impedes re-epithelialization (Baharestani, 1999). It may also mask underlying fluid collections or abscesses and make it difficult to evaluate wound depth. If the wound clearly contains non-viable or deficient tissue a method of removing it should be considered, in order



to promote healing and reduce the risk of local infection (Vowden and Vowden, 1999; Fairbairn et al, 2002). This process is usually referred to as debridement, which is widely used to leave a clean surface which will heal relatively easily. Chronic wounds are likely to require ongoing maintenance debridement rather than a single intervention (Falanga, 2002). The underlying pathogenic abnormalities in chronic wounds cause a continual build-up of necrotic tissue, and regular debridement may be necessary to reduce the necrotic burden and achieve healthy granulation tissue. Debridement also reduces wound contamination and therefore reduces tissue destruction (Sibbald et al, 2000)

In the early stages of wound healing, debridement occurs autolytically through the action of enzymes (including elastase, collagenase, myeloperoxidase, acid hydrolase and lysosomes). At the same time, inhibitors are released by wound cells to restrict the debridement action to the wound bed, minimizing damage to intact tissue at the wound edge (Schultz et al, 2003). Debridement using surgical, enzymatic, autolytic or mechanical methods is often all that is required to promote the first step in the healing process. Although debridement occurs naturally, assisted debridement accelerates the wound-healing process (Sibbald et al, 2000).

Five methods of debridement are available, each with their own advantages and limitations (O'Brien, 2002). The methods that are most efficient at removal of debris may, at the same time, be the most detrimental to fragile new growth and more than one method may be appropriate. The five methods are autolytic, surgical/sharp, enzymatic, mechanical and biological. The chosen method of debridement will depend on the patient characteristics and preferences, the knowledge and skills of the clinician and the resources available. Table 2 highlights the clinical considerations. The

**Table 2. Clinical considerations when choosing a method of debridement**

Wound
Aetiology; location; extent of tissue damage; type of tissue involvement; size and extent of devitalized tissue; amount of exudate production
Practical considerations
Clinical expertise and professional accountability; availability of resources; time available; cost-effectiveness; patients' wishes
Source: Flanagan (1997)

method/methods of debridement used should be evidence-based and evaluated in terms of their effectiveness. Specialist advice should be sought from the tissue viability specialist or wound care specialist where the wound is failing to debride with the chosen method, or when the clinician lacks the knowledge and skills to carry out the chosen method of debridement.

### **I or infection: resolution of bacterial imbalance**

Infection in a wound causes pain and discomfort for the patient — delayed wound healing can be life-threatening. The clinician needs to assess for clinical signs and symptoms of infection and intervene using the TIME table:

- Clinical sign or symptom (outlined in Table 3)
- Underlying problem: infection caused by high levels of bacteria
- Intervention: debridement, antimicrobials, anti-inflammatories.

All chronic wounds contain bacteria, and their presence in a wound does not necessarily indicate that infection has occurred or that wound healing will be impaired (Kerstein, 1997; Dow et al, 1999). However, where infection is present in a wound, as shown in Figure 2, it delays wound



healing through the maintenance of a proinflammatory environment (Schultz et al, 2003). The signs and symptoms of superficial and deep tissue infection are outlined in Table 3.

When a wound is infected it contains replicating micro-organisms which cause injury to the host. In an acute wound, *infection is met by a rapid inflammatory response* which is initiated by the release of cytokines and growth factors (Dow et al, 1999). The inflammatory cascade produces vasodilation and a significant increase of blood flow to the injured area. This also facilitates the removal of micro-organisms, foreign debris, bacterial toxins and enzymes by phagocytic cells, complement and antibodies. The coagulation cascade is activated which isolates the site of infection in a gel-like matrix to protect the host (Dow et al, 1999).



Figure 2. Infected wound.

In a chronic wound, however, the continuous presence of virulent micro-organisms leads to a continued inflammatory response which eventually contributes to host injury. There is persistent production of inflammatory mediators and steady migration of neutrophils which release cytolytic enzymes and oxygen-free radicals. There is localized thrombosis and the release of vasoconstricting metabolites which can lead to tissue hypoxia, bringing about further bacterial proliferation and tissue destruction (Dow et al, 1999).

The presence of bacteria in a chronic wound does not necessarily indicate that infection has occurred or that it will lead to the impairment of wound healing (Cooper and Lawrence, 1996). Micro-organisms are present in all chronic wounds and low levels of certain bacteria can actually facilitate healing (De Haan et al, 1974). Bacteria produce proteolytic enzymes, such as hyaluronidase, which contribute to wound debridement and stimulate neutrophils to release proteases (Stone, 1980).

### Bacterial burden

Infection is generally associated with >105 colony-forming organisms of bacteria per gram of tissue (Gardner et al, 2001). A semiquantitative swab technique is a practical and simple measure for routine assessment of bacterial burden. There remains controversy over the exact technique for taking a wound swab. It is generally recommended that the wound bed be irrigated with saline to remove superficial colonizers, followed by debridement (Sibbald et al, 2003). A dry swab can then be rolled across the exposed bed (Schultz et al, 2003). The swab is inoculated onto solid media and streaked into four quadrants. A rate of 4+ growth or growth in the fourth quadrant (>30 colonies) corresponds to approximately 105 or greater organisms per gram of tissue as measured by quantitative biopsy. This technique samples a large area of the wound surface but may also lead to an increased number of false-positive results (Schultz et al, 2003).

**Table 3. Signs and symptoms of superficial and deep tissue infection**

Superficial	Non-healing; friable granulation; exuberant bright red granulation; increased exudate or discharge; new areas of necrosis in base; <i>breakdown of granulation tissue; odour</i>
Deep	Pain — other than usually reported; increased size; warmth (abnormal/elevated temperature); erythema >1–2 cm; probes to bone or bone exposed

Source: Sibbald et al (2000)

Bacterial involvement in wounds can be divided into four levels, as listed in Table 4.

In cases of critical colonization, levels of bacteria are below those required for outright infection. However, the bacteria are responsible for delaying healing through the release of pro-inflammatory mediators. Clinically, this can first be detected when the wound margins fail to change. An increased serous exudate may be accompanied by friable, often exuberant, bright red granulation tissue. Bacteria can stimulate angiogenesis, leading to increased vascularity, an

**Table 4. Bacterial involvement in wounds**

- Wound contamination: the presence of non-replicating micro-organisms, such as soil organisms, in the wound
- Wound colonization: the presence of replicating micro-organisms which are not causing injury to the host. This includes skin commensals, such as *Staphylococcus epidermidis* and *Corynebacterium* spp., which in most circumstances have been shown to increase the rate of wound healing
- Critical colonization: bacteria cause a delay in wound healing without frank infection
- Wound infection

Source: Schultz et al (2003)

abnormal bright red colour and a friable corrupt matrix. When a dressing is removed, the wound surface may bleed easily. An unpleasant or putrid odour may also be accompanied by new areas of necrosis or breakdown in the wound base (Sibbald et al, 2000).

### Treatment for infection/inflammation

Treatment should first of all focus on optimizing host resistance, and underlying conditions which reduce immunity should be addressed. Systemic antibiotics are not necessarily the most appropriate way of reducing bacterial burden in wounds, particularly because of the threat of increasing bacterial resistance and should be used where infection cannot be managed with local therapy (Schultz et al, 2003). Other methods may be more suitable and should be considered first: debridement to remove devitalized tissue; wound cleaning; and use of topical antimicrobials, e.g. silver dressings.

There is renewed interest in the selective use of topical antimicrobials as bacteria become more resistant to antibiotics.



Studies show that some iodine and silver preparations have bacteriocidal effects even against multi-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) (Lawrence, 1998; Sibbald et al, 2001).

### Systemic antibiotic therapy

This should be used in all chronic wounds where there is active infection beyond the level that can be managed with local wound therapy (Sibbald et al, 2003). Systemic signs of infection such as fever, life-threatening infection, cellulitis extending at least 1cm beyond the wound margin and underlying deep structure infections indicate the use of systemic therapy. Most infected wounds can be treated with

**Table 5. Selecting an appropriate dressing to achieve local moisture balance**

- Maintains a moist wound environment
- Absorbs excess wound exudates
- Keeps the surrounding skin dry
- Does not require frequent dressing changes
- Decreases the risk of infection by maintaining a seal with the wound
- Is comfortable and acceptable to the patient

Adapted from Schultz et al (2003)



Figure 3. Excessive exudate.

occlusive dressings if there are no signs of exudative infection, and if the wound is largely confined to the level of the dermis. However, infected, exudative wounds do not respond well to the use of occlusive dressings and can lead to rapid wound deterioration. In these cases, it is more appropriate to follow debridement with calcium alginate dressings, foams and hydrofibres (Schultz et al, 2003).

### M for moisture: restoring moisture balance

Moisture balance needs to be restored at the wound bed to prevent desiccation and maceration. The clinician needs to assess the wound and intervene using the TIME table:

- Clinical sign or symptom: desiccation or excess fluid
- Underlying problem: desiccation slows epithelial migration while excess fluid causes maceration, and promotes a hostile biochemical environment which traps growth factors
- Intervention: appropriate dressings, compression therapy, vacuum-assisted closure (VAC).

In acute wounds, a moist wound environment has been shown to accelerate wound healing by up to 50% compared with exposure to air (Winter, 1962). Wounds that are allowed to dry develop a hard crust, and the underlying collagen matrix and surrounding tissue at the wound edge become desiccated. Keratinocytes must burrow beneath the surface of the crust and matrix if re-epithelialization is to occur as they can only migrate over viable nutrient-rich tissue and intact extracellular matrix (Schultz et al, 2003). A moist environment physiologically favours migration and matrix formation, and accelerates healing of wounds by promoting autolytic debridement. A wound that is too moist can cause maceration of the surrounding skin. Successful exudate management is about achieving a balance within a fluid environment (Bishop et al, 2003).

### Wound with excessive moisture

Numerous clinical trials have demonstrated that wounds treated with occlusive dressings are less likely to become infected than wounds treated with conventional dressings, unless the wound is clinically infected (Hutchinson and Lawrence, 1991). Occlusive dressings are relatively impermeable to exogenous bacteria, encourage the accumulation of natural substances in wound fluid which inhibit bacterial growth and reduce the burden of necrotic tissue in the wound.

However, it is now known that chronic wound fluid contains substances detrimental to cell proliferation (Chen et al, 1999), and the build up of chronic wound fluid must be managed to minimize the negative biochemical factors



Figure 4. Abnormal edge.

(Figure 3). Indirect approaches to wound exudate management focus on alleviating the underlying cause. Direct wound exudates management involves the use of compression bandages, highly absorbent dressings or vacuum-based mechanical systems (Ballard and Baxter, 2000). No single dressing matches all the requirements and the choice of wound dressing at one stage of the wound process may well influence subsequent events in the later phases of healing. Today, a number of dressings are available to achieve local moisture balance at the wound bed. A guide to selecting the appropriate dressing can be found in Table 5.

A simple alternative to the use of specialized dressings is to thoroughly clean and irrigate a chronic wound with saline or sterile water which removes exudate and cellular debris, and reduces the bacterial burden of the wound. Indirect methods of reducing exudate should not be forgotten either: wound fluid may be owing to extreme bacterial colonization or may simply involve relief of pressure or elevation of the affected limb.



### E for edge: non-advancing edge or undermining

When the wound edge fails to migrate or undermining is present (Figure 4), the clinician needs to reassess the cause and intervene using the TIME table:

- Clinical sign: abnormal epidermal margin or granulation tissue
- Underlying problem: hypertrophic epithelial margin, senescent or altered granulation cells
- Intervention: reassess status of patient and wound; if wound bed is good, consider advanced therapies.

### Non-advancing wound edge

Chronic or non-healing ulcers fail to re-epithelialize and this is usually accompanied by prolonged inflammation (Hasan et al, 1997; Agren et al, 1999; Cook et al, 2000). The epidermis fails to migrate across the wound and there is hyperproliferation at the wound margins which interferes with normal cellular migration over the wound bed.

Perhaps the clearest sign of all that a wound is failing to heal is where the epidermal edge is failing to advance over time towards closure of the wound as evaluated by the clinician when measuring the wound dimensions. If the margin is undermined, this may be a sign of critical colonization or infection (see earlier), and at a cellular level, lack of epidermal migration could be owing to non-responsive wound cells and abnormalities in protease activity which degrade extracellular matrix (ECM) as soon as it is formed (Falanga, 2000).

The overall health status of a patient has a significant impact on the wound-healing process. A general medical history, including a medication record, is invaluable in identifying causes that may prevent wound healing. Conditions, such as peripheral vascular disease, diabetes, immobility and malnutrition, must be assessed at the beginning of treatment

**Table 6. Conditions and interventions which are known to delay wound healing**

- Use of systemic steroids
- Use of immunosuppressive drugs
- Use of non-steroidal anti-inflammatories
- Rheumatoid arthritis
- Other autoimmune diseases such as systemic lupus, uncontrolled vasculitis or pyoderma gangrenosum
- Inadequate or poor nutrition

Source: Schultz et al (2003)

and corrected as far as possible before local interventions are carried out (Sibbald et al, 2000). If a wound still fails to heal, as demonstrated by a failure to re-epithelialize, it is vital to review these and other factors again and take further intervention if necessary. Conditions and interventions which are known to delay wound healing include those listed in Table 6.

### Assess tissue perfusion

Wound healing can only take place if there is adequate tissue oxygenation. A well-vascularized wound bed provides nutrients and oxygen to sustain newly-formed granulation tissue and to maintain an active immunological response to

microbial invasion. Decreased oxygen levels impair the ability of leucocytes to kill bacteria, lower production of collagen and reduce epithelialization (Schultz et al, 2003).

Wounds of the lower extremities may be particularly affected by poor blood supply. External factors, such as hypothermia, stress or pain, can all increase sympathetic tone and decrease tissue perfusion; smoking reduces microcirculatory flow. In arterial ulcers, macrovascular or microvascular disease leads to tissue ischaemia. A laser Doppler perfusion imaging is a non-invasive method for investigating skin microvasculature (Wardell et al, 1993). If the wound is recurrent, patient education, or treatment of an underlying condition, may be the critical step in bringing about wound healing. The size, depth and colour of the wound base (black, yellow, red) should be recorded by measurement, such as tracing or photography and recording the colour and type of

**Table 7. Wound assessment considerations**

- Check wound margin for callus formation, maceration, oedema or erythema
- Check for hyperkeratotic calluses on the plantar aspect of the foot in patients with neuropathy. The callus should be removed to reduce pressure
- White hyperkeratosis of the surrounding skin or ulcer margin and an overhydrated wound surface suggest excess fluid
- Limb oedema or uncorrected pressure may be causes of local oedema
- Maceration may be a sign of infection
- Warm, hot, tender erythema suggests infection
- Discrete erythema with well demarcated margins indicates contact allergic dermatitis owing to applied dressings or topical treatments

Source: Schultz et al (2003)

tissue in the wound bed. This provides a baseline against which healing can be assessed. The amount and type of exudate (serous, sanguous, purulent) should also be assessed: a heavy exudate may indicate uncontrolled oedema or may be an early sign of infection. The points listed in Table 7 need to be noted.

Continuous pain may be because of an underlying cause, local wound irritation or infection. It is important to assess continuous pain to determine if its origin is in the wound or in the surrounding anatomical region (Sibbald et al, 2000).

### Continued infection

Host resistance is the single most important determinant of wound infection and should be rigorously assessed whenever a

**Table 8. The principles of TIME that should act as a checklist when assessing that interventions have been made**

- Has all necrotic tissue been debrided?
- Is there a well vascularized wound bed?
- Has infection been brought under control?
- Is inflammation under control?
- Has moisture imbalance been corrected?
- What dressings have been applied?

Source: Schultz et al (2003)



chronic wound fails to heal (Dow et al, 1999). Systemic host resistance can be affected by many variables, some of which may be behavioural leading to non-concordance. In such cases, wound management will involve not only treatment of the wound, but also treatment of the underlying disease. The use of cytotoxic agents and corticosteroids can totally mask all signs of local or systemic infection (Schultz et al, 2003).

Host defence mechanisms may be enhanced by a number of methods appropriate to the particular condition of the patient. An infected chronic wound in the presence of critical limb ischaemia may be improved by reconstructive vascular surgery, for example, and bacterial burden may be reduced by measures designed to control blood sugar in the patient with diabetes.

### Advanced techniques

The principles of TIME should be used as a checklist to assess that all appropriate interventions have been made (Table 8).

If this systematic approach produces a well-vascularized healthy wound bed which still fails to heal, it may be that advanced therapies are necessary to 'kick-start' the process of healing. The patient will need to be referred for specialist advice and advanced therapies. The following advanced techniques are all effective if applied to a well-prepared wound bed but can only be carried out by skilled clinicians: autologous skin grafts; grafting using cultured cells/keratinocytes; bioengineered products; allogenic, bilayered tissue; and artificial skin. In addition, a number of growth factors have been developed which are usually supplied in a mesh that is applied to the surface of the wound. Data on the performance of these growth factors have been emerging over the last decade (Schultz et al, 2003):

- Basic fibroblast growth factor (bFGF): stimulates endothelial cell proliferation and migration
- Transforming growth factor $\alpha$  (TGF $\alpha$ ): stimulates the growth of fibroblasts and keratinocytes as well as the production of extracellular matrix, particularly collagen
- Endothelial growth factor (EGF): supports the growth of keratinocytes and assists the migration of keratinocytes, fibroblasts and endothelial cells
- Platelet-derived growth factor (PDGF): chemotactic for polymorphonuclear cells and macrophages.

### Conclusion

Wound bed preparation consists of basic steps which help to stimulate healing. The wound bed preparation process acknowledges that the acute-wound healing models do not apply to chronic wounds and a systematic approach is needed to address the underlying molecular and cellular imbalance that is usually responsible for non-healing in a chronic wound. The end result may be wound closure which will eliminate the need for advanced therapies or procedures. If, however, advanced therapies, such as skin grafts or growth factors and skin substitutes, are still required for wound closure the success of these techniques will be greatly improved if applied to a well-prepared wound bed.

Wound bed preparation provides a rational approach to the management of non-healing wounds, which can be supported with reference to the underlying cellular environment. Wound bed preparation is part of a more systematic — and ultimately, more effective — approach to wound management.

This paper is based on Schultz GS, Sibbald GR, Falanga V et al (2003) Wound bed preparation: a systematic approach to wound management. *Wound Repair Regen* 11(2): 1–28

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### KEY POINTS

- Chronic wound healing differs from the acute wound model.
- The principles of wound bed preparation are based on tissue, infection/inflammation, moisture imbalance and non-advancing edge (TIME).
- Chronic wounds are likely to require ongoing maintenance debridement rather than a single intervention.
- The success of advanced therapies, e.g. skin substitutes and growth factors, are dependent on preparing the wound bed.



# Wound bed preparation: TIME in practice

Wound bed preparation is now a well established concept and the TIME framework has been developed as a practical tool to assist practitioners when assessing and managing patients with wounds. It is important, however, to remember to assess the whole patient; the wound bed preparation 'care cycle' promotes the treatment of the 'whole' patient and not just the 'hole' in the patient. This paper discusses the implementation of the wound bed preparation care cycle and the TIME framework, with a detailed focus on Tissue, Infection, Moisture and wound Edge (TIME).

Caroline Dowsett, Heather Newton

## KEY WORDS

Wound bed preparation  
Tissue  
Infection  
Moisture  
Edge

The concept of wound bed preparation has gained international recognition as a framework that can provide a structured approach to wound management. By definition wound bed preparation is 'the management of a wound in order to accelerate endogenous healing or to facilitate the effectiveness of other therapeutic measures' (Falanga, 2000; Schultz et al, 2003). The concept focuses the clinician on optimising conditions at the wound bed so as to encourage normal endogenous healing. It is an approach that should be considered for all wounds that are not progressing to normal wound healing.

Wound healing is a complex series of events that are interlinked and

dependent on one another. Acute wounds usually follow a well-defined process described as:

- » Coagulation
- » Inflammation
- » Cell proliferation and repair of the matrix
- » Epithelialisation and remodelling of scar tissue.

In the past this model of healing has been applied to chronic wounds, but it is now known that chronic wound healing is different from acute wound healing. Chronic wounds become 'stuck' in the inflammatory and proliferative stages of healing (Ennis and Menses, 2000) which delays closure. The epidermis fails to migrate at the wound margins, which interferes with normal cellular migration over the wound bed (Schultz et al, 2003).

In chronic wounds there appears to be an over production of matrix molecules resulting from underlying cellular dysfunction and dysregulation (Falanga, 2000). Fibrinogen and fibrin are also common in chronic wounds and it is thought that these and other macromolecules scavenge growth factors and other molecules involved in promoting wound repair (Falanga, 2000). Chronic wound fluid is also biochemically distinct from acute wound fluid; it slows down, and can block the proliferation of cells, which are essential for the wound healing process (Schultz

et al, 2003). Wound bed preparation as a concept allows the clinician to focus systematically on all of the critical components of a non-healing wound to identify the cause of the problem, and implement a care programme so as to achieve a stable wound that has healthy granulation tissue and a well vascularised wound bed.

## The TIME framework

To assist with implementing the concept of wound bed preparation, the TIME acronym was developed in 2002 by a group of wound care experts, as a practical guide for use when managing patients with wounds (Schultz et al, 2003). The TIME table (Table 1) summarises the four main components of wound bed preparation:

- » Tissue management
- » Control of infection and inflammation
- » Moisture imbalance
- » Advancement of the epithelial edge of the wound.

The TIME framework is a useful practical tool based on identifying the barriers to healing and implementing a plan of care to remove these barriers and promote wound healing.

It is important to understand wound bed preparation and TIME within the context of total patient care. If a wound fails to heal there is often a complex mix of local and host factors which

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**Table 1**  
**TIME – Principles of wound bed preparation**

Clinical observations	Proposed pathophysiology	WBP clinical actions	Effect of WBP actions	Clinical outcome
Tissue non-viable or deficient	Defective matrix and cell debris impair healing	Debridement (episodic or continuous): » Autolytic, sharp surgical, enzymatic, mechanical or biological » Biological agents	Restoration of wound base and functional extracellular matrix proteins	Viable wound base
Infection or Inflammation	High bacterial counts or prolonged inflammation ↑ Inflammatory cytokines ↑ Protease activity ↓ Growth factor activity	Remove infected foci Topical/systemic: » Antimicrobials » Anti-Inflammatories » Protease inhibition	Low bacterial counts or controlled inflammation: ↓ Inflammatory cytokines ↓ Protease activity ↑ Growth factor activity	Bacterial balance and reduced inflammation
Moisture imbalance	Desiccation slows epithelial cell migration	Apply moisture-balancing dressings	Restored epithelial cell migration, desiccation avoided	Moisture balance
	Excessive fluid causes maceration of wound margin	Compression, negative pressure or other methods of removing fluid	Oedema, excessive fluid controlled, maceration avoided	
Edge of wound — non-advancing or undermining	Non-migrating keratinocytes Non-responsive wound cells and abnormalities in extracellular matrix or abnormal protease activity	Re-assess cause or consider corrective therapies: » Debridement » Skin grafts » Biological agents » Adjunctive therapies	Migrating keratinocytes and responsive wound cells. Restoration of appropriate protease profile	Advancing edge of wound

will need to be assessed and treated. A full and detailed patient assessment will highlight the underlying aetiology of the wound and other factors that may impede wound healing such as pain and poor nutrition (Dealey, 2000). With this in mind the wound bed preparation 'care cycle' was developed in 2004 (Dowsett, 2004) to provide a care programme that includes the TIME framework. It focuses both on the patient and on the wound in an attempt to address all factors that influence wound healing.

### Wound bed preparation care cycle

The care cycle (Figure 1) starts with the patient and their environment of care. Individual patient concerns need to be addressed as well as quality of life issues in order to achieve a successful care programme. Patients need to understand the underlying cause of their wound and the rationale for

treatments. Assessment and treatment of the underlying condition is essential as the type of wound bed preparation implemented may vary with wound type. For example, sharp debridement is common in the management of patients with diabetic foot ulceration, while compression therapy is the recommended treatment for patients with venous leg ulcers (European Wound Management Association, 2004). The cycle moves from patient assessment and diagnosis to assessing and treating the wound using the TIME framework. The importance of assessment in terms of evaluating the effectiveness of the treatment is highlighted in the cycle. Those patients who have healed come out of the cycle into a 'prevention programme' and patients who have not progressed to healing or who have palliative wounds remain in the cycle and are reassessed, using TIME.

The TIME table has been designed to help the clinician make a systematic interpretation of the observable characteristics of a wound and to decide on the most appropriate intervention:

**T** — for tissue: non-viable or deficient  
**I** — for infection/inflammation  
**M** — for moisture imbalance  
**E** — for edge, which is not advancing or undermining.

### T — Tissue

The specific characteristics of the tissue within a wound bed play a very important role in the wound healing continuum. Accurate description of this tissue is an important feature of wound assessment. Where tissue is non-viable or deficient, wound healing is delayed. It also provides a focus for infection, prolongs the inflammatory response, mechanically obstructs contraction



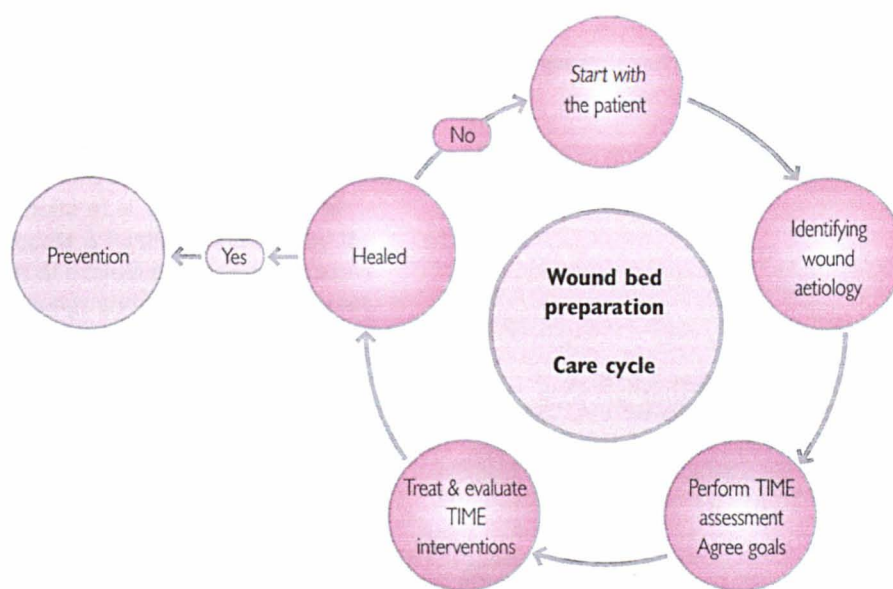


Figure 1. The wound bed preparation care cycle.



Figure 2. Fixed yellow slough on a wound bed.

and impedes re-epithelialisation (Baharestani, 1999). Necrosis, eschar, and slough are terms that describe non-viable tissue, however, little is known about their constituents.

Work undertaken by Thomas et al (1999) found that devitalised tissue has a defined structure similar to human dermis, however, there are areas of scattered, degraded or disrupted tissue present. For epidermal cells to migrate across a wound surface a well built extracellular matrix is required. Therefore, early interventions to remove devitalised tissue are an essential part of wound management.

Necrosis or eschar on a wound is usually identified through its black/

dark grey appearance and, when dried out, is tough and leathery to touch. Wound eschar is full thickness, dry, devitalised tissue that has arisen through prolonged local ischaemia (Gray et al, 2005). It is derived from granulation tissue after the death of fibroblasts and endothelial cells and may also contain inflammatory cells (Thomas et al, 1999) which increases the risk of chronic inflammation of the wound and delays extracellular matrix formation. Necrotic tissue acts as a physical barrier to epidermal cell migration, and hydration at the wound interface is significantly reduced.

Slough is adherent fibrous material derived from proteins, fibrin and fibrinogen (Tong, 1999). It is usually creamy yellow in appearance and can be found dehydrated and adhered to the wound bed (Figure 2) or loose and stringy when associated with increased wound moisture.

The presence of devitalised tissue in a wound is often a challenge to health care professionals. It is difficult to accurately assess the depth of a wound that is covered or filled with necrotic or sloughy tissue and, until removed, the true extent of the wound may not

be realised. In the majority of clinical cases there is a need to remove the devitalised tissue through a process of *debridement*, however, it is important to assess the blood flow to the affected area first, particularly if the wound is on the lower leg or foot. In cases where the limb requires revascularisation, it may not be appropriate to undertake tissue debridement until the viability of the limb is determined.

### Debridement

Debridement is the process of removing devitalised tissue and/or foreign material from a wound and it may occur naturally. However, in some cases the patient may have an underlying pathology which affects the ability of the body to naturally debride the wound. In a chronic wound, debridement is often required more than once as the healing process can stop or slow down allowing further devitalised tissue to develop. Where debridement is an option for clinicians the following methods may be used:

- ▶ Surgical
- ▶ Sharp
- ▶ Autolytic
- ▶ Enzymatic
- ▶ Larval
- ▶ Mechanical.

### Surgical and sharp debridement

Surgical and sharp debridement are the fastest methods of removing devitalised tissue and have the benefit of converting a non-healing chronic wound to that of an acute wound within a chronic wound environment (Schultz et al, 2003). Surgical debridement is normally performed where there is a large extent of devitalised tissue present and where there are significant infection risks.

Sharp debridement is more conservative, but it still requires the skills of an experienced practitioner. Clinical competencies such as knowledge of anatomy, identification of viable or non-viable tissue, ability and resources to manage complications such as bleeding and the skills to obtain patient consent are all essential before undertaking this procedure.



**Autolytic debridement**

Autolytic debridement is a highly selective process involving macrophage and endogenous proteolytic enzymes which liquefy and separate necrotic tissue and eschar from healthy tissue (Schultz et al, 2003). The natural process is further enhanced by the use of occlusive and semi-occlusive dressings and those which interact to create a moist environment. Phagocytic activity is enhanced and increasing the moisture at the wound interface promotes tissue granulation.

**Enzymatic degradation**

Enzymatic debridement is a less common method of debridement, however, it is effective in the removal of hard necrotic eschar where surgical debridement is not an option. Exogenous enzymes are applied to the wound bed where they combine with the endogenous enzymes in the wound to break down the devitalised tissue. (Schultz et al, 2005).

**Larval therapy**

Larval therapy is a quick, efficient method of removing slough and debris from a wound, however, not all patients or staff find this debridement method socially acceptable. Sterile larvae secrete powerful enzymes to break down devitalised tissue without destroying healthy granulation tissue (Thomas et al, 1998).

**Mechanical debridement**

Mechanical methods of debridement such as irrigation and wet to dry dressings are rarely used as they can cause increased pain and can damage newly formed granulation tissue (NICE, 2001).

If debridement is effective, the T of TIME is removed and wounds can progress through the remaining phases of wound healing.

**I — infection/inflammation**

Infection in a wound causes pain and discomfort for the patient, delayed wound healing, and can be life threatening. Clinical infections as well as having serious consequences for the patient can add to the overall cost

**Table 2.****Risk factors for infection in chronic wounds**

Local factors	Systemic factors
Large wound area	Vascular disease
Deep wound	Oedema
High degree of chronicity	Malnutrition
Anatomic location, e.g. anal region	Diabetes mellitus/rheumatoid arthritis
Presence of necrotic tissue	Smoking/alcoholism
High degree of contamination	Previous surgery or radiotherapy
Reduced tissue perfusion	Use of corticosteroids/immunosuppressants

**Figure 3. Clinically infected wound.**

of care. All wounds contain bacteria at levels ranging from contamination, through critical colonisation (also known as increased bacterial burden or occult infection), to infection. The increased bacterial burden may be confined to the superficial wound bed or may be present in the deep compartment and surrounding tissue of the wound margins. Several systemic and local factors increase the risk of infection (Table 2). Emphasis is often placed on the bacterial burden, but in fact host resistance is often the critical factor in determining whether infection will occur. Host resistance is lowered by poor tissue perfusion, poor nutrition, local oedema and other behavioural factors such as smoking and drinking excess alcohol. Other systemic factors that impair

healing include co-morbidities and medication such as steroid therapy and immunosuppressive drugs. Local factors at the wound bed, such as necrotic tissue and foreign material such as fragments of gauze and dressings, also affect healing and the risk of infection.

When a wound is infected (Figure 3) it contains replicating micro-organisms which elicit a host response and cause injury to the host. In an acute wound, infection is met by a rapid inflammatory response which is initiated by complement fixation and an innate immune response followed by the release of cytokines and growth factors (Dow et al, 1999). The inflammatory cascade produces vasodilation and a significant increase of blood flow to



**Table 3**  
**Differentiating between superficial and deep infection**

Superficial infection	Deep infection
Non-healing	Pain: other than usually reported
Friable granulation tissue	Increased size
Exuberant bright granulation tissue	Warmth
Increased exudate	Erythema > 1–2cm
New areas of necrosis in base	Probes to bone or bone exposed
Wound breakdown	
Odour	

(Sibbald et al, 2000)

the injured area. This also facilitates the removal of micro-organisms, foreign bodies, bacterial toxins and enzymes by phagocytic cells, complements, and antibodies. The coagulation cascade is activated isolating the site of infection in a gel matrix to protect the host (Dow et al, 1999). In a chronic wound, however, the continuous presence of virulent micro-organisms leads to a continued inflammatory response which eventually contributes to host injury. There is persistent production of inflammatory mediators and steady migration of neutrophils which release cytolytic enzymes and oxygen-free radicals. There is localised thrombosis and the release of vasoconstricting metabolites which can lead to tissue hypoxia, bringing further bacterial proliferation and tissue destruction (Sibbald et al, 2003).

The presence of bacteria in a chronic wound does not necessarily indicate that infection has occurred or that it will lead to impaired wound healing (Cooper and Lawrence, 1996). Micro-organisms are present in all chronic wounds and low levels of certain bacteria can facilitate wound healing as they produce enzymes such as hyaluronidase which contributes to wound debridement and stimulates neutrophils to release proteases (Stone, 1980).

Diagnosis of infection is primarily a clinical skill and microbiological data should be used to supplement the

clinical diagnosis. The classic signs of infection in acute wounds include:

- ▶▶ Pain
- ▶▶ Erythema
- ▶▶ Oedema
- ▶▶ Purulent discharge
- ▶▶ Increased heat.

For chronic wounds it has been suggested that other signs should be added:

- ▶▶ Delayed healing
- ▶▶ Increased exudates
- ▶▶ Bright red discolouration of granulation tissue
- ▶▶ Friable and exuberant tissue
- ▶▶ New areas of slough
- ▶▶ Undermining
- ▶▶ Malodour and wound breakdown (Cutting and Harding, 1994).

These criteria have now been modified according to wound type (Cutting et al, 2005) and are the subject of a position paper (EWMA, 2005). In this document, Cutting et al describe the results of a Delphi approach as a method of developing consensus on the criteria for identification of wound infection. The results of the study indicated that cellulites, malodour, pain, delayed healing or deterioration in the wound/wound breakdown are criteria common to all wounds, but other changes should be noted in different wound types. The Delphi process identified the criteria for six different wound types and should be used as a guide when diagnosing infection in both acute and chronic wounds.

Sibbald et al (2000) suggest that diagnosis should differentiate between superficial and deep infection as outlined in Table 3.

Treatment of infection should first of all focus on optimising host resistance by promoting healthy eating, encouraging smoking cessation and addressing underlying medical conditions such as diabetes. Systemic antibiotics are not necessarily the most appropriate way of reducing bacterial burden in wounds, particularly because of the threat of increasing bacterial resistance and should only be used where there is evidence of deep infection or where infection cannot be managed with local therapy (Schultz et al, 2003). Local methods include: debridement to remove devitalised tissue; wound cleansing; and the use of topical antimicrobials such as iodine dressings and silver.

There is renewed interest in the selective use of topical antimicrobials as bacteria become more resistant to antibiotics. Studies show that some iodine and silver preparations have bactericidal effects even against multi-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) (Landsdown, 2002; Romanelli et al, 2003; Sibbald et al, 2003). Where infection in the wound has extended beyond the level that can be managed with local therapy, systemic antibiotics should be used. Systemic signs of infection, such as fever, and cellulites extending at least 1cm beyond the wound margin and underlying deep structures, will require systemic antibiotic therapy (Schultz et al, 2003).

#### M — moisture imbalance

Creating a moisture balance at the wound interface is essential if wound healing is to be achieved. Exudate is produced as part of the body's response to tissue damage and the amount of exudate produced is dependant upon the pressure gradient within the tissues (Trudgian, 2005). A wound which progresses through the normal wound healing cycle produces enough moisture to promote cell



**Table 4**  
**Exudate types**

Description of exudate	Components of exudate
Serous	Clear and watery. Bacteria may be present
Fibrinous	Cloudy. Contains fibrin protein strands
Purulent	Milky. Contains infective bacteria and inflammatory cells
Haemopurulent	As above but dermal capillary damage leads to the presence of red cells
Haemorrhagic	Red blood cells are a major component of the exudate

(Vowden and Vowden, 2004)



**Figure 4.** Evidence of irritant dermatitis following dressing application.

proliferation and supports the removal of devitalised tissue through autolysis. If, however, the wound becomes inflamed and/or stuck in the inflammatory phase of healing, exudate production increases as the blood vessels dilate.

A description of the types of exudates can be found in *Table 4*.

Evidence suggests that there are significant differences between acute and chronic wound fluid (Park et al, 1998). Acute wound fluid supports the stimulation of fibroblasts and the production of endothelial cells as it is rich in leukocytes and essential nutrients. Chronic wound fluid, however, has been found to contain high levels of proteases which have an adverse effect on wound healing by slowing down or blocking cell proliferation (Schultz et al, 2003) in particular keratinocytes, fibroblasts

and endothelial cells. Increased levels of proteolytic enzymes and reduced growth factor activity all contribute to a poorly developed extracellular wound matrix. This in turn affects the ability of the epidermal cells to migrate across the surface of the wound to complete the healing process.

Factors such as the underlying condition of the patient, the pathology of the wound and the dressing selection all affect the production of exudate (White, 2001). Moisture in a wound enhances the natural autolytic process and also acts as a transport medium for essential growth factors during epithelialisation. If a wound bed becomes too dry, however, a scab will form which then impedes healing and wound contraction. The underlying collagen matrix and the surrounding tissue at the wound edge become desiccated (Dowsett and Ayello, 2004).

If a wound produces excessive amounts of exudate the wound bed becomes saturated and moisture leaks out onto the peri-wound skin causing maceration and excoriation. This in turn could lead to an increased risk of infection.

#### Exudate assessment

Assessment of the exudate is an important part of wound management. The type, amount and viscosity of the exudate should be recorded and dressings selected based on the exudate's characteristics. If a wound is too dry, rehydration should be the principle of management, unless contraindicated as in the case of ischaemic disease. Occlusive dressing products promote a moist environment at the wound interface. As wounds heal, the level of exudate gradually decreases. The management of excess exudate in chronic wounds, however, presents a challenge to many health care professionals. Vowden and Vowden (2004) suggest that an understanding of the systemic and local conditions influencing exudate production and knowledge of the potential damaging chemical constituents of exudates should inform management strategy.

#### Dressing selection

When selecting a dressing, consideration should be given to the volume of exudate and the viscosity as some dressings absorb a higher volume of fluid than others and some are more efficient when dealing with viscous exudate. There are a variety of dressing products available for the management of exudates ranging from foams, hydrocolloids, alginates, hydrofibres, cadexomer iodine to capillary action dressings. All play a role in the removal of fluid away from the wound surface, however, many of the products, through their ability to gel on contact with wound exudates, maintain a moisture balance on the wound surface itself.

VAC therapy or total negative pressure is a therapy which draws exudates from the wound bed through application of sub-atmospheric pressure via an electronic pump (Mendez-Eastman, 2001). Compression bandages also play a role in the removal of excess



fluid in the lower limbs in patients with venous leg ulcers and lymphoedema. The condition of the surrounding skin is also important as vulnerable skin can react to excess exudate and cause maceration, excoriation, and irritant dermatitis (Figure 4). Early application of a protective skin barrier film can minimise these risks. It is important to remember to treat the underlying clinical condition when addressing moisture imbalance in a wound (Newton and Cameron, 2003).

#### E — edge

When the epidermal margins of a wound fail to migrate across the wound bed or the wound edges fail to contract and reduce in size, consideration needs to have been given to the T, I, and M first to ensure that all aspects of wound bed preparation have been considered. The final stage of wound healing is epithelialisation, which is the active division, migration, and maturation of epidermal cells from the wound margin across the open wound (Dodds and Haynes, 2004).

There are many factors which need to be present in order for epithelialisation to take place. The wound bed must be full of well vascularised granulation tissue in order for the proliferating epidermal cells to migrate. This also ensures that there is adequate oxygen and nutrients to support epidermal regeneration. There needs to be a rich source of viable epidermal cells which can undergo repeated cell division particularly at the edge of the wound. Where cells have become senescent the process slows down or stops completely. Wounds that have a significant number of fibroblasts that are arrested due to senescence, damaged DNA or enduring quiescence do not heal (Vande Berg and Robson, 2003). Other factors, such as bacteria or the presence of devitalised tissue, which interfere with epidermal cell growth, have the potential to influence the rate of wound healing.

There are many reasons why the epidermal margin fails to migrate

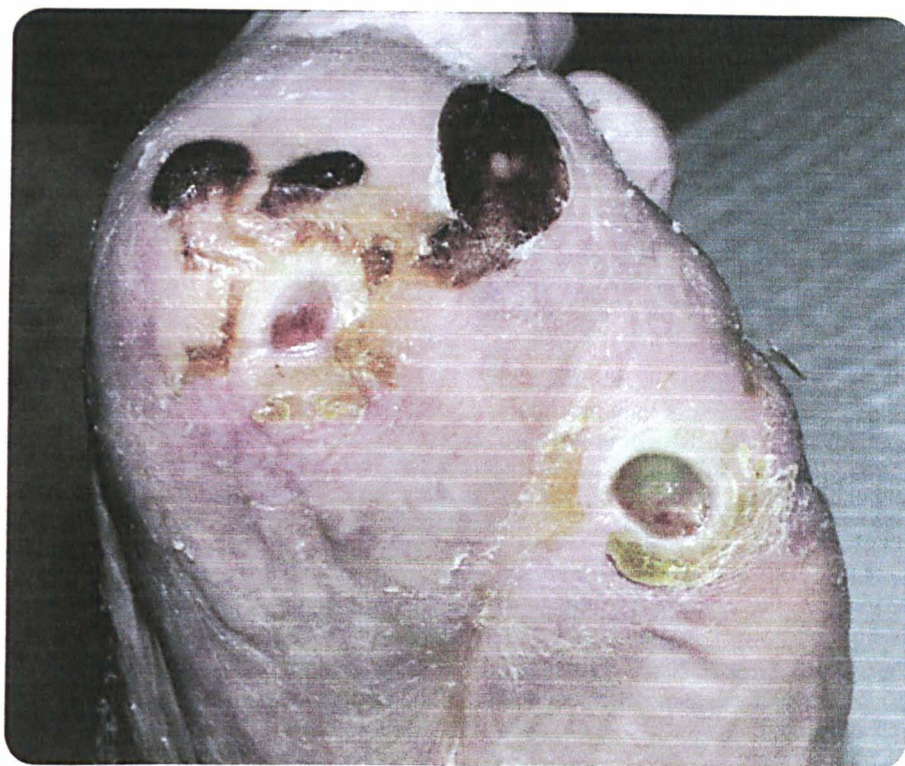


Figure 5. Diabetic foot ulcer.

including hypoxia, infection, desiccation, dressing trauma, hyperkeratosis and callus at the wound margin (Moffatt et al, 2004). For wound healing to be effective, there needs to be adequate tissue oxygenation. Decreased oxygen levels impair the ability of the leucocytes to kill bacteria, lower production of collagen and reduce epithelialisation (Schultz et al, 2003). It is important to remember that wounds rely on both macro- and microcirculation particularly in the lower limb.

A baseline assessment needs to be undertaken to determine the degree of ischaemic disease and the ability of the wound to heal without vascular intervention. Wound infection as discussed previously is extremely destructive to a healing wound. Inflammation caused by bacteria causes the extracellular matrix to degrade and therefore epidermal cell migration is interrupted. Wounds become chronic and fail to heal. Dressing products, particularly if adhered or made of fibrous materials, also cause trauma and inflammation of the wound bed which in turn delays

healing. It is important to select dressing products which are non adherent, and will not dry out or leave fibres in the wound bed.

In certain clinical conditions such as in diabetic neuropathy, there is an over production of hyperkeratosis and callus formation (Figure 5). It has also been noted that the epidermis of the skin surrounding venous leg ulcers is thicker than normal skin and highly keratinised (Schultz et al, 2005). If this proliferative, thickened tissue is not removed, wounds will fail to epithelialise. Failure of a wound edge to migrate is also thought to be associated with the inhibition of the process of normal programmed cell death (apoptosis) which particularly affects fibroblasts and keratinocytes. Cells undergo a characteristic series of changes following mechanical damage to the cell and on exposure to toxic chemicals. Cells become unresponsive and die.

Undermining or rolling of a wound edge can also influence the ability of the wound to heal. Undermining can be indicative of a chronic wound and in particular, those wounds that are



also critically colonised with bacteria or infected. Rolled edges can present in wounds that have an inflammatory origin such as pyoderma gangrenosum or in malignancy. Early diagnosis is important in these cases as failure to provide the appropriate second-line therapy such as oral steroids or tissue biopsy and excision can result in poor healing outcomes.

Measuring a wound at the start of treatment is seen as best practice to enable accurate assessment of the impact of a clinician's intervention. Subsequent measuring can identify whether or not a wound is failing to heal or deteriorating. The edge of the wound will not epithelialise unless the wound bed is well prepared. Always consider the elements of TIME first to ensure that the use of advanced therapies are appropriate and if used are applied to a well prepared wound bed to ensure optimal effect.

### Summary and conclusion

The management of chronic wounds has progressed from merely assessing the status of the wound to understanding the underlying molecular and cellular abnormalities that prevent the wound from healing. The concept of wound bed preparation has simultaneously evolved to provide a systematic approach to removing the barriers to natural healing and enhancing the effects of advanced therapies. Wound bed preparation and the TIME framework are most likely to be successful when used alongside the wound bed preparation care cycle.

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### Key Points

- ▶▶ The TIME framework has been developed as a practical tool for managing patients with wounds.
- ▶▶ The wound bed preparation 'care cycle' focuses care on the patient and their underlying condition.
- ▶▶ Patient progress and response to treatment should be regularly evaluated.

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# Reviewing the evidence for wound bed preparation

This paper explores the nature of evidence and how it has evolved in recent years, and sets out a process for assembling and assessing the evidence to support wound bed preparation as an effective method of managing chronic wounds

evidence; randomised controlled trials; wound bed preparation; chronic wounds

In an attempt to understand why a small but significant proportion of wounds fail to heal, the concept of wound bed preparation, and subsequently the TIME (Tissue management, control of Inflammation and infection, Moisture balance, and advancement of the Epithelial edge of the wound) model was developed.<sup>1</sup> This systematic approach is an effective way to treat wounds, but is there evidence for its effectiveness?

## The changing nature of evidence

The randomised controlled trial (RCT) eliminates many sources of bias present in other forms of observational evidence because:

- Random allocation of patients to the trial arms ensures groups are comparable in observed and unobserved characteristics and clinicians cannot select, adjust or modify treatment for individual patients
- Being prospective in nature, the clarity of vision that comes with hindsight is eliminated
- Patients are entered into a trial if they conform to a certain set of criteria, and cannot be excluded from the results without good reason.

As a means of making unbiased assessments of effectiveness, the RCT is an excellent tool. However, other forms of clinical study and the experience gained from uncontrolled observation are often undervalued.

The ascendancy of RCTs was largely brought about by a study that compared the findings of such published trials with those of observational studies.<sup>2</sup> In a review of the literature, six therapies were evaluated in 50 RCTs and 56 studies using historical controls. The active agent under study was considered effective in 44 out of the 56 trials using historical controls but in only 10 out of the 50 RCTs. Subjects in the treatment group had similar outcomes regardless of the study design, but in trials with historical control patients in the control groups had worse outcomes than control subjects in the RCTs.

The authors concluded that biases in patient selection in observational studies led to overestimates of treatment effects.

## Levels of evidence

Studies are now routinely classified according to 'grades of evidence', using the research design as the criterion for ranking. Higher grades are assigned to research that includes at least one properly randomised controlled trial, and case studies and expert opinion are assigned the lowest grade. This generally accepted 'hierarchy' of evidence (Table 1) can be found, for example, in guidance issued by the National Institute for Health and Clinical Excellence (NICE).<sup>3</sup>

Concato et al.<sup>4</sup> challenged the consensus on study design hierarchy in a similar study to that of Sacks et al.<sup>2</sup> Comparing the results of meta-analyses of RCTs with meta-analyses of cohort and case-control studies for each of five interventions, they found that the average results of the observational studies in all cases were remarkably similar to those of the RCTs. Contrary to common belief, the average results from well-designed observational studies (cohort or case-control design) did not systematically overestimate the magnitude of effect when compared with results from RCTs on the same topic.

Interestingly, viewed individually, there was less variability in the results of the observational studies, and it was only among the RCTs that some studies reported results in a direction opposite to that of the pooled results.

This finding has been supported by a review of more than 200 RCTs undertaken on 36 clinical topics that found numerous examples of conflicting results,<sup>5</sup> and more recent reviews of studies on the effects of monoclonal antibody therapy in patients with septic shock.<sup>6,7</sup>

It is important to explore the possible reasons for these findings:

- Observational studies usually include patients with coexisting illnesses and a wide spectrum of disease severity, with treatment being tailored to the individual patient
- The RCT will include a distinct group of patients, as defined by the inclusion and exclusion criteria
- The treatment protocol may not be representative of clinical practice

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**Table 1. Levels of evidence for intervention studies<sup>3</sup>**

**Level of evidence**

1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*
2++	High-quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal*
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus

\* Studies with a level of evidence '-' should not be used as a basis for making a recommendation

- Ethical requirements and patient-selection criteria create specific study populations that differ from the general population. The typical patient recruited into a RCT is between the ages of 18 and 65, has few comorbidities and is receiving only a limited range of comedications<sup>8</sup>
- RCTs are highly protocol-driven, whereas in clinical practice treatments and interventions are modified continually in response to the patient's condition. Therefore, one could argue that clinical trials provide only evidence for a clinical approach in a very small group of patients treated in a specific fashion — they have high statistical validity but little clinical relevance<sup>5</sup>
- Complex procedures that require skill and clinical judgement are not so easily assessed in the rigorous environment of the RCT<sup>5</sup>
- Randomised controlled trials are usually performed in skilled clinical centres, which offer a level of care and quality control not evident in small community settings<sup>4</sup>
- The close scrutiny of patients in RCTs can reduce the adverse effects of treatment, even with double blinding.<sup>5</sup>

Well-designed observational studies can include rigorous methods that mimic those of clinical trials and there is evidence that they do not necessarily overestimate treatment effects.<sup>9</sup> While the latter may differ according to the study design, one method 'does not give a consistently greater effect than the other'.<sup>9</sup>

#### Example: leg ulcer management

The majority of leg ulcers are venous in origin and caused by venous hypertension.<sup>10</sup> In most cases high-compression bandaging stimulates autolytic debridement, controls moisture balance and encour-

ages healing within 24 weeks<sup>11</sup> but a percentage requires additional therapeutic interventions.

Healing rates at 12 weeks vary widely and have been variously reported as 30%<sup>12</sup> to over 75%.<sup>13</sup> This wide range reflects the large number of risk factors for delayed healing. The percentage of wound reduction during the first three to four weeks may be a better predictor of healing: a 44% reduction in initial area by week 3 predicts healing in 77% of cases.<sup>14</sup>

There is less agreement on how to manage mixed venous-arterial and arterial ulcers, and less evidence on which to base current interventions, although there is some evidence to suggest that reduced compression will heal ulcers of mixed aetiology.<sup>15,16</sup>

#### Applying TIME to non-healing leg ulcers

The TIME model does not bring any fundamentally new interventions to the management of venous leg ulcers, but is a more logical approach based on an appreciation of the underlying molecular disorder. The model's first three components — tissue management, control of infection/inflammation and moisture balance — are assessed in turn and their effect on the fourth, the epithelial edge, is observed. These four components make up a cycle of care that can be repeated if healing does not take place.<sup>17</sup>

#### Tissue management

Most uncomplicated venous leg ulcers do not require debridement. Sharp debridement can remove superficial slough, and enzymatic preparations can remove more adherent slough,<sup>18</sup> but hydrogels and hydrocolloids are rarely effective under compression and can lead to maceration of surrounding skin. Sharp debridement is not generally appropriate for sloughy arterial ulcers. In such cases, biological or autolytic debridement is more appropriate.



### Control of infection and inflammation

Bacteria can result in persistent inflammation and production of inflammatory mediators and proteolytic enzymes. Infection is usually localised but may be systemic if the patient is immunocompromised. Clearance of devitalised tissue and foreign bodies is the first step in managing infection.

### Moisture balance

Copious exudate breaks down extracellular matrix proteins and growth factors, prolongs inflammation, inhibits cell proliferation and degrades the tissue matrix.<sup>19-21</sup> Compression therapy reduces exudate production.<sup>22</sup>

### Epithelial edge advancement

The first three elements, as described above, should facilitate a wound bed that encourages migration of the epidermal margin. However, the wound may still fail to heal due to disordered production of cytokines, growth factors, proteases or other elements of the wound-healing cascade. A number of treatments have been developed to correct these,<sup>22</sup> but success depends on a well-prepared wound bed.<sup>1</sup>

### Does TIME improve ulcer leg management?

Interventions and care strategies need to be both clinically and cost-effective. However, assessing this in relation to chronic wounds is problematic as they are subject to multiple therapies and are not necessarily at a fixed stage in the care pathway, so identifying which one brought about healing is almost impossible.

While the components of the TIME model are based on sound research and recognised as a standard of care for venous leg ulcers,<sup>22</sup> does it make a real difference to healing? To date, no study — controlled or otherwise — exists that directly compares this approach with standard care or demonstrates any additional value to using it alongside best-practice guidelines. However, a brief overview of the role of each component reveals the following:

### Debridement

According to the European Wound Management Association (EWMA) position document on wound bed preparation in venous leg ulcer management,<sup>22</sup> debridement may be beneficial in certain types of leg ulcer and in certain conditions, but no studies have conclusively demonstrated its value.

Smith's systematic review of debridement in diabetic foot ulcers revealed that hydrogels are more effective than gauze or standard care, with little evidence to support the use of surgery or maggot debridement therapy.<sup>23</sup>

No RCTs have evaluated the effect of surgical debridement or maggot debridement therapy in other chronic wounds, and none has compared the

effect of debridement with no debridement. There is insufficient evidence to promote one method over another and only one study showed a significant difference between two agents (hydrogel and polysaccharide paste).<sup>24</sup>

However, debridement has long been used in burn wounds and is supported by a substantial body of evidence.<sup>25-29</sup> These studies can provide some insights into the efficacy or otherwise of various interventions on venous leg ulcers.

### Infection

Extensive *in vitro*, animal and clinical studies confirm that infection delays wound healing.<sup>30</sup> Drosou et al.'s review concluded that the *in vivo* antimicrobial activity of iodine- and silver-based dressings is not in question and that they do not have a negative effect on wound healing.<sup>31</sup> However, very few of the studies reviewed included patients with venous leg ulcers.

A systematic review of diabetic foot ulcers evaluated antibiotic therapies, dressings and topical agents.<sup>32</sup> Inconclusive evidence existed for the use of dressings versus antibiotics, and all dressings were found to be equivalent in effect, but again the evidence arose from small studies. With very few RCTs in this area, it is difficult to draw conclusions.<sup>13</sup>

### Decision analytic modelling

Although there are gaps in the evidence on venous leg ulcers, decision analytic modelling may help in reaching a conclusion on the value of wound bed preparation as a model for wound management.<sup>33,35</sup> Such models play a central role in the NICE technology appraisal process.<sup>36,37</sup> For example, in 2004–2005, 39 out of 61 NICE appraisals considered an independent decision analytic model in addition to other evidence.

Decision analysis is a mathematical process that brings together all the available evidence to reach a decision about the value of an intervention, along with an estimate of the uncertainty surrounding the decision. For example, if a large number of controlled trials carried out on thousands of patients all supported a particular treatment, the uncertainty would be very low. By comparison, if the only evidence is observational, and derived from similar but not identical patients to those we wish to treat, the overall conclusion may be that it is a worthwhile treatment, but with a high degree of uncertainty.

Decision analytic modelling allows us to combine evidence from a variety of sources to compare treatments that may not have been directly compared in trials, and to extrapolate this to treatments in different but related pathologies and across different patient groups, while reflecting the degree of uncertainty inherent in these estimates. For example, treatment A may have been compared with treatment B

20 Trengove, N.J., Stacey, M.C., MacAuley, S. et al. Analysis of the acute and chronic wound environments: the role of proteases and their inhibitors. *Wound Repair Regen* 1999; 7: 442-452.

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36 National Institute for Clinical Excellence. Guide to the Technology Appraisal Process. National Institute for Clinical Excellence, 2004.

37 National Institute for Clinical Excellence. A Guide for Manufacturers and Sponsors: Contributing to a technology appraisal. National Institute for Clinical Excellence, 2004.

38 Thompson, C., Dowling, D. (eds). *Clinical Decision-making and Judgement in Nursing*. Churchill Livingstone, 2004.

39 Thompson, C. Clinical experience as evidence in evidence-based practice. *J Adv Nurs* 2003; 43: 230-237.

and with treatment C, but treatments B and C may never have been directly compared. While the results of A versus B, and A versus C can be used to estimate how B and C might compare, the uncertainty surrounding this estimate would obviously be higher than if they had been directly compared.

Evidence is not rejected just because it has not been gathered in a RCT. It is incorporated into the model along with a measure of the uncertainty surrounding its inclusion. This method allows:

- Use of the available evidence
- Comparison of alternative management strategies even if they have not been directly compared in clinical studies
- Reflection of the additional uncertainty introduced by using evidence of variable quality and extrapolating from the evidence available
- Extrapolation from surrogate endpoints to clinical outcomes and of costs and benefits over time in an explicit and transparent way
- Estimation of the effect of an intervention in different clinical and system settings so that it can be applied to more representative patient populations
- Comparison of a number of alternatives where these may never have been directly compared in a traditional RCT
- Characterisation of the uncertainty surrounding the estimates of effect and cost, and representation of the uncertainty surrounding a decision to adopt a particular intervention.

## Availability of evidence

There is a lack of RCTs in wound management, but a wealth of clinical data, epidemiological studies and observational data. Most patients with chronic wounds are excluded from RCTs due to their age, comorbidities or comedications. Paradoxically, RCTs therefore provide little information about the effectiveness of an intervention in the majority of patients usually seen in wound clinics. The lack of RCT evidence itself should not be used as a reason for not applying the concept of wound bed preparation<sup>18,43</sup> and does not mean the data have no value."

Some of the available evidence is for aggregated interventions, and the modelling process can be used to extract evidence for management of one particular type of wound from a number of aggregated studies. Expert judgement is also important to fill gaps in the evidence as we may have evidence about a particular treatment but not in exactly the area we want. Unlike systematic reviews, evidence will not be rejected if it has not been collected within the context of a RCT, but the uncertainty due to the amount and quality of the evidence available will be assessed and represented in the evaluation.

The modelling process would allow us to identify the key clinical events that determine the long-term impact of an intervention using the TIME model.

Research on the possible benefits of incorporating wound bed preparation and TIME into education and practice is currently under way and the preliminary findings are likely to be available at the end of 2007.

## Can we learn from further research?

Decision modelling enables us to make a judgement on the effectiveness and costs of an intervention that includes an estimate of the uncertainty surrounding that judgement. The degree of uncertainty is a way of expressing the possibility that a decision based on imperfect information may be wrong.

It is possible to go a stage further and assess the possible consequences of a wrong decision, estimating what would be the value, if any, of acquiring perfect information, without any uncertainty.<sup>45</sup> In other words, there is some uncertainty surrounding a clinical decision, but is the consequence of a wrong decision serious enough to justify the cost and effort of acquiring stronger evidence?

In order to test the relevance of TIME to the management of venous leg ulcers, we need to work through the following process, the overall objective being to see if wound bed preparation improves patient outcomes. This would involve:

- Identifying the elements of TIME that can be measured (tissue type, infection levels, exudate reduction, rate of epithelial edge advancement)
- Creating a protocol that is clear, simple, easy to implement and robust
- Defining the scope of study (for example, concurrent, historical comparison)
- Defining the measurements of success:

*Efficacy* — should it be defined as healing or as improvement in pain or other criteria?

*Efficiency* — will there be an impact on utilisation of resources within a health-care system or with respect to the patient such as an improvement in activities of daily living?

*Effectiveness* — will it improve the patient's quality of life or enable the provider to carry out wound care more efficiently?

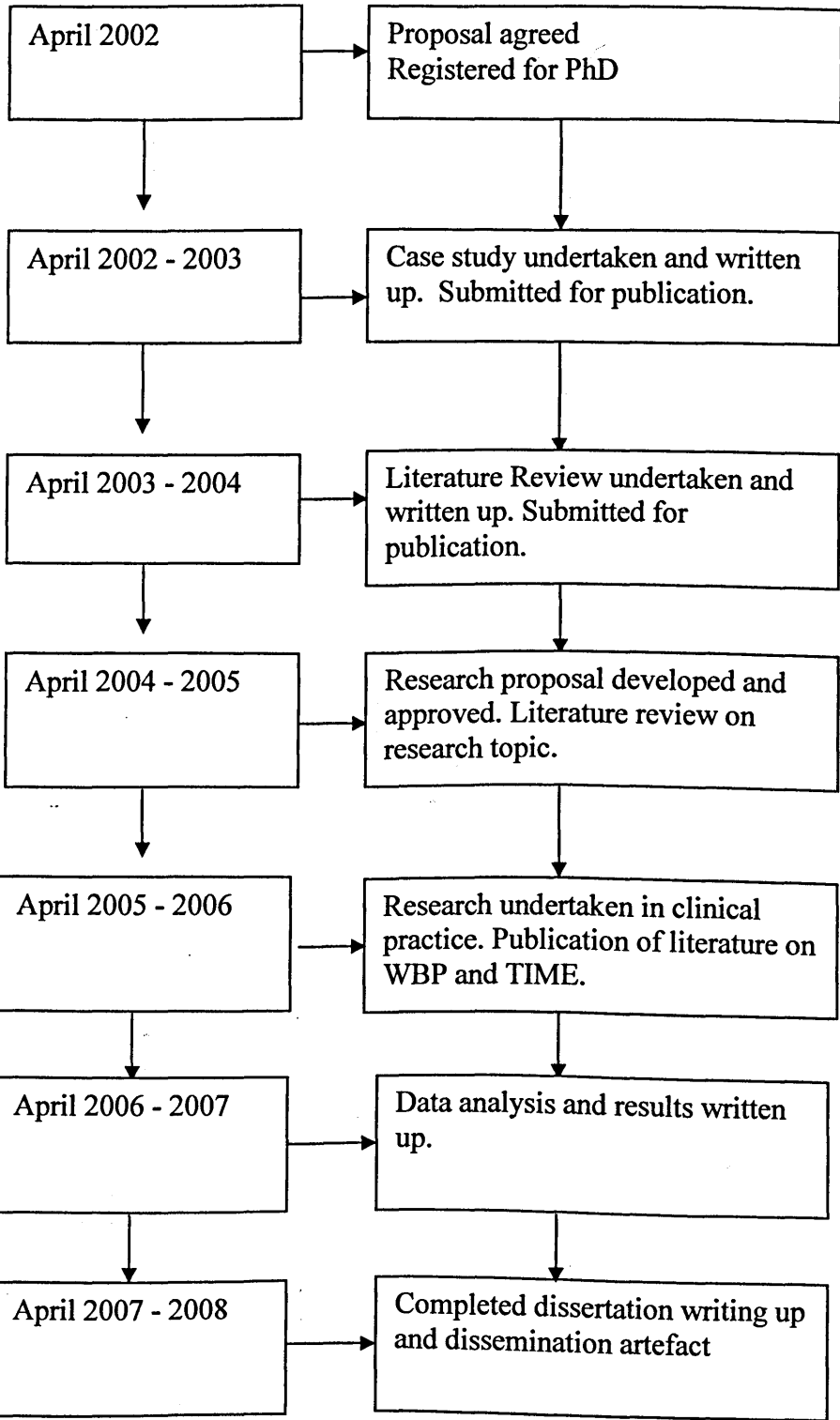
## Conclusion

Wound bed preparation is a logical systematic approach to the management of wounds based on an understanding of the underlying molecular environment in the wound and the application of accepted elements of care. In the absence of level 1 evidence for many of the components of wound bed preparation, it is possible to use modelling techniques to assemble the available evidence for benefit of effect. This exercise will be used to inform the design of a study to assess the impact of the TIME model on the management of venous leg ulcers. Wounds will be assessed and monitored using a recently developed wound management database system. ■

## **APPENDIX 1**

### **THESIS TIMELINE**

**PhD Professional Practice: Timeline**



## **APPENDIX 2**

### **LEG ULCER ASSESSMENT FORM**

## LEG ULCER ASSESSMENT

<b>NAME</b> Chris Obeh (name changed for purpose of case study)	<b>GP</b> Dr Newton
<b>ADDRESS</b>  74 Green Road London	<b>GP ADDRESS</b> The surgery Long Road
<b>TELEPHONE NO.</b>	
<b>DATE OF BIRTH</b> Aged 39yrs	<b>GP TEL NO.</b>

<b>INITIAL ASSESSMENT DATE:</b> 7/3/2002			
<b>DATE OF LAST ABPI</b>	<b>To be reassessed on:</b>	<b>DATE OF LAST ASSESSMENT</b>	<b>To be reassessed on:</b>
First assessment			

<b>PREVIOUS ULCER TREATMENTS:</b>	<b>DRUG ALLERGIES:</b>	<b>ALLERGIES TO TOPICAL PREPARATIONS/DRESSING/ PATCH TEST RESULTS:</b>	<b>PRESENT MEDICATION:</b>
Self treating with over the counter dressings	None known	Known none	Codydramol 2 tabs 4 times a day Voltarol 50mgs BD Folic acid 5mgs daily

<b>MOBILITY</b>		<b>NEGOTIATES STAIRS</b>		<b>SLEEPS</b>	
NO LIMITATIONS	✓	TOILET		IN BED	✓
WALKS WITH AIDS		TO GO TO BED		IN CHAIR	
CHAIR BOUND		WHEN OUT	✓	OTHER	

<b>OTHER INFORMATION</b>			<b>DATE</b>	<b>RESULT</b>
HEIGHT	6ft 4in	HB		
WEIGHT	12 st	WBC		
BODY MASS INDEX		IRON		
URINALYSIS		ALBUMIN		



BM stick	3.5	SUGAR		
BLOOD PRESSURE	140/ 85	OTHER		
WATERLOW SCORE		HB		
		ULCER SWABBED?	7/3/02	
SMOKES	No. per day	never	Gave up how long ago?	

### RELEVANT MEDICAL HISTORY: (PLEASE TICK)

ANAEMIA <input checked="" type="checkbox"/>	CLAUDICATION	THROMBOPHLEITIS
DIABETES	MALIGNANCIES	DEEP VEIN THROMBOSIS
PULMONARY EMBOLISM	ARTHRITIS	LEG OEDEMA <input checked="" type="checkbox"/>
ISCH. HEART DISEASE	PREGNANCY	LOWER LEG FRACTURES
T.I.A / CVA	INFLAMMATORY BOWEL DISEASE	OTHER
ABDOMINAL SURGERY	CELLULITIS	Sickle cell disorder
VASCULAR SURGERY	VARIOSE VEINS	
MYOCARDIAL INFARCTION	V.V SURGERY	

PAIN	CONSTANT	INTERMITTENT	DURING DAY	AT NIGHT	AT DRESSING CHANGE
NONE					
MODERATE			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
SEVERE					<input checked="" type="checkbox"/>

HAS PAIN BECOME WORSE DURING THE LAST TWO WEEKS? ☐ YES ☐ NO

### WHAT HELPS?

Volstarol tablets improve the pain. Needs to have dressing removed slowly. Chris feels better if he can remove his own dressing once his leg has been soaked in warm water.

\* Use Pain Assessment form and refer to Pain Team as appropriate \*

Date referred:

Outcome:

### HOW DOES THE ULCER AFFECT THE PATIENT? (WRITE PATIENT'S OWN WORDS)

I can't sleep at night  
I can't concentrate at work  
At times I feel like I can not cope

NUTRITION: (IF ANY TICK BOX BELOW TICKED PLEASE COMPLETE FULL DIETARY ASSESSMENT SHEET)

- WEIGHT LOSS IN LAST THREE MONTHS (NON INTENTIONAL) ☐
- BODY MASS INDEX BELOW 19 ☐
- POOR APPETITE/INTAKE (MANAGING LESS THAN HALF OF THREE MEALS A DAY) ☐
- HIGH EXUDATE FROM LEG ULCER/CELLULITIS/INFECTION ☐

**ULCER HISTORY:**

(PLEASE TRACE ULCER AND ATTACH WITH WOUND ASSESSMENT FORM)

		RIGHT LEG		LEFT LEG		ANKLE MOBILITY		RIGHT		LEFT	
DURATION OF PRESENT ULCER (MONTHS)		2 months				FULL		✓			
TIME SINCE FIRST ULCER APPEARED (YEARS)		At age 35years				RESTRICTED					
NUMBER OF EPISODES		4				FIXED					
<b>SURROUNDING SKIN</b>			R	L	<b>ULCER BASE</b>				R	L	
INTACT					FLAT				✓		
DRY ECZEMA					'PUNCHED OUT'						
WET ECZEMA					EPITHELIALISING						
CELLULITIS		✓			GRANULATING						
MACERATION		✓			LOOSE SLOUGH				✓		
LYMPHOEDEMA					SLOUGH WITH SOME GRANULATION				✓		
OEDEMA		✓			HARD, YELLOW SLOUGH						
BLANCHED					HARD, BLACK SLOUGH						
EXCORIATED					INFECTED						
SHINY					TENDONS VISIBLE						
HARD					HIGH EXUDATE				✓		
					MODERATE EXUDATE						
					ROLLED EDGE						

**ANKLE CIRCUMFERENCE:**

RIGHT  
24.5cms

LEFT  
23cms

DATE: 7/3/02

DATE: 7/3/02

RESTING PRESSURE INDEX: POSITION OF PATIENT DURING DOPPLER = Recumbent

DOPPLER (INSERT PRESSURE)	RIGHT	LEFT	TRI-PHASIC/BI-PHASIC/MONO-PHONIC SOUNDS?
BRACHIAL	140	140	
DORSALIS PEDIS	142	140	Bi-phasic
POST TIBIAL	150	148	Bi-phasic
ABPI	1.07	1.05	

**NOTE:**

CLINICAL FINDINGS TOGETHER WITH ABPI AND DOPPLER SOUNDS MUST BE CONSIDERED BEFORE DIAGNOSIS IS MADE

**NURSING DIAGNOSIS OF AETIOLOGY OF ULCER**

VENOUS/ ARTERIAL/ MIXED AETIOLOGY/  
TRAUMATIC/ DIABETIC/ RHEUMATOID/ VASCULITIC/  
OTHER\_\_\_Sickle cell leg ulceration

**PLAN OF ACTION**

REMEMBER TO CHOOSE THE APPROPRIATE BANDAGE SYSTEM BASED ON ANKLE CIRCUMFERENCE

Topical antimicrobial for infection management  
Foam secondary dressing due to high exudate  
3 layer compression therapy bandage

REFERRALS:

DATE:

INFORMATION GIVEN TO PATIENT:

VERBAL ☐

WRITTEN ☐

ASSESSMENT MADE BY  
C Dowsett

DATE  
7/3/02

PRINT NAME

## **APPENDIX 3**

### **WOUND ASSESSMENT AND EVALUATION FORM**

## WOUND ASSESSMENT & EVALUATION FORM

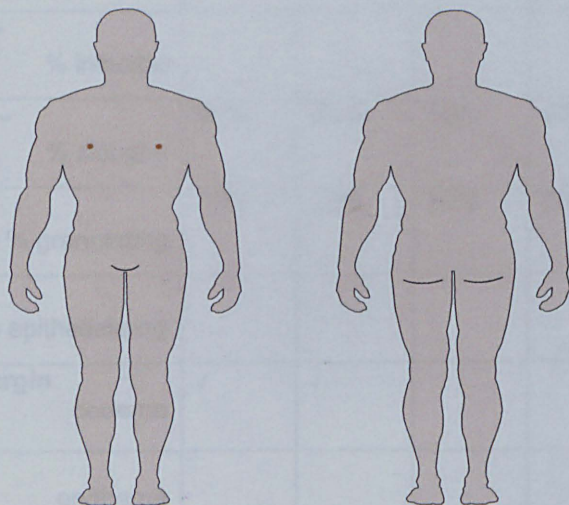
 Patient Name: Chris Obeh

 Date of birth: 39years

 Assessment date: 7/3/2002

 Named nurse: CDowsett

### Location of wound:



### Type of wound:

- ☐ Pressure Ulcer
- ☒ Leg Ulcer
  - ☐ Venous
  - ☐ Arterial
  - ☐ Mixed
- ☐ Diabetic Ulcer
- ☐ Traumatic wound
- ☐ Skin tear / laceration
- ☐ Burn / scald
- ☐ Surgical wound
- ☐ Fungating lesion
- ☒ Other (please state)  
Sickle cell leg ulceration

**Cause of Wound** (e.g. pressure, shear, trauma, shoes, etc.) trauma to skin with underlying sickle cell disorder

**Wound Duration** (e.g. age of wound) 2 months

### Factors which could delay healing

- |  |  |
|--|--|
| <input type="checkbox"/> Immobility              | <input checked="" type="checkbox"/> Anaemia      sickle cell |
| <input type="checkbox"/> Diabetes                | <input type="checkbox"/> Circulatory disorders               |
| <input type="checkbox"/> Poor nutritional status | <input type="checkbox"/> Respiratory disorders               |
| <input type="checkbox"/> Dehydration             | <input type="checkbox"/> Allergies                           |
| <input type="checkbox"/> Incontinence            | <input type="checkbox"/> Other                               |
| <input checked="" type="checkbox"/> Infection    |  |

### Dressing regime (tick primary and secondary)

- |                                       |   |
|---------------------------------------|---|
| <input type="checkbox"/> Hydrogel     | <input type="checkbox"/> Foam                     |
| <input type="checkbox"/> Alginate     | <input checked="" type="checkbox"/> Antimicrobial |
| <input type="checkbox"/> Hydrofibre   | <input type="checkbox"/> Semi-permeable           |
| <input type="checkbox"/> Hydrocolloid | Compression bandages applied: 3 layer             |
| <input type="checkbox"/> other        |   |



**WOUND EVALUATION**

Please enter amount or tick as appropriate

Week Date	Start 7/3	1 21/3	2 2/4	3 10/4	4 8/5	5 18/6	6	7	8
<b>Wound</b> Length in cm	6.5cm x 5cm	5cm x 5cm	5cm x 5cm	4cm x 4cm	4cms x 3.5cm	3.5cm x 3cm			
Width in cm	5cm x 4cm	4cm x 3.5cm	4cm x 3cm	3cm x 3cm	3cm x 3cm	2.5 cm x 2.5			
Depth in cm	superfi cial	superfi cial	superfi cial	superfi cial	superfi cial	superfi cial			
<b>Black ~</b> % necrotic									
<b>Green ~</b> % infected									
<b>Yellow ~</b> % sloughy	90%	70%	50%	50%	40%	30%			
<b>Red ~</b> % granulating	10%	30%	50%	50%	60%	70%			
<b>Pink ~</b> % epithelialising									
<b>Wound margin</b> oedema	✓	✓							
erythema									
macerated	✓								
healthy / intact									
<b>*Wound exudate</b> high	✓	✓							
moderate			✓	✓	✓	✓			
low									
<b>Wound odour</b> (yes / no)	yes	yes	no	no	no	no			
<b>Pain [at dressing change]</b> (yes / no)	yes	yes	no	no	no	no			
<b>Dressing Frequency</b>	3 per week	2 per week	2 per week	1 per week	1 per week	1 per week			
<b>Signature / initials</b>	CD	CD	JN	CD	CD				



## **APPENDIX 4**

### **LEG ULCER PHOTOGRAPHS**

# Case study photographs



## **APPENDIX 5**

### **TIME TABLE**



## TIME\*\* - Principles of Wound Bed Preparation

CLINICAL OBSERVATIONS	PROPOSED PATHOPHYSIOLOGY	WBP CLINICAL ACTIONS	EFFECT OF WBP ACTIONS	CLINICAL OUTCOME
<b>TISSUE NON-VIABLE OR DEFICIENT</b>	Defective matrix and cell debris impair healing	Debridement (episodic or continuous) <ul style="list-style-type: none"> <li>■ autolytic, sharp surgical, enzymatic, mechanical or biological</li> <li>■ biological agents</li> </ul>	Restoration of wound base and functional extra-cellular matrix proteins	Viable wound base
<b>INFECTION OR INFLAMMATION</b>	<i>High bacterial counts or prolonged inflammation</i> ↑ inflammatory cytokines ↑ protease activity ↓ growth factor activity	<ul style="list-style-type: none"> <li>■ remove infected foci</li> <li><i>Topical/systemic</i></li> <li>■ antimicrobials</li> <li>■ anti-inflammatories</li> <li>■ protease inhibition</li> </ul>	<i>Low bacterial counts or controlled inflammation:</i> ↓ inflammatory cytokines ↓ protease activity ↑ growth factor activity	Bacterial balance and reduced inflammation
<b>MOISTURE IMBALANCE</b>	Desiccation slows epithelial cell migration  Excessive fluid causes maceration of wound margin	Apply moisture balancing dressings  Compression, negative pressure or other methods of removing fluid	Restored epithelial cell migration, desiccation avoided  Oedema, excessive fluid controlled, maceration avoided	Moisture balance
<b>EDGE OF WOUND – NON ADVANCING OR UNDERMINED</b>	Non migrating keratinocytes  Non responsive wound cells and abnormalities in extracellular matrix or abnormal protease activity	Re-assess cause or consider corrective therapies <ul style="list-style-type: none"> <li>■ debridement</li> <li>■ skin grafts</li> <li>■ biological agents</li> <li>■ adjunctive therapies</li> </ul>	Migrating keratinocytes and responsive wound cells. Restoration of appropriate protease profile	Advancing edge of wound

## **APPENDIX 6**

### **MEMBERS OF THE INTERNATIONAL ADVISORY BOARD FOR WOUND BED PREPARATION**



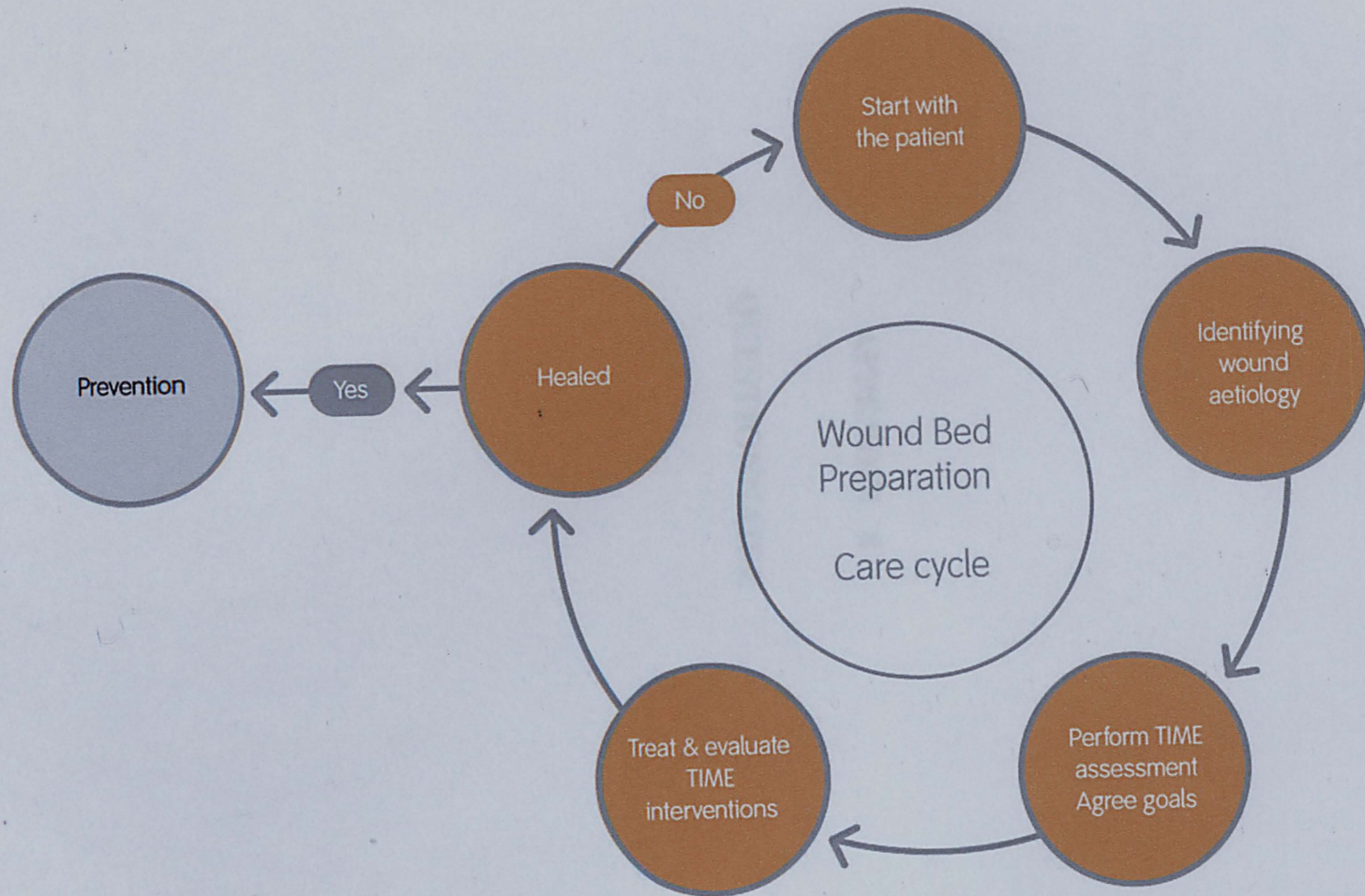
**Members of the International Advisory Board for  
Wound Bed Preparation**

Gregory Schultz, PhD	Dept of Obstetrics and Gynaecology University of Florida
Professor Gary Sibbald	Dept of Medicine, University of Toronto Canada
Vincent Falanga, MD	University School of Medicine Boston
Elizabeth Ayello, PhD	Division of Nursing, New York University
Caroline Dowsett, MSc	Nurse Consultant, Newham PCT London
Professor Keith Harding	Dept of Medicine, University of Wales
Marco Romanelli, MD	Dept of Dermatology, University of Pisa Italy
Mike Stacey, MD	Fremantle hospital, Australia
Luc Teot, MD	Montpellier University, France
Wolfgang Vanscheidt, MD	University of Freiburg, Germany

## **APPENDIX 7**

### **WOUND BED PREPARATION CARE CYCLE**

## Wound Bed Preparation - TIME in context



## **APPENDIX 8**

### **QUESTIONNAIRE**

## Wound Bed Preparation & TIME

### Wound Care Questionnaire

1. How many patients on your current caseload have a wound?

--

2. Of these how many have the following  
(Please insert a number in each box)

Leg ulcer  
Pressure ulcer  
Diabetic foot wound  
Post operative wound  
Fungating wound  
Burn  
Other


If other please state \_\_\_\_\_

3. Approximately how many of your daily patient visits  
are to carry out wound care?  
(Please tick one box only)

1 - 5  
6 - 10  
11 - 15  
16 - 20


4. On average how much time do you spend with each patient having a  
wound care per visit?

10 – 20minutes  
20 - 30 minutes  
30 - 60minutes  
60 – 90 minutes  
more than 90 minutes


5. List the factors you would assess when you first visit a patient with a  
wound?



6. List five methods used to debride wounds?

7. Which method do you mostly use to debride wounds?

8. Would you debride the following wounds and if yes which method would you use?

a)

yes


no

method \_\_\_\_\_



If no how would you manage the wound?

---

b)

yes


no

method \_\_\_\_\_



If no then how would you manage the wound?

---

**9. What factors increase the risk of a patient developing a wound infection?  
(please list *up* to 5 factors)**

**10. What signs would indicate that a patient had a wound infection?**

**11. What symptoms would indicate that a patient had a wound infection?**

**12. What treatments would you use to treat infection?**

**a) Local infection**

---

**b) Systemic infection**

---

**13. What interventions do you use to manage excess wound exudate? (Please list  
*up* to 5 interventions)**

**14. What factors that you think are important when selecting a wound dressing for a patient? (Please list in order of priority)**

**15. What methods do you currently use to measure wound progress? (List in order of most frequently used)**

Tracing

Photography

Measure length and width with ruler

Measure depth with probe

Estimate from judgement

Other


If other please describe \_\_\_\_\_

**16. On visual inspection of these wounds what do you think might be impeding healing?**

a) Healing impaired because \_\_\_\_\_

\_\_\_\_\_



b) Healing impaired because \_\_\_\_\_

\_\_\_\_\_



**17. What other factors do you think can delay wound healing? (Please list *up* to 6 factors)**

**Thank you for taking the time to complete this questionnaire.  
Please return in the envelope provided to  
Caroline Dowsett  
Tissue Viability Services  
4<sup>th</sup> floor  
Francis House  
Barking Road  
Plaistow E13**

## **APPENDIX 9**

### **OBSERVATION SCHEDULE**



**WOUND BED PREPARATION  
Observation Schedule  
POST TRAINING VISITS**

**Nurses Code:**  
**Patient Code:**  
**Wound Type:**

**Date of Visit:**  
**Duration of Visit:**  
**Frequency of visits:**

Question/Observation	Yes	No	Comment
<b>Has the patient had a full assessment? Including (score 1-5)</b>  <b>Past medical history</b> <b>Current history</b> <b>Pain</b> <b>Mobility</b> <b>Nutritional status</b> <b>Medication</b> <b>Effect of the wound on daily living</b>  <b>1 = not recorded in notes</b> <b>2 = recorded in notes</b> <b>3 = recorded in notes &amp; discussed with patient</b> <b>4 = action plan documented in notes</b> <b>5 = progress monitored and evaluated</b>			
<b>Has a wound diagnosis been made?</b> <b>Leg ulcer: Doppler done/when</b> <b>Pressure ulcer: Risk assessment done</b> <b>Diabetic foot: Sensory impairment measured</b>			

<b>Has underlying cause been addressed?</b> <b>How?</b>			
<b>Have disease factors that delay wound healing been identified if applicable</b> <b>Diabetes</b> <b>Rheumatoid arthritis</b> <b>Peripheral vascular disease</b> <b>Anaemia</b> <b>Autoimmune disease</b> <b>Use of immunosuppressive drugs</b> <b>Use of systemic steroids</b>  <b>(Adapted from Schultz et al 2003)</b>			
<b>Has the patient had a wound assessment?</b> <ul style="list-style-type: none"> <li>• <b>Assessment form completed</b></li> <li>• <b>Wound measured/How</b></li> <li>• <b>Record of dressing change</b></li> <li>• <b>Frequency of re-assessment</b></li> </ul>			
<b>'T' Is non-viable tissue present in the wound?</b> <ul style="list-style-type: none"> <li>• <b>Is non-viable tissue present?</b></li> <li>• <b>Has this been identified/recorded as a problem</b></li> <li>• <b>Debridement choice</b></li> <li>• <b>Nursing intervention</b></li> </ul>			

Question/Observation	Yes	No	Comment
<p><b>'I' Is there clinical evidence of infection?</b></p> <ul style="list-style-type: none"> <li>• local infection</li> <li>• systemic infection</li> <li>• Has this been identified/recorded as a problem</li> <li>• Has a wound swab been taken</li> <li>• Is the patient on antibiotics</li> <li>• Are topical antimicrobials being used</li> <li>• Other nursing intervention</li> </ul>			
<p><b>'M' Is there an "M" moisture imbalance?</b></p> <ul style="list-style-type: none"> <li>• Too wet</li> <li>• Too dry</li> <li>• Has this been identified/recorded as a problem</li> <li>• Has the underlying cause been identified</li> <li>• Nursing intervention</li> </ul>			

Question/Observation	Yes	No	Comment
<p><b>'E' Is the edge of the wound advancing?</b>  <b>If No has this been identified/recorded as a problem</b></p> <ul style="list-style-type: none"> <li>• <b>Undermining present</b></li> <li>• <b>Recorded as a problem/ nursing action</b>  <b>Hyper-proliferation at wound edge</b></li> <li>• <b>Recorded as a problem/nursing action</b></li> <li>• <b>Reduction in wound size in last 4 weeks</b></li> <li>• <b>How has this been measured</b></li> </ul>			
<p><b>Has the patient been referred to the multidisciplinary team?</b></p> <ul style="list-style-type: none"> <li>• <b>TV Services</b></li> <li>• <b>GP</b></li> <li>• <b>Vascular</b></li> <li>• <b>Dermatology</b></li> <li>• <b>Other</b></li> <li>• <b>Not relevant</b></li> </ul>			

## **APPENDIX 10**

### **ETHICAL APPROVAL**



# East London & The City HA Local Research Ethics Committee 3

## LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	05/Q0605/87	Issue number:	1	Date of issue:	24 June 2005
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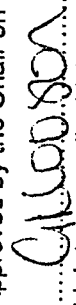
Chief Investigator:	Mrs Caroline Dowsett
---------------------	----------------------

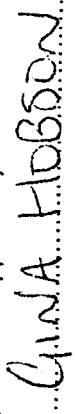
Full title of study:	Chronic wound management and wound bed preparation
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This study was given a favourable ethical opinion by East London & The City HA Local Research Ethics Committee 3 on 16 June 2005. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	Post	Research site	Site assessor	Date of favourable opinion for this site	Notes <sup>(1)</sup>
Mrs Caroline Dowsett	Nurse Consultant	Tissue Viability Services Newham Primary Care Trust	East London & The City HA Local Research Ethics Committee 3	24/06/2005	

Approved by the Chair on behalf of the REC:


  
 (delete as applicable)


  
 Gina A. Hobson (Name)

(Signature of Chair/Administrator)

**Title: Utilizing the TIME framework to improve community nurses wound care knowledge and practice: An experimental study.**

**Caroline Dowsett MSc, BSc (Hons), Dip N, RGN**

**Nurse Consultant, Tissue Viability**

**Newham Primary Care Trust**

**Tissue Viability Services**

**4<sup>th</sup> Floor Francis House**

**760-762 Barking Road**

**Plaistow**

**London**

**E13 9PJ**

**Telephone: 0208 271 1315**

**E-mail: [caroline.dowsett@newhampct.nhs.uk](mailto:caroline.dowsett@newhampct.nhs.uk)**

## **APPENDIX 11**

### **RESEARCH AND DEVELOPMENT TRUST APPROVAL**

# Newham

## Primary Care Trust



Wendy Thomas  
Director of Nursing & Clinical Governance  
Plaistow Hospital  
Samson Street  
London E13 9EH

Tel: 020 8586 6296  
Fax: 020 8586 6382

Email: [wendy.thomas@newhampct.nhs.uk](mailto:wendy.thomas@newhampct.nhs.uk)

Our Ref: LB/WT443.doc

20<sup>th</sup> April 2005

Caroline Dowsett  
Nurse Consultant  
Tissue Viability Department  
Francis House

Dear Caroline

**Re: Doctorate Research on Chronic Wound Management and Wound Bed Preparation** Ref: 05/0605/87

Newham Primary Care Trust are pleased to act as sponsor for the above research project, which you are undertaking as part of your Doctorate in Health studies.

I am sure the proposed educational intervention will contribute to improving care for patients with chronic wounds, by improving the knowledge and skills of community nurses.

I wish you every success with the project.

Yours sincerely

**Wendy Thomas**  
Director of Nursing & Clinical Governance

## **APPENDIX 12**

### **COMMUNITY NURSE MANAGER APPROVAL**



**Newham**  
Primary Care Trust



Caroline Dowsett  
Nurse Consultant  
Francis House  
760-762 Barking Road  
London  
E13 9PH

Locality Services  
Lister II Ward  
Plaistow Hospital  
Samson Street  
London E13 9EH

Tel No. 020 8586 6405 / 6  
Fax No. 020 8586 6420

20 April 2005

Dear Caroline

Thank you for attending the Area Service Manager meeting on Monday 18<sup>th</sup> April to explain your research to us.

It sounds like a useful piece of work for the service, and I am happy for the research to go ahead within the district nursing service.

Please keep me informed of progress.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Eileen Bryant', with a stylized flourish at the end.

Eileen Bryant  
Acting Assistant Director Primary Care

## **APPENDIX 13**

### **NURSE INFORMATION AND CONSENT**

## **Doctorate in Health Studies**

### **Information and Consent for Community Nurses**

**Research title:** Chronic wound management and Wound Bed Preparation

**Research question:** Will providing an educational programme on the concept of Wound Bed preparation and the TIME framework improve community nurses knowledge and skills in the assessment and management of patients with chronic wounds?

**Purpose of the research:** To determine if an educational programme in chronic wound management will improve community nurse's current knowledge and skills in assessing and management of patients with chronic wounds.

The research will involve

- The researcher (C Dowsett) accompanying you on visits to patients having wound care, to observe practice before and after the introduction of an educational programme
- Completing a questionnaire which takes approximately 15-20 minutes on the subject of wound care, before and after the introduction of the programme
- Attending two half day educational sessions on the subject of Wound Bed Preparation

Any information you give will remain anonymous and will be treated in the strictest of confidence. You will be free to withdraw from the study at any time, without explanation or any negative impact. You will receive feedback on completion of the research and the work will be submitted for publication in a peer review journal.

Caroline Dowsett  
Nurse Consultant  
Tissue Viability

---

I \_\_\_\_\_ (community nurse) agree to take part in this research study, as outlined in the above information. I understand that participation is voluntary and that I can withdraw from the study at any time.

**Name:**

**Signature:**

**Date:**

## **APPENDIX 14**

### **PATIENT INFORMATION AND CONSENT**

**Doctorate in Health Studies**

**Information and Consent for Patients**

**Research title:** Chronic wound management and Wound Bed Preparation

Dear \_\_\_\_\_

I work for Newham PCT as a tissue viability nurse. I am undertaking a research project into how community nurses manage chronic wounds such as leg ulcers and pressure ulcers. This involves carrying out visits with the nurses to observe practice, before and after they attend a programme of study on wound care. Your nurse has agreed to take part in this research and I am writing to ask if you for your permission to accompany your nurse when she visits you to dress your wound.

Your identity will not be disclosed in the study and any information you give will remain anonymous. If at any time during the visit you no longer wish to be involved then you can withdraw without an explanation.

I hope that the research will give an insight into wound care practices in Newham PCT and contribute to improving the way in which community nurses assess and manage chronic wounds.

Caroline Dowsett  
Nurse Consultant  
Tissue Viability

---

I \_\_\_\_\_ (patient of community nurse) agree to take part in this research study, as outlined in the above information. I understand that participation is voluntary and that I can withdraw from the study at any time.

**Name:**

**Signature:**

**Date:**