Understanding dressing evaluation: a pragmatist perspective

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ABSTRACT

This thesis shed light on the complexities of dressing evaluation. Dressings are categorised as medical devices and as such manufacturers are not required to provide evidence of effectiveness. Instead, they promote their products by offering clinicians samples to try during their clinical work.

Researchers using trial methodologies have been unable to provide a clinically helpful body of evidence. Placed within the movement critiquing Evidence-Based Practice, this thesis brings the discussion to the world of dressing evaluation, where an alternative methodology is proposed. This study takes inspiration from John Dewey's pragmatic philosophy; based on experimentalism, clinician's experience is given a key place within a structured inquiry and offers a vision for the development of this important branch of wound care. This offers a unique contribution to knowledge.

In order to understand the world of dressing evaluation, the study begins with the collection of qualitative data, with focus group and interviews with seven Tissue Viability Nurses and two Pharmacists. Having gained an insight into the way dressing evaluations are undertaken in clinical practice, the data inform a subsequent, mixed-methods study, with participant observation, interviews and review of documents take place with ten patients, thirty-one nurses, one orthopaedic surgeon and five trauma sisters. Using this newly designed methodology, a PHMB foam dressing is evaluated in the care of pin sites, enabling the development of a clinical protocol that has since been adopted regionally. This offers a unique contribution to practice.

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> *The two limits of every unit of thinking are a perplexed, troubled, or confused situation at the beginning, and a cleared up, unified, resolved situation at the close.*
>
> *John Dewey (1933, p106)*

- Dr Andrew Melling, for his early supervision.
- My line manager, Mrs Frances Blackburn for her continuous support and encouragement.
- My husband Mike, for doing exactly what needed to be done.
- My fellow Tissue Viability Nurses; this work is dedicated to you.

DECLARATION

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Any ethical clearance for the research presented in this thesis has been approved. Approval has been sought and granted by:

a) University of Northumbria Ethics Committee on the 22nd June 2012.
b) NHS Research Ethics on the 22nd December 2012.

Copies of the above letters are available on request; they have not been included in this manuscript.

I declare that the word count of this thesis 58,768 words.

Name: Fania Pagnamenta

Signature:

Date: 30th January 2016

Understanding dressing evaluation: a pragmatist perspective

There is no discipline in the world so severe as the discipline of experience subjected to the tests of intelligent development and direction.

John Dewey (1938b, p61)

LIST OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

Introduction to the thesis

Education is not preparation for life; education is life itself.

John Dewey (1938b, p52)

A PROFESSIONAL, PHILOSOPHICAL AND LITERARY JOURNEY

This Professional Doctorate thesis is a study into how we evaluate wound care dressings. Like all academic endeavours, this has been a journey; a professional, a philosophical and a literary journey.

Professional Journey

I am a nurse who has specialised in wound care. My job title is 'Nurse Consultant in Tissue Viability'. Tissue viability is a relatively new discipline which started in the 1980s and has been defined as *"a speciality that primarily considers all aspect of skin and soft tissue wounds including acute surgical wounds, pressure ulcers and all forms of leg ulceration"* (Tissue Viability Society 2014).

My role is corporate and autonomous. I lead a small team of clinical nurse specialists in a large tertiary Trust. As a nurse consultant, I spend fifty percent of my time in clinical practice and provide expert wound care for a number of patients with complex needs. The rest of my time is spent on service development, teaching and auditing practice. Of all the different facets of my role, wound care is the most

challenging as in order to deliver wound care, I have to select dressings from the extensive range available on the market. Evidence-based practice should underpin this choice but the reality is that most of my decisions are based on intuition, unsystematic clinical experience and pathophysiological rationale.

One of our roles is to develop a Wound Management Formulary, which is then updated every two to three years. The role of tissue viability is to select a clinically acceptable range of dressings that can treat most types of wounds and then work with procurement to negotiate the best price possible.

Working in a tertiary care provider means that our patients are referred to our establishment from neighbouring communities to which they will return once ready to be rehabilitated or to go home; therefore, any dressing regime that is prescribed in hospital has to be available in primary or secondary care. However, this is not always the case, for two reasons: clinically, patients who are nursed in smaller district hospitals tend to have less complex wounds and therefore they will not stock some of the more specialised dressings. Secondly, from a procurement point of view, big hospitals have stronger buying power and they can negotiate rebates with industry (Department of Health 2013). Despite being in the National Health Service (NHS) where prices should be the same across the land, smaller hospitals pay much more for their dressings than larger establishments and this directly affects dressing availability and ultimately patients' care.

By law, wound care dressings are listed under a section called Medical Devices (Cohen and Billingsley 2011), alongside items such as urinary catheters, nasogastric feeding tubes and so on. What this means in practice is that wound care dressings are CE marked and safe to be used in the context for which they have been designed for, but the manufacturers are not required to provide evidence of

efficacy or effectiveness[1]. Consequently, there is little incentive for industry to fund large trials similar to those required with medicines (Madden 2012). This legislation has hindered the development of research in this field, as this thesis will explore.

The selection of dressings that are available to clinicians continues to proliferate as companies want a share of a very lucrative market, with a turnover estimated at 1bn (Department of Business, Innovation and Skills 2014). Companies heavily market their products and employ representatives to promote them (Faulkner 2009). Clinicians who like the look of a new dressing may decide to 'have a try' on a few patients. This haphazard approach to dressing evaluation has created many criticisms to wound care practitioners who have often been accused of bias by competitor companies, by academia and increasingly by commissioning groups. The latter are interested in keeping costs down and see no benefits in using expensive dressings when the evidence for their use is so scant.

Madden (2012) employed a case study method using participant observation to produce a content analysis of a wound care conference that is held yearly in the United Kingdom (UK). This method has been used in medical anthropology to report on similar conferences (Sufrin 2008). Madden's (2012) analysis of the conference makes for a difficult read to those clinicians who have professionalism and ethical conduct at the core of their practice. In the above account, concerns are raised about the extent of industry's influence in knowledge production. Madden (2012) infers that we are too heavily influenced by an industry that promotes dressings using marketing techniques rather than evidence of efficacy.

My journey started with the launch of a new dressing, a foam disc impregnated with an antimicrobial solution. When the manufacturer's representative approached me

[1] The terms 'efficacy', 'efficiency' and 'effectiveness' are often used synonymously which is not technically correct, more detail is offered on page 108.

to try the new dressing on a few patients, I decided to undertake a 'proper' evaluation as a form of protection from those criticisms levelled at my speciality.

This foam disc is designed to fit around tubes or pins that are inserted through the skin for a range of treatments (see Chapter 6, p114 for more information). The manufacturer specifically promotes its use on external fixators, which are devices used to stabilise complex bone fractures in adults and children following traumatic injury (Bernardo 2001). External fixators are used to maintain the correct alignment of the broken bone until the bone heals and they can be in place for many months. The pin site is the area where the pin meets the skin (Bell et al. 2008).

Being aware that pin site care was causing concerns to colleagues in the trauma-orthopaedics wards, in terms of achieving a balance between controlling infection and skin care, the arrival of this new dressing was very welcome. My initial thoughts were to design a mixed method study that would take into account the four essentials aspects that are of usual interest when dressings are evaluated: does the dressing work; does the patient like it; do the staff like it and how much will it cost?

Data were to be collected through four self-contained studies: a small Randomised Controlled Trial (RCT) which was going to run alongside a patients' survey and a staff survey. Cost examination was to form the final aspect under study.

As per standard research protocol (Trafford and Leshem 2008), the available literature on pin sites was reviewed (see Chapter 6, p114). This literature revealed that there was an absence of methodologically robust RCTs in this area of care and much of what had been published were either descriptions of local protocols that clinicians had found to be effective in their own practice (Wood 2001; Davis 2003; Talbot et al. 2005) or case studies (Verettas et al. 2008). Temple and Santy (2004) performed the first Cochrane Database Systematic Review on the topic, which uncovered only two research articles that were considered of sufficient quality for inclusion. Lethaby et al. (2008) updated this review and six further trials were identified for inclusion, however all these studies were shown to be flawed and the

authors were unable to make a single clinical recommendation. External fixators had been used since the early 1950's (Spiegelberg et al. 2010), so why was there so little evidence?

Philosophical Journey

The biggest challenge I have faced in terms of designing this study has been to reconcile the relationship between my professional experience and the expectations of my work environment. As a nurse, I have been taught to value empirical knowledge above all, rooted in positivism with a purist approach (Billay et al. 2007). This approach is engrained in all healthcare professionals as the single methodology that offers credibility in the work place, academia, strategic and policy-making level.

A study aiming at finding out the efficacy of a dressing was expected to be using a positivist method. However, experience told me that our patients were all different, with differing co-morbidities and our surgeons and nurses were all different, with differing skills and clinical techniques. How could my professional experience reconciliate an alternative method of enquiry *and* provide academic and clinical credibility?

I started to think about what kind of data I needed to collect. A study revolving around wound care dressings was necessarily a study of both the scientific aspect of a dressing usefulness in clinical practice (*'Does it do what it says on the tin?'*) and the subjective elements that influenced how well a dressing performs, such as the nurses' skills and patients' individual activities of living. I wanted to collect data from each aspect of care and give them all the same weight as I felt they were all equally important.

I realised that all potential participants would be making individual judgements about the effectiveness of a dressing, based on tier personal and professional experiences. Dewey (1038a) assets that such judgments are never absolutely right

or wrong, but always situated within an influential context. Therefore, it became important for my research to explore the contexts within which my research participants might be making their decisions.

Positivism recommends the control of external influences on the phenomenon under study, and cold therefore no longer be suited to this enquiry. If positivism would not provide the perspective I wanted, what other philosophy would enhance dressing evaluation? A number of perspectives were explored.

Realist evaluation was one such perspective; its methodology is an approach grounded in realism, a school of philosophy which asserts that both the material and the social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change (Westhorp et al. 2011). Realist evaluation recognizes that there are many interwoven variables operating at different levels in society, thus this evaluation method suits complex social interventions, rather than traditional cause-effect, non-contextual methods of analysis (Pawson et al. 2004). Realist methods acknowledge that intervention programmes and policy changes do not necessarily work for everyone, since people are different and are embedded in different contexts. The emphasis on context is what made realist evaluation a viable contender at first.

Evaluation efforts for complex interventions are unlikely to establish firm linear causal relationships. Taking a step away from seeking to find if a programme works and moving towards highlighting the conditions necessary for success is crucial in complex intervention evaluation. The conventional approach to programme evaluation asks an effectiveness question (*'Does this programme work?'*) and seeks to quantify and/or describe the size of a programme's effect through controlled trials, systematic reviews or meta-analyses. With regards to dressing evaluations, there are a few examples in the literature (see p28). The realist approach, however, rests on the premise that social programmes only ever work for certain people in certain circumstances and the central task is to understand and explain these

patterns of success and failure. Realist researchers therefore ask an explanatory question: what is it about this kind of intervention that works, for whom, in what circumstances, in what respects and why (Pawson et al. 2004)?

At this point the focus of the study changed slightly and moved away from solely wanting to evaluate a dressing to studying the conditions within which dressings were being evaluated in practice. Realist evaluation no longer suited because the aim of this philosophical perspective would have been to evaluate a whole programme of care ('*What is about a dressing that works, for whom and in what circumstances?*') rather than gaining an understanding of one aspect of care ('*How can dressings be evaluated in the context under study?*'). I had to look at the problem from a completely different perspective.

For the same reasons, emerging concepts such as Improvement Science, Implementation Science, Translational research, Science of Quality Improvement to cite just a few, were also rejected. These concepts inhabit the sphere between research and quality improvement by applying research methods to help understand what impacts on quality improvement (Damschroder et al. 2010). Additionally, the Medical Research Council (Graig et al. 2008, p11) offered a framework on how to design experimental studies set within complex evaluations (individually randomised trails; cluster randomised trials; stepped wedge designs; preference trials and the list goes on). These concepts were yet to be clearly defined when I commenced this study. Being mindful of Walshe (2009) referring to these methodologies as '*pseudo-innovations*', I feared that they might fail to resolve the core ontological problem I was faced with. This study inscribed itself within a broader endeavor to improve practice, but its immediate focus was to understand the decision-making process of my research participants with regards to dressing evaluation.

In my mind, dressing evaluation was more about the people (clinicians and patients) rather than the dressing performance itself; therefore, I looked for a perspective

that could encompass this aspect. Ethnography was the second philosophical perspective that was considered, with its concept of going out into 'the field' and describing a group of 'exotic' people, perspective which had evolved from anthropology (Gobo 2008). Early anthropologists conducting ethnography lived with small groups of people whose ways of life were greatly different from their own, to discover behaviour patterns and knowledge systems as in the work of Malinowski (1884-1942), the founder of this methodology. Ethnography concentrates on the in-depth exploration of small groups of people to understand how they organise their daily lives and how they view their world (Helman 2007). Within the sociological tradition, the aim of ethnography is to examine people's social relationships within their culture (Hakim 2006).

Ethnographies in health are conducted by anthropologists, sociologists, nurses, physicians, social workers, occupational therapist and other social scientist who provide a body of literature that reflects the relationship between cultural beliefs and health behaviours of community members and practitioners and the ability to study the cultures of specific illness and health processes (Morse and Field 1995).

In nursing, ethnography has been used extensively as there is an intrinsic resonance between nursing practice and ethnography. Field (1990) identifies similarities between investigators who conduct ethnographic research and nurses in clinical practice, such as good interaction with people, good listening skills, good observational skills and use of 'reflexivity' (see Chapter 3, p38).

Ethnography has been used to study nursing homes, working within a 'sub-culture' (expressed in ethnography terms, Hendson and Vesperi 1995) of people who find themselves in medicalised institutions at the end of their lives to study issues such as assessing different types of residential accommodation for the elderly (Hornum 1995); relationships between staff and relatives (Foner 1995) or how they adjust to living in an institution (Powers 1991). More recently, Harper (2006) uses ethnography in a study that explores post-operative pain assessment and how this

assessment can be influenced by the military nurses' cultural background. In wound care, ethnography has been used to explore how patients who have suffered extensive burns, live the daily dressing changes (Rudge 1998). In this study, participant (patient) observations are undertaken to establish whether there is a difference in their experiences when different nurses re-dress their burns.

Ethnography is an in-depth study of culture and whilst one of the aims was to understand the context of dressing evaluation, this was not the sole focus of this thesis; therefore, ethnography as a philosophical perspective was rejected. However, ethnography is not just a *way of seeing* (philosophical perspective) but is also a *way of looking* (methods) (Wolcott 1999). So, ethnographic techniques were borrowed and adapted to operationalise dressing evaluation as I settled for a pragmatic perspective drawn from the work of John Dewey (1859-1952) and adopted a pragmatic methodology to my study; pragmatism seemed to offer a viable alternative, giving me the flexibility to collect the data that I, as an experienced clinician, saw important, whilst offering a solid philosophical framework.

Dewey was one of the original founders of pragmatism (see Chapter 3, p38) and his work resonated with me. I wanted to underpin my study with the work of a philosopher that had not yet been influenced by positivism/post-positivism, so central to health; this will be explored further in Chapter 2 (p28).

Literary Journey

Positivist reasoning demands that writing presents clear, well-reasoned arguments to culturally like-minded readers. Its author is supposed to be distanced from and objective about the topic under study. It is writing that avoids references to a self or doubt or procedural ambiguities or personal vulnerabilities (Goodall 2012) and it is how I used to write.

As the research question moved from '*Do impregnated disc work on pin sites?*' to *'How are dressing evaluations undertaken in clinical practice?' and 'How else could they be evaluated?*', a positivist approach to writing was no longer suitable; it could no longer be presented as a set of discrete and logical steps or stages (i.e. planning, access, data collection, analysis, writing up, dissemination) but as a whole event occurring over time, where stages merged and were not sequential.

My literary journey reflects this research journey. Using language to describe reality is always limiting (Goodall 2000) as we construct a truth that is not the only truth. Reality is not reproduced, but is represented through an individual perspective. Goodall (2000) explains that we learn to see things as they are because we are born, raised and acculturated in a particular way and not another. Dewey (1911, p414) says that *"our tendency to ignore the influence of tradition as a controlling factor is due the fact that when we begin to develop new methods, tradition has already done its work so completely that [...] we develop projects within limits set by custom".* I am a Tissue Viability Nurse, who has lived and breathed dressing evaluation for over a decade. I have had experiences that have influenced my thinking and from which I cannot disengage. This insider-outsider relationship within my study is further described on page 166 but is also transparent throughout the thesis; considerations on reflexivity and trustworthiness have been included on each step of the way (Chapter 4, p91; Chapter 5, p111; Chapter 6, p159 and finally in Chapter 7, p176).

The reader will notice that I use different styles of writing throughout the thesis. Goodall (2000, p42) says "*describe before you analyse"*. The focus is to accurately represent and evoke what happens; framing it and detailing the contextual condition in all its complexity. When describing, I have used the present tense; when analysing I have used the past tense.

This work is also a professional endeavour. Producing a Professional Doctorate in a field of Nursing that is deeply clinical and that remains steeped in the traditions of

Medicine, has somewhat limited my creativity; my work has to be acceptable to those whom I wish to share my contributions to knowledge with. Nevertheless, I want to acknowledge that my thoughts, ideas and beliefs were partisan to my work. My writing aims to dissolve any idea of distance. It does not aim to produce 'empirical findings', but instead it aims to provide evidence of a different nature (see Chapter 2, p28). It is credible because it is self-reflexive and offers authority only because it is richly vulnerable.

This thesis has elements that are not generalizable, such as the findings on PHMB foam disks, which have nevertheless assisted in the development of a new clinical protocol; this protocol has been adopted regionally and constitute my unique contribution to practice. Conversely, some elements are very generalizable indeed, such as the approach to practice development, staff engagement and dressing evaluation underpinned by pragmatism. The latter constitute my unique contribution to knowledge.

THE RESEARCH QUESTIONS

The primary question was: *'How are dressing evaluations undertaken in clinical practice?'* and through the professional, philosophical and literary journey described above, five sub-questions emerged:

a. *Where is the evidence for dressing selection?*
b. *Which philosophical perspective could better understand the complexities of dressing evaluation?*
c. *Who evaluates dressings in clinical practice and how are these evaluations being undertaken?*
d. *What elements ought to be included in a dressing evaluation?*
e. *How could a dressing evaluation be undertaken in clinical practice?*

The aims of this study were thus to gain an ontological understanding of this area of research well as to find a practical solution to a clinical problem.

Study design

The study was conducted in two phases. An initial qualitative data collection (focus group and interviews) with seven Tissue Viability Nurses and two Pharmacists (see Chapter 4, p51 and Chapter 5, p95) informed a subsequent, mixed-methods data collection (participant observation, interviews and review of documents) with ten patients, thirty-one nurses, one orthopaedic surgeon and five trauma sisters (see Chapter 6, p114).

Thesis Structure

Understanding dressing evaluation is like a jigsaw (Figure 1.1, p21); it involves placing each piece into a cohesive whole; it is about understanding the many forces that influence the choices that are made in clinical practice. Before answering the *how*, the *where, which, who* and *what* need exploration and each research question is addressed in turn, one chapter after the other, as detailed below.

The first piece of the jigsaw is a search for evidence in the field of dressing evaluation (see Chapter 2, p23). Through an exploration of the literature, an understanding starts to emerge as to the reasons behind the fact that there are so many dressings on the market and so little evidence to support their use. Four main reasons are given for the hampering of the development of a research methodology for dressing evaluation and will be discussed in some detail: clinical access to research and research funding; epistemological reasons and the influence that evidence-based practice and its positivist mind-set has on decision-making in health.

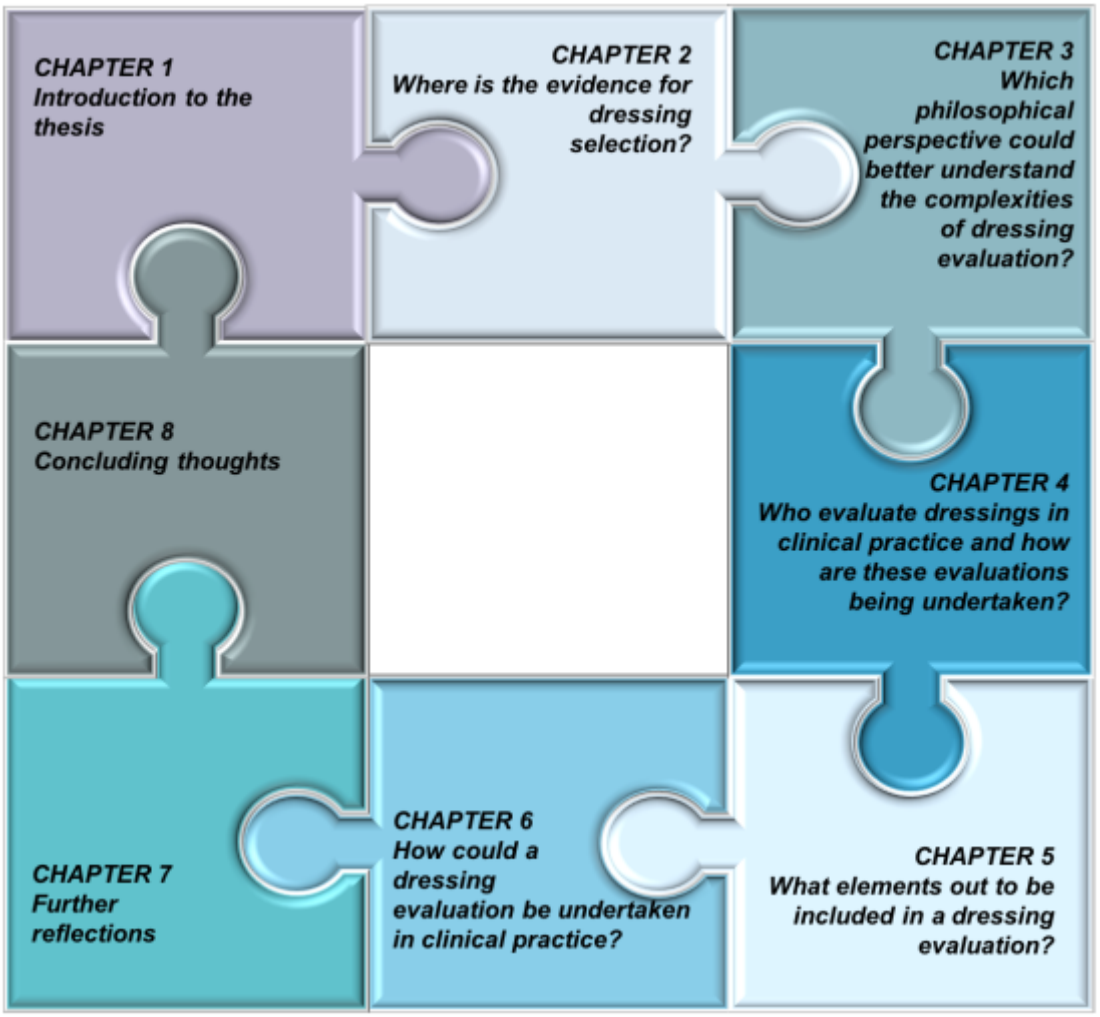

Figure 1.1*:* *Thesis structure*

Chapter 3 (p38), the second piece of the jigsaw, offers pragmatism as an alternative epistemology, specifically Dewey's brand of pragmatism as he believes that all endeavours should be *melioristic*, meaning that whilst one cannot guarantee that the enquiry will improve the situation, improvement is a real possibility. Pragmatism is a belief in what Dewey calls *experimentalism* and allowing experience to guide our inquiry. Pragmatism becomes the methodology for this study and this is described alongside the study design. True to its pragmatic foundation, a mix of methods are used to answer the research questions.

Chapter 4 (p51) sets out to answer who evaluates dressings and how these evaluations are been undertaken in clinical practice; they have the responsibility for procuring dressings for clinicians to use, so how do they justify the decision they make? These decision-makers have developed informal dressing evaluation frameworks based on elements they consider central to a 'good' dressing evaluation.

Chapter 5 (p95) explores these elements in some depth and the relevant elements are then experimentalised (set within a structure of differing methods of data collection) in Chapter 6 (p114). This chapter is about experiencing the application of Dewey's pragmatism in clinical practice where in the true spirit of pragmatism, methods are borrowed and adapted from ethnography. The foam discs given to me to 'have a try' (see p12) were evaluated in the care of pin sites.

Chapter 7 (p166) offers further reflections on whether experimentalism works in understanding the world of dressing evaluation. The original contributions to knowledge and practice are highlighted in Chapter 8 (p195) where some final thoughts conclude this thesis and frame the completed picture.

CHAPTER 2

Where is the evidence for dressing selection?

> *The path of least resistance and least trouble is a mental rut already made. It requires troublesome work to undertake the alteration of old beliefs.*
>
> *John Dewey (1933, p136)*

INTRODUCTION

The incidence of wounds in the UK population is considerable. Estimates suggest that there are more than three people with one or more wound per 1,000 of the population, of which 74% are being treated in community care and 21% in acute care (Drew et al. 2007); yet data on which dressing work best are scant (Polak et al. 2008). This chapter introduces some of the challenges that are encountered in the development of evidence for the utilisation of dressings in wound care.

Chapter Structure

An historical, cultural and literary background to the study is offered in the opening paragraphs of this chapter. Producing evidence for dressing selection has been challenged by a number of issues, such as balancing the competing demands of clinical research and practice; the lack of resources allocated to this topic; most importantly to the role that evidence based practice (EBP) has within health in generally and more specifically within nursing. This engenders an epistemological dilemma, which is discussed at the end of the chapter.

WOUND CARE, A NURSING ROLE

Wound care was one of the first tasks for nurses, particularly when caring for casualties of war (Maher 1999) and remained as such for decades, mostly under doctors' orders (Pijl-Zieber 2013). Dressing materials were simple and not always efficient; the outcome improved dramatically with the post-war use of antibiotics (Queen et al. 2004). At that time, it was thought that a wound would heal well if it was allowed to dry out and form a scab; Winter's (1962) seminal work on pigs, discovered that wounds healed best if kept moist. This finding revolutionised clinicians' understanding of wound healing.

Our understanding of the science behind wound healing has continued to develop, which has been described as *"a well-tuned orchestra where each instrument plays a key part in the process"* (Sen 2011, p518). Researchers have been working in laboratories to understand the science of wound healing and have applied some of their findings to the development of new dressings.

Dressing materials have become technologically advanced: some contain alginates (seaweed), some contain silver; some contain honey in varying percentages; some contain new applications of known antimicrobials; some have been layered with silicone to prevent adhesion to the wound; some absorb and some donate moisture and the list continues. Selecting a dressing is now a complex affair.

Wound dressing has remained a nursing task and the discipline has developed under the nursing umbrella; in fact, most wound care takes place without medical supervision. As selecting a dressing has become so complicated, medical teams rely heavily on their nursing colleagues to choose appropriate regimes for wound healing. Friman et al. (2010) report on a qualitative, descriptive study where in-depth interviews were conducted with eight experienced district nurses in Sweden. The organisation of healthcare is similar in the UK and the findings of this study are therefore relevant. Data from the interviews were analysed using qualitative content analysis and three main themes where identified: nurses felt responsible

for the delivery of wound care over their medical colleagues; they felt that they offered expert skills to wound care and they performed wound care in a less-than-optimal work environment (i.e. the patient's home). The study revealed that nurses believed that they had more skills in wound care than their medical colleagues. The GPs trusted their clinical judgement and skills, often due to their many years' experience in the field. Friman et al. (2010)'s findings are echoed in the UK and can be extended to hospital doctors, possibly with the exception of those who work within Burns and Plastics, Vascular and Dermatology.

Wound care teaching is limited in medical school. Patel et al. (2008) present the results of a retrospective study which was performed in the United States (US), the UK and Germany where data were obtained from medical schools. The total hours of required wound education received in the US was 9.2 hours in the 4 years of medical school; the UK, the total time devoted to wound-related issues equalled 4.9 hours over 5 years and in Germany, a total of 9 hours of wound education was provided over 6 years. The authors concluded that all three education systems were deficient in preparing future doctors to treat wounds.

Nurses' wound care training is also limited to a few hours, nevertheless they are exposed to wound care whilst on placement throughout their three years training (Ousey et al. 2013) and once qualified, wound care becomes a principal role. It is estimated for example that up to 66% of community nursing time is dedicated to the provision of wound care (O'Keeffe 2006; Clarke-Moloney et al. 2008). Wound care is no longer seen as a delegated task but a key responsibility for nurses for which they are held accountable (Nursing and Midwifery Council 2015). The support for those nurses who undertake day-to-day wound care comes from more senior, experienced and academically qualified nurses, usually TVNs, rather than medical staff.

EVIDENCE FOR DRESSING SELECTION

Dressings are listed as medical devices and the wound care industry is not required to provide evidence to support their use in clinical practice (Cohen and Billingsley 2011; Medicine and Healthcare Products Regulatory Agency 2015). Nurses have become proficient in choosing dressings for patients care on evidence defined by experience, rather than by empirical research. Using unpolished language, nurses have developed their expertise by 'having a try', rather than 'having a trial'. This reflects the way nurses develop some of their skills in clinical practice.

Thirty years after Benner (1984) first described how nurses move from being novices to experts in making decision about their patients' care, this process of expertise development has not lost its salience. Changes in performance occur in movement through the levels of skill acquisition: firstly, there is a movement from a 'reliance' on 'abstract principles and rules' to 'experience'; secondly it sees a shift from 'reliance' on 'analytical, rule-based thinking' to 'intuition'. Thirdly, there is a change in the clinician's perception of the situation from viewing it as a compilation of equally relevant factors to viewing it as an increasingly complex whole in which certain parts are seen as more relevant than others. Finally, there is a progression from a detached observer, standing outside of a situation, to a position of full involvement and engagement (Benner 1984).

In wound care, it is very easy to see the manifestations of each stage of this continuum: some nurses adhere very strictly to written protocols even when the wound fails to heal; others, in the middle of the continuum, would continue to use the initial protocol, but would ask for support from the specialist, whist a minority would be so experienced that they would use intuition to decide which dressings should be used instead. As the nurse gains experience, clinical knowledge becomes a blend of practical and theoretical knowledge, a blend of dressing preparations and wound healing theory.

This way of working defines nursing, but does not help new comers to the profession, especially when the protocols required by novices are not based on empirical evidence. Furthermore, with the large numbers of dressings available on the market today, the way these dressings are evaluated in clinical practice has been criticised by a number of authors (Al-Benna 2012; Weller and McNeil 2010 and Jeffcoate 2013) but none as vehemently as Madden (2012). Whilst she acknowledges that dressings are medical devices, she criticises clinicians for their unwillingness to seek better evidence for the products they use in clinical practice.

This raises the question of why nurses have not undertaken more research in dressing evaluation. On examination of the literature, it would appear that there are a number of reasons for this. Firstly, the practicalities of balancing clinical demands with research endeavours; secondly the limited financial resources available in this field; finally, the traditional epistemology that sees evidence-based practice central to 'quality' research and its predilection for trial methodologies. These reasons are explored in some depth below.

The Competing Demands of Clinical Research and Practice

The career pathway for nursing described in *Modernising Nursing Careers* (Department of Health 2006) sees four separate careers for nursing: clinical; managerial; educational or research. The development of the 'Clinical Academic Nurse' described by Coombs et al. (2012) has only recently started to emerge, where specialist nurses share time between clinical practice and university, which enables them to undertake research. The vision offered by Coombs et al. (2012) is somewhat rose-tinted and does not match, even remotely, to my experience in clinical practice. For example, they describe a ward sister studying for a Professional Doctorate: the reality is that a large number of our ward managers have yet to complete their first degree. The NHS does not routinely support ward sisters to undertake doctorate studies, in terms of paying university fees or offering study

leave. Medicine, on the other hand, has research strongly integrated to a doctor's career pathway and research activities are emphatically prioritised.

Lack of Resources

The opportunities for nurses to undertake research in the field of dressing evaluation are limited as funding is often not available. Under the current European regulatory framework for evaluating and regulating medical devices (CE marking), manufacturers are only required to demonstrate safety and fitness for purpose (Cohen and Billinglsey 2011) and do not require to be subjected to trials before being used in clinical practice. Furthermore, the manufacturing of dressings is an industry that operates in an open market where competition is seen as a positive step to reduce dressing prices (Propper et al. 2004). Angell (2005) explains that there are genuinely few innovations in wound care; industry introduces small deviations for what is essentially the same product, copying from each other and changing little more that surface feature or minor attributes. Arguably, some of these minor changes may be clinically significant and worthy of a clinical evaluation but without financial resources, this research is unlikely to be undertaken. Madden (2012, p2050) explains that once a dressing is launched onto the market, the incentives to conduct research on clinical use are reduced because research is expensive and seeking proof of efficacy threatens to remove lucrative products from the market.

The Role of Evidence-Based Practice in Wound Care

The conceptual model of integrating evidence in clinical practice was first introduced by the Evidence-based Medicine Working Group in 1992 (Fox 1993). They believed that there all healthcare providers should be required to base their interventions and activities on the most up-to date evidence of knowledge available (Fox 1993). As a concept, evidence-based practice (EBP) was meant to offer the integration of individual clinical expertise with the best available clinical evidence from systematic research (Bensing 2000; Pearson et al. 2007).

David Sackett (1996, p71) defined EBP as *"the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research."* Sackett's vision of EBP was the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Unfortunately, EBP has become to signify a clearly articulated hierarchy of scientific evidence based upon study design, where trial methodologies are regarded as the most scientifically rigorous method of evidence generation (Upshur and Colak 2003; Weller and McNeil 2010) and the basis for the development of healthcare policy and practice, such as Cochrane Database Systematic reviews (Chandler and Hopewell 2013); National Institutes for Clinical Excellence guidelines (Rawlins 2004) or the National Institute for Health research (Brouwers et al. 2010).

The debate regarding the value of what EBP has become in healthcare is not new (Smith and Pell 2003) and is persisting within a movement that unites academicians (Greenhalgh et al. 2014; Martin and Félix-Bortolotti 2014; Every-Palmer and Howick 2014; Hofmeijer 2014) with clinicians (Glogowska 2011; Greenhalgh 2012); some of these critiques are in wound care (Harding 2000; Leaper 2009; Grocott 2010); with regards to dressing evaluation, the issues surrounding EBP have been debated at wound care conferences (Harding et al. 2010) but have not been published in peer-reviewed literature. Possible ways forward have also yet to be proposed.

Trial Methodologies in Dressing Evaluation

Traditionally, trial methodologies have been considered the method of choice to produce evidence in wound care. A number of studies have been successful; for example, in establishing that compression bandaging is the gold standard for healing leg ulcers (O'Meara et al. 2009) or that patients who are kept warm during theatre will be less likely to develop post-operative wound infection (National Institute for Clinical Excellence 2008a, 2008b). However, it has become evident that trial methodologies have not been successful as methods for evaluating dressings

used on complex wounds and researchers who have tried have produced methodologically flawed studies (Horkan et al. 2009).

Not surprisingly therefore, systematic reviews which identify, critically appraise and synthesize the evidence produced in dressing selection, reveal a lack of studies of sufficient quality with a predominance of small, underpowered and methodologically flawed RCTs. Furthermore, the reviews' inclusion criteria demonstrate a poor understanding of clinical reality. For example, Reddy et al. (2008) reviewed all available RCTs on dressings used in the treatment of pressure ulcers. They reviewed sixty-three RCTs (with 3330 patients) and only included seven studies because they reported healing outcomes (wound size reduction or complete healing). Bell-Sayer (2009) questioned the benefits of using 'healed wounds' as a marker of quality evidence as in clinical practice a variety of dressings are used to progress a wound through the healing continuum. Whilst 'fully healed' is understandingly a desirable goal, control of odour could be a more relevant measure of success in a fungating wound (Lund-Nielsen et al. 2005); exudate management in a fistulating wound (World Union of Wound Healing Societies 2007) or infection in pin site care (Lethaby et al. 2008) as will be explored further in Chapter 6 (p114). In addition, Harding (2000) explains that determining healing rates is a difficult process. Wound measurement could be taken two-dimensionally or three-dimensionally; currently there is not an efficient way to measure the wound surface or the wound depth, therefore healing can only be measured at its fully healed point with a very variable and subjective starting point (Weller and McNeil 2010).

Horkan et al. (2009) analysed all the systematic reviews undertaken on wound dressings for period of ten years (1998-2008). They analysed thirteen such reviews and meta-analysis papers which identified recurrent themes relating to wound-dressing studies. They concluded that the methodological quality of dressing trials was poor, namely the number of participants recruited was consistently low, the sample size being erroneously estimated prior to the commencement of the study.

Sufficiently powering studies has been reported as a difficulty by a number of other authors (Gottrup 2006; Leaper 2009; Harding et al. 2010) due to the challenges of recruiting a homogenous group of patients. In fact, there are great variables amongst patients who have a wound, such as their co-morbidities, their wound aetiology and their wound healing stage. Additionally, there are a wide range of treatment options that further compound the problem (Harding 2000).

Horkan et al. (2009) were also critical for the lack of study homogeneity in terms of intervention and control and a lack of transparency in the methodologies used. This prevented data pooling for meta-analysis and made comparing studies difficult.

In an attempt to standardise the base line of a dressing evaluation study, many researchers base standard care on the use of gauze. In the UK, gauze is very rarely used as a primary dressing[2] and therefore any study or review that compares a dressing to gauze will fail to reflect clinical realities. Furthermore, with so many dressings available, standard care can differ substantially from one setting to another (i.e. acute care versus community care) or even in a similar setting but different Trusts, depending on what list of products each Wound Management Formulary holds. The selection of a dressing evolves from clinical practices which are context bound. Lack of generalizability of the results is a well described disadvantage of trial methodologies (Banerjee 1998; Al-Benna 2012) but is especially critical in dressing selection.

Designing methodologically sound RCTs in dressing evaluation involves the further challenge of being unable to blind participants or researchers to the dressings used as dressings feel and look very different from each other and are therefore easily recognisable (Eskes et al. 2012). In addition, clinically essential issues such as

[2] Primary dressings are dressings that are placed directly on the wound bed; secondary dressings are dressings which are placed on top of primary dressings.

comfort, ease of application or ease of removal are non-validated subjective assessments and cannot be considered in trial methodologies as they are likely to engender errors in interpretation of the results (Weller and McNeil 2010).

An Epistemology Reason

Covert, a strong nurse advocate, proclaims that *"nursing is a science, based on facts established by medicine"*; she states that "*practice without theory is quackery"* and that *"science ... is necessary to get safe practice"* (Covert 1917, p107). In her eyes, nursing needed such knowledge to underpin its practice. Nurses adopted the positivist approach from medicine to attain a measure of credibility within scholarly and professional communities (Adams 1991; Moule and Goodman 2013).

This approach has never really fitted nursing well and in 1970, Kuhn argues that science represents a philosophical orientation rather than a basic truth. He believes that genuine advancement in knowledge proceeds not in the form of cumulative developments proposed by positivists but more typically in the form of dramatic shifts in perspective (Adams 1991). Kuhn explains that major advancements in knowledge are experienced when the dominant perspective no longer offers solutions to important problems and thinkers experience a 'paradigm shift'. Within nursing, many thinkers jumped ship and for a considerable period of time, dialogue within nursing research was dominated by discussions of the comparative worth, value and rigour of the qualitative or quantitative approaches (see Haase and Taylor Mayers 1988; Jones-Porter 1988; Moccia 1988).

The discipline of nursing embraces the physical science in which the domain of inquiry is objectivised and reducible with the social and human science where knowledge is relative and contextual (Newman et al. 2004). Many nursing theorists recognise that nursing is not just a science or an art but is a mix of both, where objectivity is the essence of science and subjectivity is essence of art (Rogers 1988). Nursing has objectivity and subjectivity in its core and dressing evaluation is an

example of how research undertaken in this field has to take this dualistic view into consideration.

The seminal work of Carper (1978) on the fundamental patterns of knowing helps to understand that wound care mirrors nursing and its multi-faceted aspect. Carper (1978) describes fundamental patterns of knowing in nursing: *empirical knowledge*, the basis for this pattern is positivistic (objective data, measurement and objectivity); *aesthetics* (nursing art and subjective knowledge gained through caring engagement); *personal knowledge* (rational, interpersonal knowing and therapeutic use of self) and *ethics* (ethical and moral component of knowing). White (1995) suggests a fifth way of knowing, called *socio-political* knowing, relating to how cultural differences, political awareness and policy issues are addressed and adds a contextual component to nursing care. I can relate to Carper's (1978) and White's (1995) work in my experience of nursing patients, as should one fail to acknowledge any of these five aspects, wounds are unlikely to heal. Dressing evaluation requires access to both traditions: epistemologically objectivistic with a quantitative perspective (infection rates for example) and qualitative perspectives in terms of pain, comfort, concordance and socio-economic aspects.

Within health, a number of professions are undertaking a journey similar to nursing; for example, speech and language therapy (Glogowska 2011). Even medicine which remains deeply embedded in the 'science is knowledge', is gently moving towards conceding that knowledge maybe fallible (Johnson and Gray 2010). Within medical education, challenges to the dominant positivist perspective have been directed to the prevailing use of experimental methods to undertake research (Kuper et al. 2007; Dornan et al. 2008). Bunniss and Kelly (2010) argue that the discipline must engage in epistemological discussions about the nature of knowledge and move from the assumption that the basis for all knowledge resides uniquely in the empirical epistemology.

In the world of wound care the debate continues to rage between advocates for the strict implementation of the scientific approach to all aspects of wound care (Sauerland 2007; Bell-Sayer 2009; Weller and McNeil 2010) and clinicians who are asking for a different approach to generate evidence especially in dressing evaluation (Harding 2000; Leaper 2009; Carter and Warriner 2009). The problems addressed in dressing evaluation are complex and the use of either quantitative or qualitative techniques by themselves is inadequately restrictive to address this complexity.

Mixed-methods research is considered an emerging, innovative research strategy that is used across disciplines and combines qualitative and quantitative data collection (Simpson 2011). Nevertheless, using mixed-methods is not to be seen as a license for sloppy research (Greene and Hall 2010). Creswell and Plano Clark (2011) recommend that mixed-methods studies have structure, set within a defined number of different types of mixed-methods designs. Leech and Onwuegbuzie (2009) propose a three dimensional typology for mixed-methods designs: the level of mixing (partially mixed versus fully mixed); time orientation (concurrent phases versus sequential phases) and emphasis of the approach (equal status versus dominant status). The matrix of crossing these three different key aspects yields eight types of mixed research design[3].

I would argue that these matrixes stifle creativity without necessarily adding rigour or credibility to mixed-methods as a methodology. Creswell (2014) agrees that the

[3] (a) partially mixed concurrent equal status designs; (b) partially mixed concurrent dominant status designs; (c) partially mixed sequential equal status designs; (c) partially mixed sequential dominant status designs; (d) fully mixed concurrent equal status designs; (e) fully mixed concurrent dominant status designs; (f) fully mixed sequential equal status design and finally (g) fully mixed sequential dominant status designs (Leech and Onwuegbuzie 2004, p268).

formal design structure he had recommended in his earlier work does not reflect the variety of designs used in mixed-methods studies (Clarke 2009; O'Cathain 2009). Following a pragmatist approach (detailed in Chapter 3, p48) and believing that mixed methods afforded me the flexibility to bespoke my study design, I have tailored the use of different methods to each research questions (see Figure 1.1, 'Thesis Structure', p21) .

From an epistemology point of view however there are controversies. Some authors question the ability of mixed-methods to concurrently meet the expectations of both positivist and constructivist philosophies (Crotty 1998). Purists would argue that methods have to be in absolute accordance with the dominant philosophical stance; in contrast, proponents of the 'complementary strengths' agree that assumptions from different philosophical traditions are useful and could meaningfully inform the same study, as long as each arm of the study remain separate so that philosophical and methodological integrity can be maintained. Proponents of the 'dialectic' believe that the philosophical assumptions are important but that they should dialectically engage in dialogue (Greene and Caracelli 1997).

Creswell and Plano Clark (2011) suggest that multiple philosophical perspectives could be related to different phases of the research thus linking philosophical perspectives to research designs. Johnson and Onwuegbuzie (2004) advocate the selection of one underlying philosophy that marries well with a mixed-methods study: pragmatism. Pragmatism emphasizes the importance of the research question(s), the value of experiences and practical consequences, action, and understanding of real-world phenomena. Johnson and Onwuegbuzie (2004, p16) believe that pragmatism is the "*philosophical partner for mixed-methods research",* therefore countering all the above epistemological controversies.

CONCLUSION

This chapter has explained how challenging it has been for clinicians to evaluate dressings following the traditional empirical approach and its method of choice, the RCT. Firstly, trial methodologies are difficult to execute in dressing research because of lack of funding, difficult or complex study designs, narrow focus, extensive inclusion/exclusion criteria and the problem with endpoint (Carter and Warriner 2009). Secondly, while testing under controlled conditions is desirable to initially ascertain efficacy, the results may not be generalizable because a high proportion of our patients have many co-morbidities that are typically excluded from controlled trials (Morrow 2008). Thirdly a wound can receive many different treatments from inception to healing, because of the many phases of wound healing (Broughton et al. 2006), therefore identifying suitable comparator group in any comparative trial, can be problematic (Serena et al. 2012). Consequently, many wound care studies are of small scale and observational by nature, constituting an immature body of knowledge with little transferability potential. These challenges may indicate that the empirical methodology is not suitable for dressing evaluation.

This chapter also explained that wound care is mostly a role for nurses and Benner (1984) believes that nurses develop their skills though knowledge that comes from experience. In order to develop protocols that are needed for the inexperienced nurses, the experts need to look at how their knowledge is acquired, how it is constructed.

The next chapter explores pragmatism as defined by the work of John Dewey (1859-1952) who believes in experimentalism, not with the undertaking of experiments but with the integration of experience within a structured approach to produce evidence that is valued in clinical practice. In the early vision of EBP, clinicians' cumulated experience, education and clinical skills would be integrated with each patient's personal preferences and unique concerns, expectations and values. Sackett et al. (1996) believes that the best research evidence was to be found in clinically relevant research that had been conducted using sound methodology. In

the next chapter I explore the possibility of using Dewey's pragmatism to achieve this.

CHAPTER 3

Which philosophical perspective could better understand the complexities of dressing evaluation?

> *Every great advance in science has issued from a new audacity of imagination.*
>
> *John Dewey (1929, p136)*

INTRODUCTION

This study seeks to understand how a dressing can be evaluated in clinical practice with the integration of experience into the evidence produced. This quest is framed by a pragmatic philosophical perspective, based on the work of John Dewey (1859-1952)[4].

Chapter Structure

This chapter commences with an exploration of pragmatism. Dewey (1925) has clear ideas of how an inquiry develops; his 'Patterns of Inquiry' provides an excellent framework to understand dressing evaluation and is used on page 48 to set each chapter around one of the research questions. The concept of

[4] Please refer to Appendix I (p226) for a short biography of John Dewey's life and work.

experimentalism where experience is embedded in the process of inquiry is defined. The second part of this chapter is dedicated to detailing how pragmatism has been operationalised in this thesis.

PRAGMATISM AS A PHILOSOPHICAL PERSPECTIVE

The relationship between a researcher and philosophy is a reflection of how one views life and how dominant this view is transmuted into one's work (Greene 2007). From an epistemological point of view, the idea that knowledge comes from experience is known as empiricism (Atkinson et al. 2008) and according to that way of thinking only what is experienced with our five senses is knowledge that can be proved or disproved by observation, experiment or experience (Johnson and Christensen 2008). The EBP movement has embraced a positivist view of knowledge, which stipulates that the only truth that exists is that which can be known through empirical data collection (Wotring 1997). This focuses on measurements, observations and experiments and dismisses experience as too challenging to quantify.

Research in health has been dominated by empirical research based on quantitative data collection, development of diagnoses, intervention strategies and quantifiable outcome measures (Kohr 2007). Facts and figures are what matters in this philosophical perspective and it is unsurprising that my first approach to designing this study was a RCT, which turned out to be unsuitable. This was explained in Chapter 1 (p9) and is supported by critiques of EBP.

Constructivism, on the other hand, asserts that there is no objective truth waiting to be discovered (Crotty 1998) and truth comes into existence in and out of our engagement with the realities in our world, with our experiences set in a specific context, "e*xperiencing means living; and living goes on in an environing medium, not a vacuum"* (Dewey 1919, p111), where meaning cannot be discovered but can be constructed. Constructivist methodology focuses on experience and dismisses

observations and experiments as too reductionist and therefore lacking the connection with the 'environing medium'.

Pragmatism emphasises the existence of a real world separate of our observation of it, but highlights that our empirical approach to the world is shaped by our experiences. Truth can thus be discovered *and* constructed. This thesis views the world of dressing evaluation with a pragmatist lens. Immersed in the work of Dewey, his philosophical beliefs have shaped and framed my work and constructed a reality that allows for a different methodology to be developed for dressing evaluation.

Wound care and dressing selection rely on more than a list of facts that is waiting to be discovered. Orthodox enquiry struggles to provide a definite indication about which dressing provides optimal treatment in complex wound care as *"bodies arrive for treatment in quite different states of repair"* because *"they are controlled by capricious, wilful human agents"* (Pawson 2013, p45). Each patient is a medley of risk factors that added to the heterogeneity of nurses' skills and techniques, gives too many variables to *discover* if dressing A will be better than dressing B. But, I argue, experience can *construct* a reality where dressing A performs better than dressing B within a well-defined context.

I am very excited about the possibility to release some of the knowledge that is locked within experience. Neubert (2009, p164) agrees that human beings grow up and live in life-worldly contexts long before they begin to think about their lives and contexts. Life-experience, says Dewey is "*already overlaid and saturated with the products of the reflection of past generations and by-gone ages*" (Dewey 1925, p40). He further explains that "*it would take more wisdom than is possessed by the wisest historic scholar to track all of these absorbed borrowings to their original sources"* (Dewey 1925, p40). One can never be truly objective in dressing evaluation as our personal experience does interfere with the process; truth as a single entity does not exist but needs to be continually revisited in a way that is context sensitive.

Constructing Realities

Constructivists, unlike positivists, do not look for an outer observable and tangible reality. Rather, they see humans as observers and participants who actively generate and transform the patterns through which they construct (Reich 2009, p41). Constructivists remain open to experimental learning (Crotty 1998), but learning that includes experience rather than just experiments (Dewey 1933). Constructivism like any other approach looks for methodological procedures, logical accuracy and unambiguous analysis of preconditions and consequences. Constructions are neither arbitrary nor subjective but depend on the unique and concrete perspectives of observers and participants (Reich 2009). These constructors are embedded in the social and cultural conditions of their time (Hickman 2009) and what remains as truth is only temporarily valid within a certain context.

Dressing evaluation needs to be underpinned by a philosophy that is multifaceted, encompassing the biological, physical, psychological, emotional, cognitive and spiritual dimensions of patients and their wound, as well as the contextual economic and socio-cultural environment that influence decision-making. On further reflection upon Greene's (2007) stances (see p36), I am not a purist as exclusive dichotomies are not helpful in the study of complex real life situations. Greene (2007) joins Johnson and Onwuegbuzie (2004) in proposing pragmatism as an alternative constructivist philosophical perspective. I see all traditions as having something to offer as they complement each other and should not be kept separate.

Pragmatism

Pragmatism is intrinsically an American philosophy developed from the writing of Peirce (1839-1914), James (1842-1910) and Dewey (1859-1952), born in a country with only a few centuries of history (Marsoobian and Ryder 2004). The history of the development of pragmatism as a philosophy shares similarities with nursing, in

so far that both American history and nursing history have a relatively short past. Marsoobian and Ryder (2004) explain that most Americans have recently come from somewhere else, and that the immigration experience has made Americans different from most other. They suggest that most other people have a definite sense of what is ancient, and find themselves in local histories, within genealogies that reach into a boundless past, they can point to places that developed their beliefs and their sense of identity. Immigrants do not have that deep sense of belonging and must rely on themselves for strengths and support. The past is distant and irrelevant in this new land and what one does in the present must work for the future.

Parallels can be drawn to nursing: a new profession who reminds itself of medicine but that lacks its deep historical roots. Whist medicine is established as a profession by Hippocrates (460 – c. 370 BC), the origins of nursing are much more recent as Florence Nightingale (1820-1910) lays the foundations for our profession only a hundred and fifty years ago. Wound care sits within nursing; dressing evaluation, a subset of wound care, stems from the development of the first modern dressing in the early 1980s with Granuflex™, the first hydrocolloid dressing (Queen et al. 2004). It becomes clear why the speciality identity is only beginning to emerge and therefore we should be looking for a philosophy that reflects its younger age still.

In the absence of deep traditional roots, pragmatism offers a way to be guided by the future rather than the past. Pragmatism tests beliefs by examining their consequences or more accurately what happens when the beliefs in question are acted upon (Pratt 2004). As it looks to future consequences rather than past causes, pragmatism argues that a belief is meaningful only if its adoption changes the future.

Dewey's Pragmatism in Dressing Evaluation

Pragmatism has been described as a patchwork, emerging from the writing of three disparate sources: Pierce first, then James followed by Dewey that have very little

overlap in terms of the subject matter and inquiry pattern each favoured (Margolis 2004, p44). Neo-pragmatism philosophers such as Rorty (1931-2007) differ significantly from the early writers known as the First Pragmatists (Rorty 1979) and therefore one must not adopt pragmatism as an umbrella philosophy without being clear on which specific pragmatic philosopher's views one has affinities with (Greene 2007). Dewey's pragmatism is well suited to underpin a study on dressing evaluation and I will attempt to provide a rationale for this choice.

Dewey defines inquiry as the transformation of a situation, he identifies the topic of the inquiry as the conditions upon which the occurrence of qualitative experience depends on experimental, instrumental knowing and explains that truth is simply a process of verification. As there is no dichotomy between subjective and objective, experience is both and neither and it is the reflection on the experience that produces knowledge. Dewey's perspective rejects the idea that science and practice are different in an epistemological sense (Biesta and Burbules 2003).

Pragmatism is well versed to the discipline of dressing evaluation because it embraces the physical science philosophy (in which the domain of inquiry is objectivised and reducible) with the social and human aspect where knowledge is relative and contextual (Newman et al. 2004). With Dewey's pragmatism, the basic assumption of knowledge construction departs from the classic view of subjective and objective, where science is purely concerned with knowledge and practice is based on that knowledge or that practice is simply based on action. Dressing evaluation is a mix of subjective and objective; subjective in how a dressing 'feels when touched' and objective in how a dressing achieves what it is supposed to achieve, for example reduces odour, infection or promote granulation. In Dewey's terms, dressing evaluation has to be built from interacting inquiry with practice and thus construct knowledge.

Dewey (1925, p110) articulates five logical steps that he thinks are present when "*good thinking"* is encountered. First of all, there must be a difficulty as if no

problem is present there would be no need for inquiry. Identifying a problem in wound care prior to undertaking a dressing evaluation is challenging as the nature of the problem could be real or perceived. Dressing manufacturers employ marketing strategies to create desire (Gilbert 2013), which often results in making clinicians feeling doubtful about their practice. As dressing can be sold without being subjected to rigorous trials, the issue of identifying a real clinical problem in wound care is critical to good dressing evaluation.

The second logical step identified by Dewey is that the problem must be located and defined. Much of the work of solving a problem lies in the successful completion of this step. In wound care, a real problem could take the shape of patient's dissatisfaction with a dressing resulting in poor concordance; costs of dressing regimes is another recurrent reason for looking at different products or as in the case of pin sites, a clinical issue with standard care and dermatitis with long term use of Chlorhexidine and alcohol on the skin, which will be discussed further in Chapter 6 (p114).

The third step is the suggestion of a possible solution and in wound care there are a number of dressings that could be used to solve the problem for each situation. The fourth step is a reasoning process that eliminates a number of options. At this stage of thinking, Dewey explains that some of the solutions are discarded as being impractical.

Finally, there is additional experimentation or observation that is required for the leading solution to be either accepted or rejected. The process of inquiry is complete until the next doubt or problem ensues and in dressing evaluation this stage could return every few months as the next company produces a different dressing that may perform better than the one that has just been evaluated. This study does not seek to test this theory, but simply to use it as a framework for understanding how the process of dressing evaluation develops in practice.

Experimentalism

Dewey is committed to experimentalism but his experimentation does not lead to findings which result in a linear, certain, clear cut solution (Schön 1987). As everything that is known or knowable exists in relation to other things, there is no such thing as an absolute value, because what is valued is often subjective or relative (Campbell 1995). The test of an idea is its outcome and the test of an outcome is whether it resolves a problematic situation in a satisfactory manner with the understanding that the solution may only be temporary and the issue may need revisiting.

Dewey's understanding of the notion of inquiry is applicable to dressing evaluation, where wound care is non-linear, uncertain, complex and conflicting. Dewey argues that a pragmatic inquiry aspires to contribute to workable solutions and in order to do so any method may be used depending on the situation at hand.

Dewey's pragmatism is completely at home with evolutionary naturalism and Darwin's (1809-1882) evolution theory, by how well we are empowered to adapt and thrive in a changing environment. Dewey (1919, p180) says,

> *The human being reacts upon the environment to bring about modifications favourable to their own future. The human being has upon his hands the problem of responding to what is going on around him so that these changes will take one turn rather than another. It is obliged to struggle, to employ the direct support given by the environment in order indirectly to affect changes that would not otherwise occur*.

In clinical practice and especially with dressings, we modify our techniques to the environment we are in, to the patient we look after (their living requirements), to the staff we work with (skills and abilities), to the materials we have available. Experimentalism becomes a fluid entity, what is right today may not be right tomorrow.

Experience in Experimentalism

Dewey believes that knowledge construction emerges from human beings having experiences in a social context. Knowing is something that occurs as we live and in the contextual situation in which thinking occurs. Knowing in dressing practice emerges as an adaptive activity along with several of knowing's most important patterns: doubt, belief, inquiry and judgement (Hildebrand 2008) which experience gives us. It is in experience that one finds patterns of inquiry and logic useful for ordering and directing future events (Campbell 1995). Dewey explains that knowledge is a quality that brings experience from *that* specific experience (i.e. *that* meal, *that* dressing change, *that* holiday) and which is constituted by a single quality that pervades the entire experience and reflects on *that* quality that gives the experience momentum. The qualitative character of experience is not something subjective, it simply occurs and when connected by reflection, it becomes a reference, an anchor in time.

As a nurse, I can identify with these words: *that* patient with *that* wound sticks in my mind more than the thousands of patients I have looked after during my career. As we proceed from novice to expert, Benner (1994) explains how we progressively gain the ability of recognising patterns on the basis of deep experiential background with one of the key aspect of the expert nurse's practice has been described as having a clinical grasp and resource-based practice. Experience in the Deweyan sense is characterised by continuity and interaction and in its most comprehensive sense, experience means the sum of life-experiences, a life-career of individualised activities and learning processes that each in their turn contribute to the quality of subsequent experience. When we are involved in such problematic situation, it demands inquiry into constructive elements in order to resolve the problem at hand. Dewey makes it clear that for him this is a process of construction that implies a circular logic of reflection.

Experience is experimental, practical and quantitative in nature (Campbell 1995) but it is also historical, comes from the past, and moves to the future, there never will

be an end to experience or a finality of knowledge. Dressings are a medium for invention and tailored care to each patient and I never cease to be surprised how inventive my colleagues can be when redressing wounds, which means that some dressings are used in ways far removed from anything the manufacturers had ever anticipated. This requires observation and interaction with patients and colleagues in an environment which, as a specialist nurse, is familiar to me as a frequent visitor, but as I am not a permanent member of *that* ward's team, I am not imbued in their culture. The cultural diversity, the attitudes to wound care differ from ward to ward depending on the speciality; a medical nurse for example, has a very different attitude to wounds than a surgical nurse, partly due to the exposure to those wound care skills but mostly by their individual personalities, their philosophy of life which attract one nurse to a speciality rather than another. That individuality has to be captured in dressing evaluation.

A philosophy that believes that clinical practice and experience produces knowledge and that this could be academically accepted is a breakthrough for dressing evaluation, in so far that the two fundamental assumptions that underpin Dewey's philosophy are the core rationale for dressing evaluation. There is a *melioristic* belief that although there cannot be guarantees that the enquiry efforts will make the situation better, the improvement of the situation is a real possibly. The aim of any dressing evaluation is melioristic, its fundamental aim is to improve conditions, will it be healing, odour control, pain at dressing change, or provide better aesthetics for the patient or simply to reduce costs. There is an understanding that one may get it wrong but even so, it will offer learning experiences and ultimately knowledge. Therefore, there is the possibility of *growth* by learning from our mistakes (Hildebrand 2008).

I find this last aspect so liberating. McGee (1999, p28-29) points out that a pragmatic and experiential approach to problem-solving relieves clinicians from the destructive pressures they feel subjected to in order to arrive at a final and conclusive answer. Criticism and condemnation becomes irrelevant once decision-

making is undertaken with a pragmatic lens, with its integral acceptability that any present solution may need to be revisited in the future. Far from being an attitude of compromise and accommodation, Dewey's philosophy is constructivist and critical, where self-reflection is critical of the results that emerge.

OPERATIONALISING PRAGMATISM

In this thesis, Dewey's five logical steps in pragmatist inquiry are taken in turn. The paragraphs below chart how there steps map onto the research questions and the thesis structure, illustrating my operationalisation of pragmatism.

a. Where is the evidence for dressing selection?

Chapter 2 (p23) explained that the paucity of evidence to support dressing selection is well recognised (Reddy et al. 2008; Horkan et al. 2009); evidence for dressing selection is non-specific and unable to provide clear guidance (Dugdall and Watson 2009). There are large numbers of in-vitro studies, animal research, ideas, editorials and opinions, case studies but almost no trial methodologies based studies, as this method is challenging to evaluate dressing. The first step of the pattern of inquiry described by Dewey (1925) is the identification of the problem: dressing selection has become a nursing role and nurses are dressing wounds with intuition that is developed through experience rather than through empirical research.

b. Which philosophical perspective would better understand the complexities of dressing evaluation?

The second step in Dewey's pattern of inquiry is the location and definition of the problem: dressing evaluation has been sitting under the empirical philosophical umbrella, which has limited the development of an alternative methodology.

Dewey's work on inquiry (knowledge, meaning and action) and experience (mind, body and environment) was presented above. This specific brand of pragmatism calls for experimentalism, not in the empirical sense of conducting experiments, but

in the pragmatic sense of including experience in inquiry and offers the third step into Dewey's pattern of inquiry, the suggestion of a possible solution.

A number of options have been considered and discarded (i.e. realist evaluation and ethnography, see p13). The forth step is the consideration of alternatives and this thesis embraces Dewey's pragmatism. Finally, we can begin with data collection to answer the remaining three questions.

c. Who evaluates dressings in clinical practice and how are these evaluations been undertaken?

In order to answer this question, one focus group is undertaken with four in-house TVNs and one pharmacist. In addition, in-depth interviews are undertaken with a further three regional TVNs and one pharmacist/commissioner. Further details of the data collection, methods and analysis are given in Chapter 4 (p51). In this chapter, the inquiry proceeds into contextualising dressing evaluation in an attempt to understand how these clinicians list dressings onto the Wound Management Formulary in the absence of empirical evidence.

d. What elements ought to be included in a dressing evaluation?

The same interviews provide the data to answer this question. Further details of the data collection, methods and analysis are given in Chapter 5 (p95). In this chapter, the study seeks to understand which elements are key in dressing evaluation in the eyes of the decision-makers, in order to select the appropriate methods in clinical practice.

e. How could a dressing evaluation be undertaken in clinical practice?

The fifth and final step of Dewey's pattern of inquiry concludes with a clinical experimentalisation to establish if the leading solution is workable in practice. A dressing evaluation is undertaken using a mixed-methods pragmatic approach where a PHMB foam disc is evaluated in the care of pin sites. Further details of the data collection, methods and analysis are given in Chapter 6 (p114).

To provide a tool for experimentalism, strategies are borrowed from ethnography, namely participant observation, interviews and the analysis of available documents.

CONCLUSION

This study is steeped in Dewey's brand of pragmatism. His commitment to experimentalism believes in a structured approach to inquiry, where practice and experience produce knowledge that aims to improve conditions for patients (melioristic) and accepts our fallibility and opportunity for growth. Such philosophy needs a pragmatic methodology with a set of methods that allows for the process of learning from experience in practice, within a well-defined context. The next chapter explores this context; to understand how TVNs select dressings in the light of such limited evidence.

CHAPTER 4

Who evaluates dressings in clinical practice and how are these evaluations being undertaken?

> *Man is not logical and his intellectual history is a record of mental reserves and compromises. He hangs on to what he can in his old beliefs even when he is compelled to surrender their logical basis.*
>
> *John Dewey (1922, p244)*

INTRODUCTION

Expert wound clinicians, such as TVNs assess wounds and select dressings for their patients every day. Whilst published empirical evidence for dressing selection is limited for reasons highlighted in Chapter 2 (p23), wounds still heal with the dressings we select and use.

It is therefore key to understand this selection process. The structured operationalisation of Dewey's experimentalism commences with this chapter and provides a detailed description of the context of dressing evaluation.

Chapter Structure

This chapter begins with a traditional structure, in that it describes the methods used to collect and analyse the data. Then, before detailing the findings, data are first presented as a descriptive, and then around two main themes. The chapter concludes with a commentary on reflexivity and trustworthiness.

METHODS

Sampling and Recruitment

Seven TVNs and two pharmacists-commissioners were recruited to the study.

A non-probability sampling technique was used, called judgement sampling (Marshall 1996), known also as purposive (Palinkas et al. 2013). This technique relies on a prior knowledge of the 'universe', where personal judgement is used to select those participants who illustrate the feature of interest (Silverman 2013). Conscious criteria for selection were established and participants were chosen strategically, on the basis of their attributes (Roper and Shapira 2000), specifically for their decision-making roles in dressing selection. They were selected on the structure of society (the TVNs' world) and the context of the inquiry (the UK's north-eastern region) (Crang and Cook 2007).

The rationale for selecting TVNs and commissioners from the region was because we often share patients as they move from a community setting (where they live) to large tertiary hospitals (where they are treated) to district hospitals (where they are rehabilitated), moving in effect from one Trust to another in the same region. Dressing evaluations must be set into the geographical context that surrounds the patient and their journey through differing healthcare providers. This provides theoretical adequacy, which means the understanding of the contexts of their work, the similarities and differences of our clinical settings (Crang and Cook 2007).

There are six lead TVNs who work in the north-eastern region and three agreed to participate to the study: two were on long-term leave and therefore not available; one declined the invitation giving work-constraints as a rationale for non-participation.

A further four TVNs were recruited from my Trust, N1, N2, N3 and N4 work in my team. A further member was unable to participate as on maternity leave when the focus group took place.

Selecting participants that are managed by the researcher may seem contra-intuitive; however, these nurses heavily contributed to the decisions made with regards to the Wound Management Formulary. Furthermore, they shared extensive clinical experience: N1 had ten years' experience as a TV in the community; N2 had only recently joined the team but had many years' experience working in a related wound care discipline and N3 had three years' experience in tissue viability, with a specific interest in monitoring compliance to the Wound Management Formulary. Their experience and length of service brought valuable understanding to the way TVNs make decisions with regards to dressing selection for Wound Management Formulary inclusion. N4 had only recently been appointed to her post and whilst her experience was very limited, her new eyes brought freshness to the study.

Most participants were female with a few exceptions. To preserve their identities all the interviewees are represented as female. N1, N2, N3, N4, N5, N6 and N7 are all TVNs with varying level of experience, responsibilities and academic qualifications. Their key attributes in terms of role, responsibilities and academic qualifications are described in Table 3.1 (see p54).

In England, nursing as an all-graduate profession commenced in 2013 (Nursing and Midwifery Council 2009); all TVNs held a first degree and most had undertaken further studies to gain this academic qualification. Tissue viability is a specialism and as such requires nurses to demonstrate an equal commitment to high levels of clinical practice and academia before being recruited to the post. N7 and N1 were Master-level trained and N6 was undertaking a Professional Doctorate. Beside their pharmaceutical degree, P2 and P1 had both undertaken post-graduate studies. N1, N3, N7 were Nurse Prescribers.

Participant	Health Professional	Study level
N1	Tissue Viability Nurse	Master
N2	Tissue Viability Nurse	Degree
N3	Tissue Viability Nurse	Degree
N4	Tissue Viability Nurse	Degree
N5	Tissue Viability Nurse	Degree
N6	Tissue Viability Nurse	Prof Doc candidate
N7	Tissue Viability Nurse	Master
P1	Pharmacist	Post-graduate Diploma
P2	Pharmacist	Post-graduate Diploma

Table 4.1: *Participants attributes (September 2014)*

N5, N6 and N7 led the tissue viability services for their Trust, whist P2 and P1 were key decision makers in their role of formulary pharmacists. The Regional Drug Formulary contains a chapter on wound dressings which is why their involvement in this study was considered appropriate.

Most Trusts have at least one TVN; large tertiary centres may have up to eight to nine TVNs[5]. In my establishment, there were three TVNs in the acute setting and two in the community setting and I oversaw both teams.

N5 was the only TVN for a fairly large tertiary centre (1400 beds); N6 led a small team of two TVNs in a small district hospital (970 beds) and N7 led a team of four TVNs for seven district hospitals and its feeding community across the largest county in the UK. Interestingly, there are no national directives to the number of TVN per size of hospital or per number of population, therefore each Trust operationalises their TV services as they see fit.

Data Collection

1. A focus group with four TVNs and one pharmacist (N1, N2, N3, N4 and P1). Prior to the meeting, a copy of Madden's (2012) article[6] was given to each participant to read.

2. Individual interviews with three TVNs and one pharmacist/commissioner (N5, N6, N7 and P2).

The focus group was undertaken in August 2014 in a large seminar room in my establishment. The four interviews were conducted in September 2014 over the course of one week at each of the informant's place of work. The focus group yielded 1.5 hours of recorded data whilst the interviews yielded 4.5 hours of recorded data. An external company was used to transcribe *verbatim* the content of

[5] Quantifying TVNs in a team is complex, as some may work part-time.

[6] Madden's (2012) main concern relates to the quality of the evidence that supports the manufacturers claim for their dressings' efficacy. She believes that TVNs are too heavily influenced by industry and their marketing techniques.

the focus group and all the interviews. Each transcript was checked against the original recording for accuracy. A copy of the recording as well as the verbatim transcription was sent to each participant; giving them the opportunity to listen/read what was said and comment if they so wished. None of the participants requested amendments. Further explanation of the development of themes and sub-themes can be found on p73.

Ethical Considerations

Ethical approval for staff interviews and focus group was not required for research involving NHS or social care staff when recruited as research participants by virtue of their professional role (Health Research Authority 2015). However, all participants involved in this study gave verbal consent. They all received a copy of their interview/focus group and its transcript.

The aim of this focus group was two-folds: to discuss and agree that we would no longer 'have a try' with dressings left by company representatives and to explore their understanding of what 'evidence-based practice' means to the speciality. Whilst it may sound counter intuitive from a research ethics viewpoint, undertaking the focus group in this manner felt like a more natural, embedded way to nurture a discussion with colleagues. The focus group participants were fully aware of the dual purpose of the meeting (see p57 for further details).

Understanding Each Individual Contexts

Goodall (2012, p42) says "*describe before you analyse"* and this section endeavours to describe each interview to offer context of each participant's working world. These are reported in two ways, firstly with a description of the interview context to engage in the process of reflexivity where my voice is clearly heard in each description (written in the present tense) and secondly with an in-depth analysis of each theme that emerged (written in the past tense).

Focus Group with P1; N1, N2, N3 AND N4

We meet in a large meeting room, around an oval table. I sit on one side; P1 opposite and the rest of the TVNs sit together at the other end of the table. I think they are concerned as research methodology is not their forte and are worried about what I will be asking. Plus, the whole interview is recorded and although they have given full consent, they may feel slightly uneasy about this. I am their manager and have reassured them that participation is purely voluntary but I am aware that they probably feel they do not have a choice. N1 has interviewed peers for her master degree so she knows what is required and plays the game well from the start, she leads the discussion. She is the most senior TVN there.

I have given them Madden's (2012) article to read to 'get them fired up' but also to trigger reflection on their current practice. Most have read it, however P1 was honest in stating that she had not.

N1 finds the article patronising and feels that she has to defend herself from these criticisms. She wonders if the reason for the lack of RCT in dressing evaluation is due to the fact that TVNs work autonomously, without direct medical supervision, which is what makes tissue viability different from other specialities. Infection control, for example, is greatly supported by medical staff (Kinnair 2013). However, N1 feels that experience is the single most important aspect for decision-making in her role,

> *The starting point is with the patient and then we need a product that will meet what we need. Whether we've identified there's a wound infection, there's oedema to manage, there's a bleeding wound. Are we going to stick dry gauze on a bleeding wound? We know in practice, we haven't got an RCT, but we know that will not help a bleeding wound, to stick gauze on it in the long term. We can't just brush under the table the years of experience we've brought to the table, to know that alginates, hydro fibres, will arrest bleeding in a wound.*

N3 voices that some of the literature produced by industry can be of use to assist decision-making, even if it is not based on RCTs, "*I think some of those are valid*

although they haven't necessarily been tested against all the different measures that you would for an RCT".

They all seem to agree that 'chocolate fountain and free pens' do occur at conferences but do not seem to take Madden's critics as an attack to our profession. N2 agrees that from an outsider looking in the world of tissue viability it could be perceived as bribery,

> *I can see it as an outsider coming in and observing that, would perceive that a lot of nurses that were attending there were being wooed by the companies. I think they're led to believe that the nursing staff or TVNs in there were going to take on that dressing to then go out and use it. ... we're not always as gullible as some people might like to think we are and we do have our own experience, clinical experience, that we will take into consideration when we're looking at new products that have been forwarded to us, or marketed to us whether they're going to fit in with the type of patients that we see, and whether there might be benefits before we even start to look at whether we're going to try those products on patients.*

This focus group has two aims: firstly, to explore their thoughts on the level of evidence required for dressing evaluation but also to ensure that they no longer accept boxes of sample dressings to 'have a try' in *lieu* of a structured and transparent evaluation. The focus group needs to accommodate both aims as the reality is that there is no time for two different meetings to keep the research aspect separate from the clinical/operational aim. The strength and weakness of undertaking a Professional Doctorate will be explored further in Chapter 7 (p166).

For the experienced TVNs in the group (N1, N2) this is a difficult concept: N2 has introduced many new products to the Wound Management Formulary for doing just that, 'have a try'. She defends herself by quoting a honey based product evaluation she undertook a number of years previously, where fifty patients were entered to the study (patients were not consented as the study was not randomised). In her mind, this is a very good number of patients to test a new product on. N1 is less defensive but is a nurse prescriber and she justifies her

actions by the fact that dressings need to be prescribed in the community before they are used and if they are listed on the British National Formulary[7], it provides a rationalisation for her prescribing habits.

P1 explains that dressing evaluation should not be about using one dressing on one patient and if it works then try it on a second patient and then on a third. Then she continues, "*in our mind suddenly we feel there's a pattern, there's a pattern because in two out of three or four, five patients [the dressing worked] and then suddenly it's used extensively*", without being rigorously evaluated.

Representatives come with new products to create desire; good marketers do not sell products; they create a desire (Godson 2009). P1 says,

> *I see, three or four seven major classes [of dressings] ...unless the company is coming to you with a brand new product, a completely different mode of action that we don't know yet ..., really, what difference is it going to make? So what are they selling to you?" she* continues: *"I'm struggling to see that there's anything new out there unless it's a completely different product, a completely different mode of action, a different approach to wound healing, that's going to be different to what we've already got on the Wound Management Formulary.*

The conversation continues between TVNs who are trying to defend their ways of working and P1 who voices that human beings are biased.

N2: *Repeated experience of using something.*

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[7] The BNF is a pharmaceutical reference book that contains information and advice on prescribing medicine and dressings. It is used by pharmacists and doctors (and by other prescribing healthcare professionals (such as nurses, pharmacy technicians, paramedics, and dentists) as a reference for correct dosage, indication, interactions and side effects of drugs and dressings (British National Formulary 2015). By listing all the available dressings, there is a tacit assumption that the same level of evidence for drugs applies to dressings.

P1: *Yes, but that's bias because that's coming from your own experience.*

N2: *Well I don't know about that.*

P1: *You're biased by your own experience.*

N1: *Is it bias? Benner [Benner 1984] would say that that's an expert prognosis.*

P1: *Yes, but that's biased. Because it's biased when experts say you've got a certain impression…*

N1: *But the mind doesn't close to trying an alternative.*

P1: *That is why the only gold standard evidence is through an RCT ...we are fundamentally biased and experts are biased because they have their own years of practice which is completely ... biased. It's natural. It's human. We look for patterns. That's why you have to have RCTs.*

The group continues to discuss this issue and for a while I listen to the debate. It is clear to me that my TVNs see their role as having the responsibility to each individual patient and all want the freedom of choosing whatever they think is best. The requirement for evidence to support their choice is seen as the 'white elephant in the room'; a squeaky wheel of a trolley that is just not going away. They find all sorts of arguments to circumnavigate this issue. Surprisingly most of them struggle with understanding the research process (beside N1 who is trained at Master level). N2 is outraged with P1 when she argues that it does not matter that she had recruited fifty patients to a study; what she needed was a further fifty as a control group to become a worthwhile evaluation.

They strongly believe that their experience should count *instead* of evidence. Evidence is only required to protect them from the assault of cheaper dressings that

is flooding the markets (the so called 'me-too'[8]) and from commissioners wanting to impose these dressings onto clinicians.

In the absence of evidence, how can we justify using more expensive ones? They suggest reducing waste. N1 says, *"There's other ways to save money. And there's so much wastage. There are other prongs to take this along".*

Eventually it is agreed that the way forward is not to use samples on our patients to 'have a try'. If we find a product that we feel may be helpful for a number of patients, a formal request will be made before the product is applied to a wound. Dressing evaluation is not about the one individual patient that requires something special because his/her needs are not met with the products listed in the Wound Management Formulary. Dressing evaluation is about constructing a body of evidence for the products listed in the Wound Management Formulary.

I am grateful to P1 for providing a realistic account of the criticisms levelled at our ways of working. I am somewhat surprised how limited their[9] understanding of the research process is and how reluctant they are to acknowledge their vulnerabilities with regards to their professional credibility in how they select dressings for their patients.

Interview with TVN – N5

I meet my colleague N5 at the entrance of the hospital, an old, flat building, well-kept with easy parking for visitors. We walked to her office; we zigzag along the corridors down to a windowless room. Tissue viability in this Trust has only been running for the last 18-24 months and this is reflected in the somewhat dismissive

[8] 'Me-too' dressings are imitation dressings, which have also been through the CE marking process; they are therefore legal dressings.

[9] The participating TVNs.

office. I am being told that this is their third move, the office getting bigger and better as the team expands. I am lucky with my office; it is palatial in comparison but then our tissue viability service has been running for nearly two decades.

We start the interview; the tape is running and makes N5 nervous and careful to what is recorded, despite my assurance that whatever is said is said in confidence. Trying to make her feel more comfortable I talk quite a lot at the beginning, I explain my project, my journey and what I am trying to achieve. Slowly she lets go and we get to the 'nitty-gritty'. N5 says,

> *I like random [sic] controlled trials. I like to see that it's independent evaluations, with dressings from an inside source. Just to see that it's not just the company singing its own praises. I like to see comparisons with different rival products.*

N5 further explains that there is no value to an evaluation if there is no baseline to work from. She adds that if there are ten dressings all doing a similar job, comparator studies are difficult to achieve in vivo. A solution in her eyes would be to ask what is different with their new dressing, in effect allow the company to sell their product.

N5 would only evaluate a new dressing if she had trust in the company and in the brand as well as if the representative demonstrated professionalism. The representative's enthusiasm would be the first point along with honesty; for example, if the only difference is cost then that should be clearly stated.

The support for staff education is equally important. She gives an example of a product that her team has evaluated where the rep provided support and education. The representative also provided the dressings free of charge. N5 explains that sometimes, a dressing is trialled when a representative is too-insistent, simply to get rid of him/her.

Evaluation parameters include, beside costs and effectiveness (i.e. measures such as 'it does what it says on the tin'), patient satisfaction where the patient is asked if they like the dressing. N5 explains that nothing is formalised. There is no audit trail of what has been decided, how that decision has been arrived at. The need for more transparency and open and honest care has been addressed by the Regional Tissue Viability Group (N5, N6 and N7 all belongs to this group), where a grid of key elements has been developed and the members of the group score each dressing.

N6 calls this a 'table-top evaluation'[10] as very few new dressings are clinically evaluated. Some are discarded very quickly as they cause irritation to the skin of the group members, as the dressings are applied to each other skin to "*see how it feels*" (N5); sometimes they are discarded because the box does not contain a patient leaflet, or because it looks cheap, or it does not look safe or because the company has irritated one of the group members. Again the relationship with the representative and the company seems to be very important to N5, where a company that invests in its representatives is a company that must ultimately be caring about patients.

N5 does not agree that we could become biased to the larger companies because they have more manpower to support the brand and the introduction of a new dressing to the clinical setting. N5 offers me the example of a large company that produces a wide selection of the same type of foam dressing but only one is accepted on the Wound Management Formulary.

[10] Further explanation and discussion about this 'table-top' evaluation will take place in Chapter 5, p95.

Controversially, I ask if the 'table-top' evaluation is an attempt to offer a facsimile of robustness to a process that is not robust. N5 agrees that it would be less time-consuming if she did not have to attend the 'table-top' evaluations, but believes that we have a duty of care to evaluate *all* dressings, to make sure we don't miss something new. I am surprised: my motto has been to be the most time-effective possible with a duty of care to the taxpayers who ultimately pay my wages. I never thought that I may have a duty to evaluate all the dressings so not to miss a good one.

N5 believes that we should develop pathways, agree them regionally and evaluate them instead. The dressings used will change between sites to reflect each regional formulary, but N5 agrees that this does not constitute a method for dressing evaluation. But I think this could be a different way to look at the problem of dressing evaluation.

N5 agrees that there are different cultures within each ward and each hospital and that dressings' selection should reflect that individuality. Wound Management Formularies can restrict what one wants to do, they can stifle innovation but too much individuality prevents standardisation of practice. A balance has to be achieved. Staff satisfaction with a dressing is very important in the dressing evaluation process as well as issues such as procurement (i.e. who delivers the products).

N5 discloses that the 'table-top' evaluation is paying lip service to industry, *"we need to be seen to be fair"*. Duty of care comes up in the discussion again, where Trusts could be held accountable for not reviewing dressings and be accused of favouritism if dressings are not evaluated. N5 describes how one of the companies did just that when their product ceased to be used and was replaced by another product,

> *At this Trust, we've had issues where we've changed a product all above board, all before the end of the contract, as we're entitled to do. But we were accused of underhand dealing, which was absolutely preposterous. That, sort*

of, scars, it sticks, and you're always conscious of that, because the extra work that takes you away from your patient bedside to deal with that kind of thing isn't worth it. So, it's about getting it right, demonstrating to be seen fair.

I know what she means, I have been there too and it makes one feel very vulnerable. She explains how she is currently evaluating two very similar products, both cost the same, but one has a higher level of evidence for its effectiveness than the other. But she is trialling them both so not to *"create a problem*".

We conclude the interview with N5 agreeing that following patients when doing an evaluation is very difficult to do, especially with the many pulls of the job. Patients are discharged, transferred or die and one can simply not follow them up.

I leave the hospital and the city full of thoughts and new impressions; in the car I reflect to what I have learned. I need to explore the issue of duty of care further.

Interview with TVN – N6

I interview N6 in her office. She is currently undertaking a Professional Doctorate like me and I am looking forward interviewing her as I think she will understand very well what I am doing and where I come from. It is the first time that I meet her on her patch and it feels nice and strange at the same time.

We start the tape, N6 looks comfortable with the process, she always appears very confident. N6 tells me that she sees sales representatives all the time, but she approaches dressing evaluations from a different angle: she looks at what problems she has in clinical practice and then looks at industry to see what choices they can offer to solve the problem, rather than starting the evaluation from a box of new dressings dropped off by a passing sale representative.

N6 also belongs to the Regional Tissue Viability Group and explains that the 'table-top' evaluation is based primarily on costs and how a product feels on when applied to the evaluator's arm; patient's experience are not sought. N6 disagrees with the

above process *"because your skin is not that of a ninety-year-old skin in a bed".* N6 confirms that the 'table-top' evaluation is a tick exercise to cover oneself when TVNs make the final choice. I ask*, "To cover themselves from whom?"* N6 is clear: from industry. However, she does point out that industry deserves a fair evaluation rather than bias.

N6 is very clear that she will not evaluate any dressings unless her work is published, thus gaining peer-review credibility. In order to get her Trust to change practice, she uses three points of reference: the data provided by the 'table-top' evaluation; her published work and finally, she ensure that patients' say-so is part of this process. These three parts come together and she is then able to go to her Trust's procurement to change or to add a product to the Wound Management Formulary. The audit trail for the process is very open and auditable, she explains further,

> *My three points are; you need to see the proof of the products yourself as a clinician, and that can only be done by your own independent evaluation. The tick box exercise regionally is more about do they have the right price, do they have the right literature, do they have the right packaging? It isn't about so much the effects on the patient, it's about the whole package of the package. But the third one is about the patient's voice, the patient's experience which is not acknowledged.*

N6 also includes staff voice in the evaluation because if they do not like the product, they will not use it at all or use it wrongly,

> *We did two evaluations for two competitors. The staff and patients could tell no difference between its benefits. They could tell no difference between the skin condition after [application of the product], so the mechanics of the products were identical. However, the patients and staff liked one product more than the other because of the smell. And that is what I could take back to the company and say, "This is why we're going with yours and not that one.*

N6 explains that industry and the NHS need to work together, they need to *"be business partners for best outcome for the patient".* The role of the TVN is to ensure each aspect (patient satisfaction, staff satisfaction and product effectiveness) is given due consideration.

N6 tells me that other TVNs might evaluate what interests them, not what is required by the population they serve. To the question how feasible is to undertake a RCT in dressing evaluation, her reply is direct: *"impossible,"* she says.

She adds,

> *Because, in wound care, you need a lot of patients, no patient is the same as the next patient. So to reduce your variables in your patient population is nigh on impossible, and by the time you've got to the end of that piece of research, it's out of date and five other products have come in place that are better.*

We also discuss how the time constraints attached to the process of gaining Research and Development and Ethics may prohibit clinicians who do not have protected research time in their job description to engage in such endeavours.

She explains that we need to keep individuality in our work practice and in the way we evaluate dressings and believes that,

> *Evaluations that are done properly to a formula will give you just as much evidence as an RCT, but it'll be evidence that is relevant at that time. It's real evidence, local evidence. So the problem you've got is with your population.*

Finally, she tells me that she does follow up all the patients that she recruits to the evaluation as she needs the data to publish her findings, so it becomes a priority when planning her day. We conclude the interview and I drive home thinking how she so fully understands the challenges of RCTs as a method for dressing evaluation, whilst it has taken me two years of doctoral studies for the penny to drop. I feel a bit embarrassed.

Interview with Pharmacist – P2

I interview P2 on warm autumnal afternoon, in a brand new open-plan building with ponds filled full of carps and lovely reed beds, set by the river. I feel somewhat intimidated by the setting, a lamb in a lion's den, because P2 is a key decision-maker in what is included in our region's Wound Management Formulary and has vested interest in any outcomes of dressing evaluations. She makes me wait for a while but I have arrived a little early, so I sit patiently on a leather couch in the large, open-plan foyer.

We start the interview and P2 is clear that the gold standard for evidence is systematic reviews or analysis, if these are not available, the single RCT would have to do. Issues surrounding concordance and patient's opinions could be included in a well-designed RCT as long as they are set out as primary or secondary outcomes. So RCTs could be used as a method in dressing evaluation. She is quick to add that in dressings, there are few RCTs and she considers that to be a big gap but she understands the issue well: as dressings are medical devices, there isn't the necessity to have this level of evidence before dressings are sold.

P2 explains that she has responsibilities towards the tax payer, to use the money allocated to dressings effectively. In the absence of traditional studies, she believes we should devise our own methods for evaluating dressings. P2 agrees that to conduct studies is both costly and time-consuming. She does believe however that funding should come from a national body, such as the Nursing and Midwifery Council for example. This is an interesting idea: P2 states that as dressings are undertaken by nurses, then it would make sense for the Nursing and Midwifery Council to support research in dressing evaluation and wound care, with direct funding or at least lobbying for funding from Central Government. Dressing companies should also be lobbied to produce their own research; however, she does question what it will do to the price of each individual dressing. Industry could be writing the protocols, prepare and submit all the paperwork which is so time-consuming to clinicians. This may be possible for larger companies, I argue, who can

fund this but would be difficult for smaller companies. P2 explains how lots of smaller companies start out with products that have been copied from other companies, the so called 'me-too' products; that is a good process for the NHS, she says, as it brings price down but is poor for funding research and development of new ones.

Devising our own evaluation method will have to include a comparator against standard care. We agree that training is also essential but who provides this training remains controversial: should it be the companies or the NHS?

P2 believes that there should not be any element of subjectivity in a dressing evaluation. Nurses' *"touchy-feely experiences"* (P2) should not be included as they are far too subjective. P2 introduces the concept of *"surrogate marker"* to create an evidence-base. She explains that, *"it doesn't necessarily have to go through horrendous processes with your RCTs and they're expensive and I understand that you can't get to them*" but feels that a body of expertise within the region could create that evidence-base. P2 discusses the 'table-top' evaluation previously described by N5 and N6 as an evaluation process,

> *It may not be ideal, far from ideal, but it's better than nothing, and it's better than opinion. That really is something that we need to move away from, moving away from opinion.*

She is aware of that the 'table-top' evaluation undertaken by the Regional Tissue Viability Group has a number of parameters which she cannot recall by memory, but is surprised when I explain that most evaluated dressings have never been put on a patient's wound. Her perception is that a new product would be used on a few patients. She adds,

> *It's been authorised. It's been given a British product licence number. So we're not really talking about doing a trial, as in using a trial drug where you absolutely have no idea whether this is going to harm the patient or not. That's not the case because that dressing has already been approved. So it's not going to do any harm to the patients.*

There seem to be significant contradiction between her earlier statement that the best-evidence is a RCT as a minimum standard but it is acceptable to put a new dressing on a patient without any formal evaluation process because it will not hurt the patient. She acknowledges that *"it is not ideal but what else can you do?"*

I explain my reasoning: undertaking a mixed-methods study to evaluate dressing may offer a way forward (participant observation, interviews and the analysis of available documents). She agrees that these elements are important but also brings another element in the mix, whether the patient has been assessed thoroughly and establishing if we have missed anything else that could be treated before starting the evaluation. From a research point of view, this is about 'controlling the variables'.

We agree that each area has to develop a Wound Management Formulary that serves the needs of the population and that brings about a discussion about subjectivity and individualism. P2 believes that it is fundamentally wrong in healthcare to allow for any subjectivity and individualism. Individuals should never have enough power to be allowed to be subjective in their dressing selection and usage. She misunderstands what I mean by subjectivity and individualism: I refer to a group of people using subjectivity and individualism to meet the need of the population they serve, rather than serve the ego of one single clinician. I explain this better, I make the analogy of making a Bolognese sauce where there are many different recipes but at the end of the day, it serves one purpose, to 'fill the tummy'. P2 agrees it does, but within a set budget we have to use what we can afford, therefore individual subjectivity should be eliminated. Innovation in practice involves the 'self' but P2 is clear that any innovation must be strictly controlled and always peer-reviewed.

We get into a lengthy discussion about appropriateness use of dressings and not wasting resources, all of that has little to do with the topic of my interview, but this

is another important aspect of our work, mine as a clinician and hers as the budget holder. This conversation enables to develop a relationship as whilst I know all the other interviewees well, P2 is the one I know the least, having met her only once prior to this interview. It brings to the fore once more how much I am part of this region and how much individuality and subjectivity I bring to this study.

Interview with TVN - N7

My forth interview is with N7. She has been a TVN for the last eighteen years. We have not always had a smooth relationship so I drive to her office with some apprehension. I arrive to my destination with over thirty minutes to spare; I read my questions over and over to make sure I am as prepared as possible for the interview. Her office is at the back of a healthcare centre, which is shut during the lunch time period. The area is deserted; I know she is here as her car is in the car park. Her office feels like an impregnable fortress; there is not even a door bell to ring. She emerges when the time comes and leads me to a meeting room. I decide to adopt an honest and humble approach and tell her the story of my difficult Professional Doctorate journey, how I wanted to undertake a robust dressing evaluation but struggled with the whole concept.

She is kind and magnanimous in my failings and recognises that whilst RCTs are said to be the best, they are *"not going to happen".* She is open and clear with what she does and is refreshing in the acceptance of her limitations. She describes herself as not being of a scientific mind. She openly admits that what matters to her is to understand the different elements of a dressing and how it is expected to work on a wound. The most important thing is that explanations must be kept simple, *"brought down to a level that a generalist nurse understands"* as if a dressing *modus operandi* is not understood by her nurses, the product will not be used appropriately.

N7 believes that the level of training and support offered by manufacturers is very important; costs are important, testimony that N7 has budgetary responsibilities for the dressing spend across her Trust.

She also expresses cynicism as her vast experience dictates that very rarely a new dressing will yield such fabulous results to merit our attention. Most dressings, she says are 'me-too', copies with minor alternations of the original ideas. N7 only evaluates dressings that catch her attention. When she evaluates a dressing, it will be done in the community setting as she believes that district nurses are more knowledgeable in wound care and more reliable than acute care nurses.

N7 questions the requirement of providing RCT level of evidence and states that she has a pragmatic view on dressing evaluations. She does not feel guilty that she is not using empirical evidence to base her decisions *"there is none, so why should I worry"* and wonders if we are getting *"too scientific"* about dressing evaluations. In her mind, her patients are getting effective care and their wounds heal, so why trying to fix something that is not broken. She does not *"lose sleep"* over the lack of evidence in dressing evaluation.

She describes the Regional Tissue Viability Group's evaluation as a desk top affair and confirms that very few dressings are evaluated in practice. She agrees that an element of comparison should be included in an evaluation, along with patient and staff opinions and costs. Adherence to the Wound Management Formulary is what is most important to her, as she feels no dressing is superior to another and it is all about how one sells the idea rather than the evidence available. It is about the context, the setting, the environment where wound care is undertaken rather than about the dressing itself.

I respect her honesty and openness that comes from a successful tissue viability career; she does not try to hide behind vague justifications: she selects dressings that work in practice, not only for patients but for nurses who have to use them and

for those who look at rationalising the number of dressings on a Wound Management Formulary to decrease costs.

The interview ends, I thank N7 and leave. During the journey back I reflect how confident she is on her approach to dressing evaluations.

Data Analysis

The data collected was uploaded onto NVivo, a qualitative data analysis software, which allows for cross-case thematic analysis (Bazeley and Jackson 2013). Data was thematically analysed following a six-phases guide described by Braun and Clarke (2006). Firstly, I familiarised myself with the data, with immersion (repeated reading), searching for meanings and patterns. As explained on page 55, transcription was undertaken by an external company, therefore, each transcript was checked against the original recording for accuracy. Data cleansing took place before uploading all documents on NVivo, because whilst the transcribers had medical knowledge, they did not always understand the specific terminology. The second phase was to generate initial codes. Each transcript was coded manually line by line. Codes identify a feature of the data that appears interesting to the analysis (Boyatzis 1998) and a list of codes was produced. Once all the interviews and focus group were coded, a list of all the codes was generated after removing duplicate meanings. During the third phase, I searched for themes and started to sort the different codes into potential themes. I then reviewed the themes (phase four) and refined them. Data within each theme started to become more coherent. Themes were then defined and named (phase five), and for each theme, I conducted and wrote a detailed analysis which is presented later on in this Chapter (phase six). Figures 4.1 (p74) and 4.2 (p73) offer a diagrammatical representation of the thematic analysis leading to the development of Theme 1 (p76) and Theme 2 (p83).

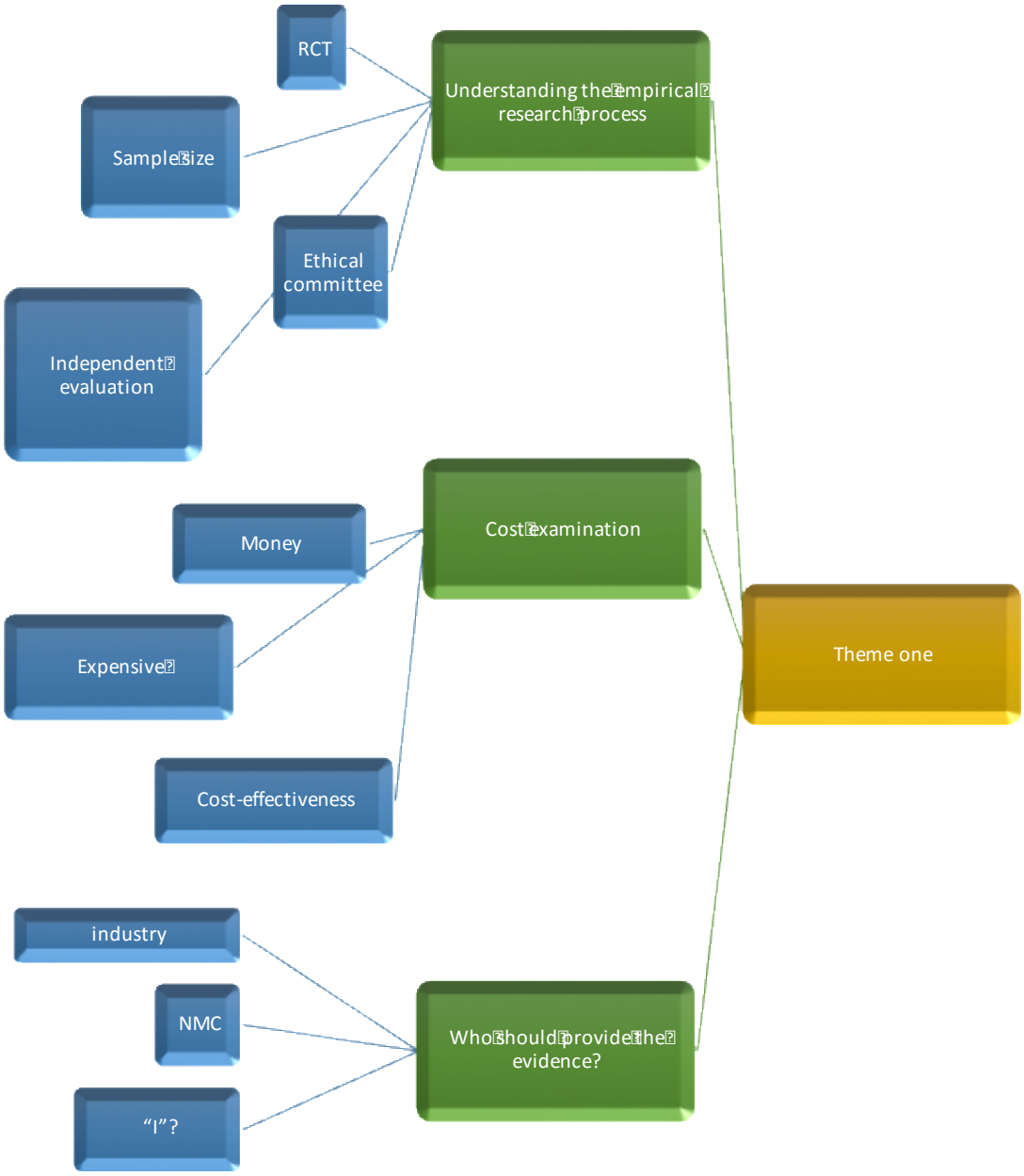

Figure 4.1: *Diagrammatic representation of the thematic analysis leading to Theme One (Expected Level of Evidence for Dressing Evaluations)*

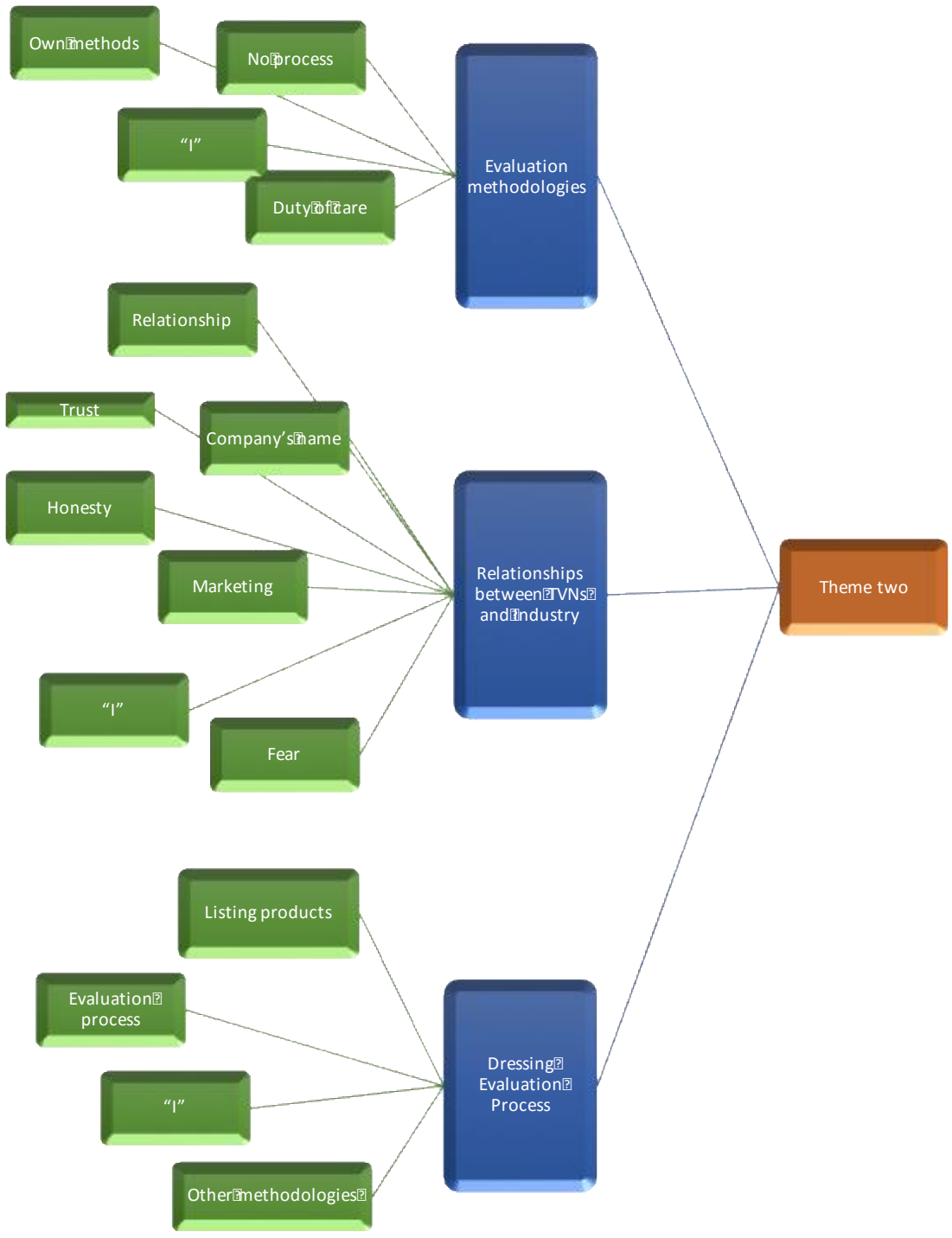

Figure 4.2: *Diagrammatic representation of the thematic analysis leading to Theme Two (Accepted Level of Evidence Used to Select dressings)*

UNDERSTANDING EVIDENCE IN DRESSING EVALUATION

Data analysis revealed two overarching themes: the *expected* level of evidence for dressing evaluations and the *accepted* level of evidence used to select dressings in clinical practice. Theme one pertains to the level of evidence that is expected to inform clinical practice: these have been grouped into three sub-themes: '*Understanding the empirical research process'; 'Who should provide the evidence'* and *'Cost examination'.* Theme two pertains to the accepted level of evidence that used to select dressings: these have been grouped into three sub-themes: *'Evaluation methodologies'; 'Relationships between TVNs and industry'* and *'Dressing evaluation process'.*

As each interview was described before undertaking the analysis (recommended by Goodall 2012), it is inevitable that the reader will encounter some repetition of what the participants have expressed in the analysis below.

Theme One: Expected Level of Evidence for Dressing Evaluations

Understanding the Empirical Research Process

The term 'research literate' is used to describe the skills that are required for research (Moule and Goodman 2013) with capacity for critical thought; analytical skills; the ability and skills to gain access to relevant evidence. Despite the call from governing bodies for nurses to become research literate (Department of Health 1993, cited in Bowling 2014), to what level nurses in clinical practice engage with this call, varies greatly.

This is evident within the seven TVNs I interviewed. On one hand, nurses voiced the need to base their practice on evidence, but on the other hand, their voices spoke of a very superficial understanding of the research process. When asked what type of evidence they felt should be available for dressing evaluation, N5 stated, *"I like random (sic) controlled trials. I like to see that it is independent evaluation"*, confusing the research method with the process of evaluation. N7 on discussing a

company that has tried to provide RCT level evidence for their product, *"They [the company] have done a couple, they've done a couple but I don't think the numbers were big enough to be transferrable if I'm honest".*

N2 explains how she had conducted a case study using honey, "w*e had a cohort of fifty patients that we looked at; so fifty patients is quite a large number. It's not massive, I understand that, but that is just in with one particular area of practice ..."*, where the significance of randomisation to two treatments is missed, sample calculation to achieve statistical significance is not understood and the belief that recruiting fifty patients means having produced a good study. "*So you would say that fifty patients was [sic] not enough?"* P1 immediately argues that another fifty patients should have been recruited as the control arm for the study, again demonstrating the difference between healthcare professionals' knowledge of the empirical research process.

By contrast, the two pharmacists fully understood the methodology used in quantitative research. P2 states, *"we would be looking at what we call 'gold standard' evidence, so it's either a systematic review or analysis, which are the top pinnacle"*, making reference to the pyramid of evidence that promotes RCT as the highest form of evidence (Straus et al. 2011). She continues, *"if you haven't got that, then RCTs".*

All interviewed understood that there are very few RCTs in the literature. P2 explains that *"within dressings there are very few [RCT], and I think that's a big gap around dressings, around evidence-based so a lot of the evidence-based tends to be outdoor [sic], and that's where it is difficult to influence prescribing, really, because there isn't any solid, cast-iron evidence around dressings"*. N7 states, *"RCTs are the best, but ... they are not going to happen,"* introducing the reasons for this lack of RCT in dressing evaluations. N6 summarises the discussion well,

FP: How feasible is it to do an RCT [for dressing evaluation]?

N6: *Impossible.*

FP: Why?

N6: *Because, in wound care, you need a lot of patients, no patient is the same as the next patient. So to reduce your variables in your patient population is nigh on impossible, and by the time you've got to the end of that piece of research, it's out of date and five other products have come in place that are better.*

The process to set up a RCT is complex and time-consuming. This is well recognised by the more research savvies participants as a barrier to undertake RCT,

> *I would think, probably, because of the process you have to go through. In order to do a proper RCT you have to do a full submission to your research body. I've seen them before and they are quite lengthy.* (P2)

> *Oh my God, pages and pages, and the time to do an RCT. It takes forever*. (N6)

Controlling the variables, especially defining standard care, has been clearly described in the literature as a difficulty for dressing evaluation (see Chapter 2, p23) and this is reflected in the participants' opinions, as they find many issues that will prevent them from using a piece of work as evidence to support their practice, highlighted by N6,

> *I think in wound care in dressings, they focus so much on RCTs, but because they're not [feasible]- if you ask any TVN they'll all say the same. "Oh yeah, RCTs, what's the point?*

Standard care can substantially vary and has to be the best that can be achieved before a new dressing is evaluated. Some participants recognise that this is a challenge,

The thing [that] is often missed is about looking at the patient holistically, so you should be looking at the hydration level; or if they've had heart failure [for example]. You could treat them with a dressing until they're blue in the face, but if they've got soggy tissues or heart failure, you're wasting your time. This is often not done, especially by maybe some of the junior nurses who don't maybe have that level of background. Your medication [also affects healing ability], so if you've got somebody that's on a steroid or if you've got somebody on a beta-blocker, they're not going to heal as quickly as they would with a patient who is not on those drugs. How many district nurses are aware of what drugs effect wound care healing? Probably not many. (P2)

In order to standardise standard care, many studies compare a product to gauze. N3 says, *"Often when they bring the RCT back we go, "Oh no, that's not good enough. Go away and do it again, basically because there's gauze in it".* Gauze is not used in the UK as a primary dressing, which makes the study irrelevant to clinical practice.

Conversely, the participants believe that an element of comparison should be present in a study, as long as it is not gauze.

N5: *I like to see comparisons with different rival products to try improve a similarity, or if it's better than the other.*

FP: *If you want a comparative study between product A and product B, product A will have to be something that you use already?*

N5: *Yes*

This is almost impossible to achieve in view of the thousands of dressings available on the market.

Differences between the two healthcare professions are evident on the beliefs that the two pharmacists hold on RCTs as the only way forward,

> *That is why the only gold standard evidence is through an RCT where the people… where nobody knows what's happened because we are human beings. We are fundamentally biased and experts are biased because they have their own years of practice which is completely appropriate and ... but it's just, you're biased. It's natural. It's human. We look for patterns, we look for things. That's why you have to have RCTs and even then if they're not properly conducted, it's biased.* (P1)

Nurses are open for different approaches, which will be explored later.

Who Should Provide the Evidence?

A number of interesting beliefs and suggestions were articulated: firstly it is thought that companies should produce their own evidence and that should be at RCT level (P2, P1) or at least fund them. P1 says, "*Within the field of tissue viability and in wound care nationally there is a responsibility to say to these companies, "Get stuffed, go and get an RCT and come back with some evidence. It can be done".* However, P2 suggests an alternative.

P2 believes that as dressing evaluation and wound care is a nursing domain, the regulatory body for nursing should fund dressing studies. The Nursing and Midwifery Council (NMC) is the regulatory body for both nurses and midwifes. Registration to the NMC is compulsory to all who wish to practice nursing or midwifery in the UK. Nurses and Midwifes pay an annual retention fee and re-register every three years. This is the only source of income for the NMC and has to cover all its regulatory activities (Nursing and Midwifery Council 2012). P2 states, "*your professional body is the NMC [and they should] actually try to pull together some national [funding], or lobby on behalf of the nursing body to actually get this evidence-base" or*, as P2 further suggest, to lobby the companies that make the dressings, especially for those dressings that appear to be more expensive per unit cost.

P2 believes that nurses are responsible for accepting low level of evidence from the companies as they would not accept this if it were a drug, *"So why are there doing it*

around dressings? I wouldn't do that". P1 agrees, "*We should be forcing dressing manufacturers to do RCTs but even then they can be flawed"*, recognising that conducting RCTs in dressing evaluation is not straight forward.

N5 is however concerned about the appropriateness of companies producing evidence as she was concerned that this could be intrinsically biased. N7 raises the issue that companies will only publish positive outcome studies as publishing rights are strictly controlled if they fund a study,

> *The ones we hear about are the ones that come out as a good result for that company who sponsored that study, but there's lots that we don't hear about because the results aren't what the company expect them to be. You can understand that ... they are only going to put their money where their mouth is*.

To the question to whether it is the responsibility for a government body to provide evidence and fund it, N7 believes that the National Institute for Clinical Excellence and Cochrane provide evidence. This is theoretically true but these two bodies review evidence, they do not provide new evidence nor fund studies. Asked if the Department of Health is likely to ever fund studies that look at dressing usage, N7 says, *"Not in my life time I don't think".*

Cost Examination

If the RCT is the gold standard for evidence, there is not a body of evidence to support dressing selection. Consequently, it would be logical that clinicians are put under pressure to use the cheapest dressings available and in many Trusts this is what is happening. Costs are mentioned in the focus group/interviews as being the threat that less performing dressings could be imposed in the light of no evidence to support the contrary. N7 is the most experienced of all the participants and also the most direct,

> *We have to be realistic about it. We're all going to have to make savings, were not going to get away with it, I think cost is important. I would like to say it is probably forty percent out of one hundred percent [important*].

As P2 is a pharmacist working for the commissioning group that commission healthcare in the region, costs are central to her argument but she is careful to ensure that we don't misrepresent the word 'cheap' with 'less cost-effective'. Correct terminology dictates that efficacy can only be ascertained with RCTs under controlled conditions (Serena et al. 2013) and effectiveness is the ability to elicit an effect in real world practice (Carter and Warriner 2009); P2 believes that the term 'value for money' is a more appropriate term[11].

P2 welcomes the development of new dressings, especially copy dressings, the so-called 'me-too' dressings within the wound care world as she believes that this will enhance competition on the market which will ultimately have an advantage to the NHS as it will drive the prices down. P2 believes that *"as a person, a public health worker who is publicly employed by the NHS has to justify what we do and what we're using in terms of [dressings] to the general public and the taxpayer".*

P1 adds, *"it is about saving money and so it should be. You pay tax and I pay tax. We all pay tax"* and should be able to justify to the wider public why we are spending on more expensive dressings when cheaper ones may do. Few nurses see their responsibility in providing value for money. In the eyes of the TVNs participating in the focus group, their responsibility is to their patient and each patient deserves the best (N1, N2, N3 and N4). N1 explains that the starting point is usually a patient who has a specific problem and cost becomes somewhat irrelevant.

[11] See p108 for a definition of efficacy, effectiveness and value for money.

This has been identified in the literature. Gillespie et al. (2014) used a descriptive cross-sectional survey design to establish nurses' knowledge in wound care. A convenience sample of 120 surgical nurses was surveyed. Only 6 (5.0%) respondents considered the cost of a dressing product as being important. N7 concludes,

> *At the end of the day, money still speaks highly. That's why all the pressure is on the nurses because it's all to do with money. So we are financially driven, we've got no way, you know, can't get away from that we are financially driven and there may come a point where there is a danger that we will end up being told we have to have the cheapest.*

The issue of cost driven evaluation will remain controversial as patients also pay tax. They demand the best as they are increasingly well-educated and well-informed (Glicken 2005). With the increased media scrutiny, lawsuits and compensation few have the stomach to reduce spend on dressings without the support of wound care experts. N7 summarises this well, "*so far we haven't done badly without RCTs [in] making arguments for having the products that we've want".*

Theme Two: Accepted Level of Evidence Used to Select Dressings

Evaluation Methodologies

In the absence of empirical evidence, listing products for the Wound Management Formulary can be challenging. P2 says, *"There is no process for dressings, which I struggle with. So we have to really look at devising our own methods of evaluating dressings*".

N5 mentions that we have a duty of care to evaluate all the dressing on the market. N7 agrees, *"We do have a duty of care to look at every product but we also have a duty of care to be able to justify why we would or would not use it",* but this does not include undertaking clinical evaluations. N6 says, *"I'm very interested in learning about what is out there, but I will only evaluate something that the patient is going to get a clinical benefit from"*. N7 looks at *"the product they present to me, I look at what I've got on the Wound Management Formulary, I've got enough to do, if it's*

working I'm not going to fix it" and will therefore not clinically evaluate the dressing.

Relationships between TVNs and Industry

The relationship between TVNs and industry can be incestuous and all participants have expressed this. One of the interviews produces this candid and open answer,

> *It depends on the relationship you have with the company ... If you know their products, you know that they're very well respected, and well used, and very effective, then you, usually, tend to think, well, perhaps, I could use – try one of their dressings ... on the basis that they have a very good reputation; they do what they say on the tin. And they're reliable and honest when they come and deal with you. And we get honest [replies to our questions], and openness.* (N5)

When asked what would bring her to evaluate a dressing, N5 explains that it's a trust in the sales representatives and their enthusiasm in believing that what they are selling is worthwhile and innovative.

Dressing materials have become really complex. The case of silver dressings is a good example of the challenges faced by wound practitioners. Whilst there is evidence that silver is a powerful antimicrobial (Cooper 2004), there are over 25 different types of silver dressings, all available on the NHS, on which 26 million was spent in 2009 (Health and Social Care Information Centre 2009). They all contain silver but the silver formulation differs and clinicians are expected to have the depth of knowledge for all these products especially TVNs who are responsible to appraise the evidence and then select the one(s) they feel would be best for their Wound Management Formulary. However, at times industry cleverly uses new twists on existing technology to promote their dressings and the information that industry provides can be 'dressed up' as something it is not, to ensure a sale. N5 says,

Honest answers as if you were to ask the question, 'Why should I use this?' If it's down to cost, you know, I would expect them to say, 'This is the real reason', rather than trying to fudge it, saying, 'There's X many parts of a million of a dressing, if it's a silver dressing, compared to its rival, which is Y – a million parts of a dressing of silver'.

It would be fair to say that some TVNs struggle with understanding the more scientific mode of action for each dressing. N7 says,

I'm not very scientific, I don't want to be particularly scientific, I've had colleagues who are really scientific and who were really looking at this thing about MMPs[12]. I have to admit I'd be the person going, "Can I see it, can I see it in a wound?" "How are my general nurses going to know that?" ...they [industry] have to really break it down for me to a level that a general nurse could understand.

The participants undertake a collaborative 'table-top' evaluation, which will be described further in Chapter 5 (p95). Some in the group have called it a smoke-screen to defend tissue viability from the wrap of industry if their product is not listed or from the wrap of commissioners when the dressing selected is expensive. Industry is powerful and can offer uncomfortable pressures to TVNs if their product is not selected. N5 relates such an experience,

We've had issues where we've changed a product all above board, all before the end of the contract, as we're entitled to do. But we were accused of underhand dealing, which was absolutely preposterous. That, sort of, scars, it sticks, and you're always conscious of that, because the extra work that takes you away from your patient bedside to deal with that kind of thing isn't worth it.

[12] MMPs = The matrix metalloproteinases (MMPs) are enzymes that play an important part in wound healing.

N7 says,

> *It's a tick box exercise to cover yourself when the final choice is made. The regionally tick box exercise is more about do they have the right price, do they have the right literature, do they have the right packaging? It isn't about so much the effects on the patient, it's about the whole package.*

N6 agrees, "*You cover yourself against industry because it's a cut-throat business out there".*

On one hand, we rely on industry to sell us dressings that are the tool for our trade. N5 states, *"companies are out there to exist"* and we want to treat them fairly; *"they need that justification, because it's only fair to. Because they do not want TVN bias, which we know traditionally has occurred,"* says N6. On the other hand, industry sends sales representatives to do precisely that, to sell their products. The techniques used to sell, begins with the development and nurturing of interpersonal relationships (Godson 2009). N7 summarises this well,

> *"I think what we need to have is a structure that is transparent to both the companies and the Trust that we work for of how we've come to the decision of the dressings that we've got."*

Some dressings are listed on the Wound Management Formulary because neighbouring Trusts are using the product. Patients move from one setting to the other and come from their home to tertiary hospitals, are treated and then move to smaller district hospitals for rehabilitation. N7 describes how she has listed products simply because the neighbouring area had them,

So I thought, 'Well, why am I going to be different; it makes the patient's journey much easier', but I don't know [if the product will work] ... I'm very pragmatic that way because it makes life easier for everybody, you know, and it is a good product, I mean, I wouldn't put rubbish in there [Wound Management Formulary] but it is a good product so why not go for it, you know, rather that, than us fight.

Dressing Evaluation Process

The main dichotomy in thoughts and beliefs comes in deciding what constitutes a dressing evaluation. As explained before, all interviewed believed that RCTs are the best way to evaluate dressings; they all agreed that there are very few RCTs available and that the few available have not been able to control the variables or when they have attempted to, the results are not applied in clinical practice as they do not correspond to the reality of our day-to-day experiences.

P2 is very clear in her mind that governing bodies or industry should fund dressing evaluations to RCT level, which necessitate lengthy, complicated and time-consuming ethical approval. But interestingly, what is accepted in practice is the very opposite,

As a new dressing comes along, you would just say, 'Okay, we've got a new dressing. This is supposed to be reasonably good in this sort of wound. I've got a patient who maybe isn't responding very well to what you would call conventional therapy, let's give this a go and see if it's any better'. (P2)

It is about giving it a go**:**

FP: *Do you feel it is acceptable to test new dressings that are coming on the market on patients without going through trial?*

P2: *Well, they're not like a trial drug. That's slightly different. We're talking about a product that's already been approved through -*

FP: *It's fit for purpose, that's what they say. Fit for purpose.*

P2: *It's fit for purpose.*

FP: *But we don't know if they actually do what they say on the packets.*

P2: *Exactly, but it's not dangerous. It's been authorised. It's been given a British product licence number. So we're not really talking about doing a trial, as in using a trial drug where you absolutely have no idea whether this is going to harm the patient or not. That's not the case because that dressing has already been approved. So it's not going to do any harm to the patients. The issue is, is whether it's going to work or not, whether it's going to be better than what we've got now.*

Legally, manufacturers have to get CE marker to officially launch a product, but often the sale representatives start with the marketing of the product whilst waiting for this approval to come through. N3 explains how some of the products that come to the table are not acceptable "*because sometimes they're not even packaged in a sterile way".* N1 describes dressings that disintegrate when opened, where particles could potentially be left in a wound and become foreign objects.

Ethically, one would argue that we could be putting our patients at risk whenever we use a new product that fails to be effective. Some of these risks are not negligible, for example in the case of a topical antimicrobial used to combat a wound infection where a failing new dressing could cause infection, septicaemia (infection in the blood) and possibly, death.

This 'have a try, not a trial' pattern of wound evaluation is common in wound care (Madden 2012), where the company representative simply offers boxes of samples for clinicians to apply to a wound.

FP: *So, you just, basically, got the box from the rep?*

N5: *From the rep.*

FP: *And then you applied onto –*

N5: *Well, we read what it was for and how to use it.*

FP: *Yes.*

N5: *Yes, absolutely. Making sure we were working within manufacturer's recommendations.*

It has to be noted that the manufacturer may offer some form of recommendations but the dressing might have technically never been applied to a human wound before.

N6 has developed her own methodology, which she calls 'triangulation' as information gathered by three distinct sources. First of all, she starts with a clinical problem and then invites industry to offer her a solution within the dressings they sell. She undertakes an evaluation and always publishes her case studies findings in a peer-reviewed journal[13], thereby gaining national credibility in the eyes of her Trust. This provides the first pillar of her triangulation. The second aspect is the data generated by the 'table-top' evaluation which give it a regional expert voice, even if the exact methodology is not fully understood by the non-members of the group. Finally, whilst undertaking her evaluation, she collates the patient's voice, the patient's experience that she believes is not acknowledged in the 'table-top' evaluation.

Finally, P2 suggests looking at what she calls 'surrogate marker', which she defines as *"to actually replace what's not there in the evidence-base and create an evidence-base"* and recommends that a TVNs and other with valuable knowledge form a body of expertise within the region, she recommends that evaluation criteria are established by consensus as common ground. She recognises that *"it may be far*

[13] A note of warning for the non-wound clinician reader: a number of 'peer reviewed' journals in wound care are heavily funded by wound care industry. It is very rare for these journals not to publish a submitted article.

from ideal" but it is better than personal opinions. None of the other interviewees was able to offer a better alternative. A thematic evaluation of the 'table-top' evaluation will be discussed in Chapter 5 (p95).

REFLECTIONS

For this piece of the jigsaw, experimentalism meant that a qualitative approach was required, with a focus group and interviews. A small number of selectively chosen participants can yield more valid information than a larger group of general informants (Johnson 1990) and this was certainly the case for this part of the study, as it is not the sample size that is important but the quality of the analysis (Silverman 2013). The aim was to select information rich cases (Grbich 1999) that would provide meaningful data related to the research questions. On reflection, as each participant offered key insights to the context of dressing evaluation, they had been selected well. It is worth noting that similar themes emerged from each interview precisely because participants belonged to the same professional community and this meant that theoretical saturation was quickly reached (Crang and Cook 2007). It would have been unlikely that recruiting more participants would have yielded a different picture as this study was set within a well-defined geographical context, the north-east of England.

The analysis constructs a picture where there are different forces that influence dressing evaluation. Firstly, it is unquestionable that amongst the participants there was a limited understanding of the empirical research process, highlighted in the many contradictions expressed in the focus group and interviews. The fact that each participant believed that RCTs should form the basis for all dressing evaluation is seen as a mantra repeated over and over without a full understanding of what this actually entails. Nevertheless, all participants knew that they were not using RCT data for making their decision and it was almost with a sense of guilt that they admitted that their evaluation methodologies lacked robustness.

Throughout the data, there appear to be an unspoken theme: power. Generalist nurses often believe that dressings are a highly technical element of the wound healing process. TVNs and other decision-makers are seen as knowledgeable and therefore powerful in this small area of healthcare; to admit that this knowledge is not based on RCTs means losing credibility, especially in front of medical colleagues. Fear of losing control over what is selected for the Wound Management Formulary and therefore power within their organisation is a theme that merits further reflection and will be discussed in Chapter 7 (p166).

Participants discussed openly the influences that industry has on (some) clinicians. Crucially, whilst most TVNs interacted with industry out of necessity, none of the participants held a business qualification. Conversely, industry understands business well; each representative is given quarterly targets and financial bonuses for achieving these targets (Godson 2009). This is a world far removed from the NHS and it is with some naivety that TVNs enter this "*cut-throat*" (N6) business. The marketing of relationships is another power line travelling across the context of dressing evolution, which also merit further reflection (see Chapter 7, p166).

Reflexivity and Trustworthiness

Interviewing participants is about actively constructing knowledge around questions and answers (Holstein and Gubrium 2000). I approached each focus group/interview with the same general questions but have had to adapt my interviewing schedule to the data emerging depending on the different responses. Interviewing is a skill based on having good interpersonal communication skills (Marshall and Rossman 2011), made easier on one hand by the fact that I knew all the participants, but on the other hand, made more challenging because this was a new relationship: interviewer-interviewee and a tape recorder between us. I interviewed colleagues, some were my equals in other Trusts, some I managed and some were higher in the strict hierarchical NHS, defined as 'elite participants' (Marshall and Rossman 2011). These professional relationships had not always been

easy over the course of time. Some of the participants were selected specifically because they had contrarian views which increased the chances of gaining a broader perspective (Seidler 1974). There was the possibility that some of responses could be tainted by our previous professional relationships. Nevertheless, having acknowledged this possibility, I fostered a culture of openness and equality.

With regards to the regional TVNs, this would have been the first time that they had seen me as an interviewer, a student working on her 'essay' and in the whole process, I was probably the one feeling uncomfortable and out of power. This awkwardness was acknowledged in each narrative presented at the beginning of this chapter.

Altheide and Johnson (1998) explain how reflexivity is about being immersed in the setting, context and culture that one tries to understand with objectivity and at the same time being transparent with one's subjectivity. We learn to have certain perspectives because we are born, raised and acculturated in a particular way and not another (Goodall 2000) and acknowledging this partisanship in one's work allows for trustworthiness.

At the beginning of these interviews, I was somewhat concerned with maintaining objectivity; but being professionally central to this region and working within its largest establishment, the picture I was painting would have had a large piece missing if I were not included. I would have liked to have interviewed FP[14] but, on reflection, this would have been unnecessary; my colleagues expressed thoughts, beliefs and described experiences that were similar to mine.

None-the-less, my voice is not silent in this work; when it does emerge within the *verbatim* of the data, it is made explicit with my choice of literary style. Firstly with

[14] FP = Fania Pagnamenta, author of this thesis.

the conscious decision to narrate the focus group and each interview with thick description before analysing the data, following Goodall's (2000) guidance (see p 56); secondly, by using the 'I' voice instead of the objective style favoured by the positivist approach. I hope this offers reassurance as to the trustworthiness of my work.

Trustworthiness is about asking the questions: *'Did I get it right?'* and explore internal validity. And, '*To whom, if anyone, can I generalise?'* and explore external validity. This chapter is only one piece of the jigsaw; therefore, these questions can only be answered once the whole study has been completed. So, trustworthiness is explored at the end of Chapter 4 (p91), Chapter 5 (p111), Chapter 6 (p159) and finally, drawing it altogether, in Chapter 7 (p176).

CONCLUSION

This chapter has described and analysed the content of one focus group and four interviews with fellow TVNs and pharmacists who all have an active role with dressing selections. Analysis revealed a dichotomy between what participants believe they should expect to see in terms of dressing evaluation and what they all accept in clinical practice. The TVNs demonstrated a limited understanding of the empirical research process that has to be followed to produce a good RCT, but were quite aware of the fact that their evaluation methodologies were not rigorous. Pharmacists were the most contradictory in describing what they believed should be happening and their tacit acceptance of the regional practices that produced Wound Management Formularies. They were also ambiguous about their beliefs on how evidence should be produced and funded and how value for money could be achieved within wound care dressings.

It appears that it is up to each clinician to establish if a dressing works in their own setting, however the lack of a structured methodology for dressing evaluation leaves clinicians vulnerable to criticism. The threat of being imposed cheaper and possibly less effective dressings forced the development of a 'table-top' evaluation,

which provides a smokescreen for the limited evidence available to select dressings. To admit this in a *milieu* where evidence-based practice reigns as king amounts to professional self-destruction.

The easiness that one can procure a box of dressing and 'have a try' has prevented clinicians and decision makers to engage in the development of an alternative approach. As I see it, TVNs are at a cross-road. We could continue the way we have always done, after all, N7 correctly points out that we have some authority and autonomy to select what we wish for our Wound Management Formularies and so far, nobody has really questioned our decisions too much. Alternatively, we could change our approach by voicing openly that trials are not the suitable method to evaluate dressings and develop an alternative. I owe it to my professional *raison d'être* to, at least, have a go. Therefore, this thesis proceeds with discovering what elements should be included in a pragmatic alternative.

CHAPTER 5

What elements ought to be included in a dressing evaluation?

A problem well put is half-solved.

John Dewey (1938, p111)

INTRODUCTION

There are a number of elements to a dressing evaluation, which require definition before deciding what methods should be used to research them. From the interviews undertaken in the previous chapter, it emerged that a number of participants belonged to a Regional Tissue Viability Group whose remit was to evaluate dressings. This merited in-depth exploration in order to find answers to the fourth research question and forms the focus of this chapter.

Chapter Structure

This chapter begins by listing the methods that were used, before giving a little historical background to the 'table-top' evaluation, and detailing its content. It then distils key elements that need to be considered for a through dressing evaluation.

METHODS

Sampling and Recruitment

Sampling and recruitment occurred as described in Chapter 4 (p51), though the data used in this chapter only includes the interviews with N5, N6, N7 and P2.

Data Collection

a) A copy of the 'table-top' evaluation, which is a dressing evaluation matrix used in the region. This is an Excel spreadsheet where all the elements considered are listed. For each element a Yes or No answer is entered (see Appendix II, p228).
b) Interviews with three TVNs and one pharmacist/commissioner (N5, N6, N7 and P2). The interview schedule was adapted to the responses provided by participants. As each participant mentioned the 'table-top' evaluation, some of the interviews time was spent clarifying the process.

Data Analysis

The 'table-top' evaluation offers a basic framework where each element is scored and is compared to other dressings with the same characteristics. Each element has the same weighting and therefore using a thematic analysis is appropriate as it provides an indication of what is considered of value (Patton 2015) amongst TVNs. This thematic analysis was undertaken by grouping each 'table-top' question into sub-themes. The thematic analysis led to the identification of four general themes: packaging; quality; education and evidence (see Table 5.1, p100).

Subsequently, NVivo was used to search the manuscripts of the four interviews to identify further elements that, according to the table top evaluation format, ought to be included in a dressing evaluation (presented on page 102); thematic analysis was undertaken using the same six-phases guide (Braun and Clarke 2006), described on page 73.

Finally, a word statistical analysis was undertaken on the four interviews and a visual picture of the content of the interviews was created to offer further data (presented on page 105).

10726 words were included in the analysis (the transcripts of the four interviews), selecting the first 1000 words containing 3 letters or more, used more than 9 times. 251 words were selected, analysed and the data cleansed to exclude colloquialism such as *yeah* or commonly used words such as *maybe, do, and, etc.* used in the English spoken language. Words were then grouped into 17 subgroups by their meaning (see Table 5.2, p105): for example 'dressing/dressings' and 'product/products' were grouped together. A word cloud was then created to illustrate the findings (see Figure 5.1, p106).

A word cloud (or text cloud) offers a visual sense of the key terms in a piece of writing at a glance. Each cloud visually represents the number of times certain words have been used within the interviews. The words are listed alphabetically and weighted to allow easy identification of the use frequency for each key word. The larger the font size, the more frequent the key word (Bateman et al. 2008).

One popular application area for word clouds is text summarisation (Heimerl et al. 2014), where word clouds are used to give an intuitive and visually appealing overview of a text by depicting the words that occur most often within it. Such a summarization is helpful to learn about the number and kind of topics present in a body of text, a starting point for a deeper analysis. I used it here to explore whether there was consonance or dissonance between what the four participants said during the interviews and what the 'table-top' matrix analysis highlighted as being important.

One drawback is that word clouds provide a purely statistical summary of isolated words without taking linguistic knowledge about the words and their relations into

account (Heimerl et al. 2014) and an element of subjectivism in the cleaning of the data has to be taken into account.

UNDERSTANDING THE REGIONAL TABLE-TOP EVALUATION MATRIX

The results of this analysis are peppered with explanations steeped in my own professional knowledge of the region in order to offer clarity to the reader, for example with the historical background described below.

Historical Background

A little historical background is necessary to understand the role of this evaluation matrix in the region. Faced with an increasing number and variety of dressings (Fletcher 2015), a group of TVNs formed a Regional Tissue Viability Group to rationalise usage. For a couple of years, some Trusts paid a retainer in the hope for a cut in the costs and subsequent reductions in their dressing spend; contracts with companies were signed for a better price for volume. This was largely led by procurement. Larger Trusts did not join as they could achieve the same savings without having to pay for the privilege. After a few years, the group had not made the predicted savings, so it dissolved. Nevertheless, the requirement to provide a modicum of rigour to the process of dressing selection for their Wound Management Formulary continued and a new reformed clinical group continued to operate but this time without procurement. Again, not all Trusts joined, because this evaluation process remained very controversial. This historical background was not discussed with the participants as there is a tacit understanding and acknowledgement of our shared historical past.

The 'Table-Top' Thematic Analysis

In this evaluation matrix (see Table 5.1, p100) most of the weight was on the packaging which constitutes 46.5% (13 questions out of 28) of the questions: the importance of being sturdy but not bulky as there is limited room on wards and

patients' homes; easy to open and the availability of the product in a range of sizes, should this be desirable.

Our shared experience dictated that packaging should be clearly labelled especially as companies brand their products with the same prefix, for example: Mepore, Mesorb, Mepitel, Mepilex, Mepilex Border, Mefix or Urgotul, Urgosorb, Urgoclean and so on; this can be very confusing to staff and is often the source of costly mistakes; this was the reason for inclusion in the 'table-top' matrix. A further consideration was the availability of the dressing from a procurement point of view, as some are available in hospital (via NHS Supply Chain) and are not in community (on prescription, known as FP10); this issue can cause concerns to patients when the product that they have been using successfully in hospital cannot be obtained once they have been discharged home. For this reason, products listed on the Wound Management Formulary have to be available in both settings.

Dressings should no longer contain latex due to the increased sensitivities to this material, however many dressings still do. Twenty-eight percent (eight questions out of twenty-eight) of the total matrix was given to the quality of the product in terms of manufacturing standards. It is known that a number of dressings are marketed before being CE marked and therefore the quality can at times be questionable. Question asked was: '*If a dressing sheds fibres, what is the clinical implication when these fibres are left in a wound?*' as if these fibres are biodegradable they will not become a foreign-body in the wound.

One question regarded information available to patients, where the group tried to ensure that the patient information leaflet (usually placed inside the packaging) was well written and legible. One question was centred on what staff education the company was able to provide. Larger companies can usually provide more education as they employ nurse advisors to ensure that their products are correctly applied. Finally, four questions (14.3%) were about the evidence of effectiveness and most of these questions were centred on laboratory data (fluid handling data,

important when selecting an absorbable dressing (Fulton et al. 2012); MTVR (Moisture Transmission Vapour Rate) data – pertaining to the breathability of dressing, important when selecting post-operative dressings (Palamand et al. 1992) and clinical evidence.

1. PACKAGING	2. QUALITY
- Quality of the outer packaging (sturdiness) - How much packaging is used - Ease of opening the inner packaging, does it easily rip/tear or require excessive force to open. Is opening the product difficult. - Does the packaging contain any latex - Is the size of any labelling acceptable on outer packaging - Does the clarity of the label on inner and outer packaging allow the user to clearly identify the product brand, size and type. - Indications clearly stated on application - Contraindications clearly listed on application - Latex - Side effects clearly labelled - Range of sizes - What is the level of risk of contaminating the dressing surface when removing the backing sheet or breaking seal of product or opening the sachet/tube - Available on FP10	- Ease of application - Wear time - Easy to remove in one piece - Bio-absorbable - No fibre shedding - Welded seams if applicable - Proof of quality standards - Overall fluid handling in 24 hrs
3. EDUCATION	**4. EVIDENCE**
- Patient Information: is the product information clear (quality, size of text) on IFU sheet - Staff Education	- Fluid handling data - MVTR data - Clinical evidence - Marketing Information

Table 5.1: *Thematic analysis of the regional 'table-top' evaluation matrix*

Interviews Analysis

The interviews revealed dichotomies of thoughts. First of all, the evaluation process is described as a 'table-top' evaluation by N5, N6 and N7, where boxes of dressing provided by the companies are reviewed by TVNs sitting around a table. Companies submit their products to be evaluated; each application is logged; the group undertakes the 'table-top' evaluation. Each member subsequently explores costs to see if the product offers value for money to their individual organisation. N7 further explains her approach,

> *We look at the quality of the boxes; we look at the cost. The product has to be available on FP10 and NHS supply chain because it's no good otherwise. We do a 'table-top' exercise, we look at... things like how much water it will absorb, we've had people take them home and put them in bath tanks before... if somebody has used it in the group, we will consider what they've found and then we will feedback.*

N7 states that *"I can honestly say, we don't do very many [clinical] evaluations at all".* This is not P2's understanding of the process, "*Well I don't think it's only done by 'table-top'"* she says when questioned, she believes that dressings are applied to patients' wounds.

Not everybody agrees that the 'table-top' system offers a good methodology for dressing evaluation. N6 goes along with the process because it provides 'peer justification' for some of her decision-making.

The Regional Tissue Viability Group provides a forum which could be developed to gain an interpretation of what standard care means across the region. P2 says, *"You've got a body of expertise within an area, where you have all the local tissue viability nurses coming together as a body of people".* N5 agrees that the Regional Tissue Viability Group meeting provides a forum for discussion and sharing of expertise and offers the following example, *"We're trying to come together to reduce pressure ulcers, and one of the things on the agenda is standardised*

pathways of care". Clarifying pathways of care and variations between healthcare settings is in a way more valuable than evaluating all the dressings that come on the market. In the development of a pathway of care, what dressing is recommended takes secondary position. This will be explored further in Chapter 7 (p166).

Interestingly, the 'table-top' evaluation matrix does not include costs; what each dressing costs is not considered when each TVN sits around the table. As N7 explains, each Trust has different buying powers and is therefore able to negotiate individually a deal with industry.

Elements for Evaluation

The interviews offered a window to what each participant would like to see in an evaluation and these elements are considered below.

Clinical usefulness

The first element to be considered is an evaluation of clinical usefulness. Whilst Chapter 2 (p23) described the challenges of using a RCT in wound care, most participants agreed that an element of comparison should be included, as a new dressing must be better than what was used before, to be true to the fundamental assumption of Dewey's philosophy; it has to be melioristic, therefore aiming to improve matters.

N2 explains that industries are often able to offer some comparative data for a like-for-like product, usually laboratory data, especially if they were marketing their product against the market leader. For example, if a dressing's main property is to absorb exudate, the companies would bring data that demonstrate that their product is more absorbent. The laboratory liquid that is used does not have the same viscosity as a real wound exudate, which changes in consistency between patients (White 2006), often therefore the laboratory data do not match clinical reality.

P2 explains that in order to "*create an evidence-base"* (see p69), there needs to be an element of comparison. *If you're using a comparator and where that has happened is, is you could do a comparator against usual care ... even if your usual care is not brilliant, then that might mean that your new product is exactly what's needed in the market, in which case comparing usual care, which is better than nothing, but still not perfect.* (P2)

The element of comparison between what was used and what has been used should be clearly described to give context to the evaluation, when reporting the findings, for example in a series of case studies. Published case studies tend to simply describe how a product has performed in a number of patients without detailing what would have been previously used.

FP: *How often in the case studies are we able to describe that that's what we used before and now that's what we're using now?*

N7: *Well, case studies don't do that.*

FP: *Do you feel there is a necessity to show what the comparator was?*

N7: *I think that, yes, there is a necessity because you need to show that because otherwise it doesn't make the case studies credible because it's not giving you the true picture of what was happening.*

Critically, participants agreed that it was not necessary to randomise the comparator. As described in Chapter 2 (p23), blinding is a near impossibility in wound care as both clinicians and patients would know which two dressings are used, therefore the main benefit of randomising patients becomes lost. Furthermore, if randomisation is not required, then the evaluation proposal "*…doesn't have to go through horrendous processes"* as P2 described the process for seeking ethical approval (see p69).

How many patients should be included in a dressing evaluation?

If the RCT methodology is not used, achieving statistical significance is not essential and therefore the issue of powering a study becomes somewhat irrelevant (Creswell 2014).

In the previous chapter, it was explained how N2 believed that a series of case studies including fifty patients was the mark of a quality study. Nevertheless, if we agree that an element of comparison should be incorporated in a dressing evaluation, N2's study would have necessitated the recruitment of a further fifty patients in the standard care group, data for which could have been collected *before* the evaluation was commenced. If we reject validity as a measure of positivist quality (Gobo 2008), we can agree that randomisation is not required in a dressing evaluation. If trustworthiness is accepted as the measure of pragmatic quality (Loh 2013), the element of comparison will simply require the inclusion of a standard care group and a *subsequent* group of patients with similar numbers.

It remains unclear how many patients should be included for a dressing evaluation to become clinically acceptable. N7 suggests,

> *I've no idea what's enough because at the end of the day [we know] that patients are not [all the] same ... You know, this characteristic in that wound was different to that one but they were mobile and they weren't so you can't compare them. So asking for a number, what does it mean, it doesn't mean anything. Not to me.*

It is therefore not about the number of patients one recruits but it is about the detailed description of the context where the evaluation is to take place; it is about describing standard care with accuracy so that a comparison can be made between an old dressing and a new one.

Users' involvement (patients and staff)

Patients input is advocated by many (Simon and Bielby 2014), and in the UK, government policy and research evidence suggest that the active involvement of service users (patients' carers and the public in health and social research) is very desirable. All informants agreed that patients' views should be incorporated.

Undertaking a word count of each word used in the interviews (see Table 5.2, p105) highlights an interesting fact. The most used words were *'dressing/dressings' and 'product/products'* (used 436 times); the term *'evaluate/evaluation'* was used 143 times. This is not surprising for interviews set on the topic of dressing evaluation.

However, the second most used word was *'patient/patients'* which was used 176 times but this did not correlate with the level of involvement that patients had in the 'table-top' matrix. Similarly, nurses were mentioned 111 times and not included in the process.

WORD	COUNT
RCT/RCTs	32
company/ companies	79
care	84
people	89
cost/cost/money	94
evidence	95
wound	95
formulary	105
nurse/nurses/staff	111
evaluate/evaluation	143
patient/patients	176
dressing/dressings/product/products	436

Table 5.2: *Sub-groups of meaning*

The following word cloud (see Figure 5.1, p106) was designed with the above data,

Figure 5.1*:* *Word cloud of the 17 most used words in the interviews*

That 'patients should be central to all we do' was agreed by all participants; what was not clear was how this could be achieved,

FP: *And how do you measure patient satisfaction?*

N5: *We ask them, verbally. How was it? Was it comfortable? Do you have any pain when it's removed? We've got nothing concrete, nothing tangible as an audit ..., but we ask how was it? What was your experience of the dressing at the time?*

Interview with N7,

FP: *So we've talked about patient satisfaction; do we do something in terms of quantifying the satisfaction with smiley faces or do we do something more robust, something else…?*

N7: *Well, we could, we do it as part of our patient satisfaction series so the feedback then is, you know, 'How was your treatment?' 'Did you get offered treatment options?' 'Were you happy with the treatment choice?' So we do ask those sorts of things, you know, survey for our service so we do get them back so that does give us some information and, I mean, ... yes, there are things we could probably use to help towards ... new formularies and things so, yes, there is some of that.*

N6 explained how she used a questionnaire and one question was for patients. "*Do you want to continue with this product? Yes or no?' If they say yes in that evaluation process I will then publish it*" to gain peer-review (see Chapter 4, p51). That one

single question is what N6 termed 'patient involvement' in dressing evaluation: *"I've got the patients voice"; "it's the needs of the patients"; "Procurement need to know that the clinicians are happy with it and the patient [is too]".*

The analysis of the interviews highlights the paternalistic attitude towards patients; their voices come through nurses asking one single, closed question. N5 see it as her responsibility to protect them from industry, *"we wouldn't let any reps* [sales representatives] *meet a patient, full stop".* Industry and tissue viability are seen as business partners, helping the powerless patient. N6 says, *"I think the NHS is a business and it's just recognising that you're both business partners for the best outcome for the patient*".

This is not malicious; it is part of the culture of nursing. N6 continues,

> *Because an evaluation is a short term thing, but we're actually affecting how a patient sees their care. So if they get a dressing that they really like, and I'm writing down they really like it, we can't then say, "Sorry, the evaluation is finished, you can go back to what you didn't want". That's not ethical. So it is about giving the patient a voice, but us holding up that contract with them to say, you will always get this product now, you've told me that's what you want.*

The assumption that we know best is ingrained, N7 will not take time to evaluate dressings because she knows that *"the patients get the best care they can at this point in time"*; she adds, *"You know, my patients...they're getting effective care".* She further states, "*I know my patients are being well looked after, I can go home and sleep at night knowing that I haven't got any qualms about that at all"* and once more, *"I'm confident my patients are getting good care".* But patients are not aware when new dressings are available, they do not attend the Regional Tissue Viability Group meetings; they are, in fact, a very carefully controlled voice.

Dressings are very much a nursing task (see Chapter 2, p23) therefore it seem intuitive to expect that they should be involved in dressing evaluations. All

informants were in agreement with this and voiced that staff should be asked to complete an evaluation form but none of the participants included staff survey in their evaluation process. Interestingly, they agreed that what staff say they do, differs from what they actually do, but once again, none of the interviewees undertook observation studies during their dressing evaluation process.

Patient stories and medical histories

N7 voices that each patient story is different as each patient undertakes different activities in their living. Each patient recruited to an inquiry should be able to enter their own version of events to the mix. Medical records reflect the paternalistic attitude that we have with patients, where their medical history is interpreted and transcribed with the eyes and mind of the clinician. Nevertheless, it may be worthwhile to look at medical records at the end of the patient's episode of care to make sure we have not missed some key information, some treatment or some entries that had subsequently been entered (lab reports, x-ray reports, medical photographs, dictations and so forth).

Cost examination

"Cost is an issue, but it should never be the final decision, it's about quality" (N7); however, savings on dressing spend is seen to be an inescapable reality. N5 believes that cost should have a forty percent weight in any evaluation. N7 agrees and believes that TVNs are under great pressure to save money and therefore this element should be included in an evaluation, with the understanding that the examination of costs will remain context-bound.

At this point, a note on terminology is required. The terms 'efficacy', 'efficiency' and 'effectiveness' are often used as synonymous in clinical practice but this is incorrect.

Efficacy refers to the intervention's ability to do more good than harm among the target population in an ideal setting; it is measured though randomised controlled clinical research trials involving carefully selected patients and outcomes (Schillinger

2010). Efficiency investigates the ability of a new treatment to be translated into everyday practice and effectiveness relates to the cost of the new treatment. Effectiveness refers to the intervention's ability to do more good than harm for the target population in a real world setting. Cost-effectiveness includes cost of the treatment, health professional time and clinical outcomes (Robinson 1993). If the cost of each dressing is higher, there must be savings to be achieved with faster healing rates or a reduction in the frequency of dressing changes, or significant improvement in the patient's quality of life (Marley 2000).

These definitions are terminologies used in EBP[15] (see Chapter 2, p23) and are not appropriate terms for a pragmatic dressing evaluation. The term 'value for money' was also explored. Value for money is a term used to assess whether or not an organisation has obtained the maximum benefit from the goods and services it both acquires and provides, within the resources available to it (High Education Funding Council for England 2015). Some elements may be subjective, difficult to measure, intangible and misunderstood and judgement is therefore required when considering whether value for money has been satisfactorily achieved or not. It takes into account the mix of quality, cost, resource used, fitness for purpose, timeliness and convenience to judge whether or not, together, they constitute good value (High Education Funding Council for England 2015). For this reason, it is only at the triangulation stage that true value for money can be determined. Only the costs for each comparator can be established rather than true value for money and this is the reason why I used the term 'cost examination' throughout this thesis.

Staff training

In an ideal world, staff education should be undertaken by the NHS; however, there are far too few TVNs to provide education to all the nurse generalists. For example,

[15] EBP = Evidence-based practice

with my team of four TVNs it would be unachievable to provide education to the 4000 nurse generalists employed in our Trust and we therefore rely on industry to assist with this task, actively encouraged by some (Flanagan 1998; Watret 2005) but strongly criticised by others (Madden 2012).

This is yet another element that muddies the water between TVNs and industry as small companies may have a good product but are yet unable to employ more staff to offer training and therefore their product is not selected; or companies produce very acceptable cheap dressings but as they don't make enough profit to employ nurse advisors, their dressings are not selected. Whilst this element had been given the same weight in the scoring matrix as other points, the reality is that this single element could make or break a company's chances to have their product listed on a Wound Management Formulary.

REFLECTIONS

The weaknesses of the 'table-top' evaluation are not in the elements considered, as they all have a rationale for investigation; it is not in the equal weighing of each question, even if one remains surprised that 'evidence' weighs the same as 'packaging'. Conversely one could argue that we might as well give little value to evidence when there is so little to be had! The weakness is in the putting up a façade, a "*smoke-screen*" (N5, see p86) to protect TVNs from criticisms, rather than 'taking the bull by the horn' and develop an alternative methodology for dressing evaluation.

As mentioned in the previous chapter, the unspoken theme of power travels through each interview. There appears to be a tacit desire for TVNs to maintain control. To control industry who must submit their product to the Regional Tissue Viability Group to be 'table-top evaluated' and be judged by their boxes rather than by what it contains; to control generalist nurses input by excluding them from the decision-making process and finally to control the voices of patients. Patients are

considered central but in fact they are very much a third party in this decision-making process.

In its current format the matrix does not provide a comprehensive evaluation in the form of a written body of knowledge that can be shared as best practice. By itself, the 'table-top' evaluation cheats patients, staff and industry of a fair three hundred and sixty degree look at each product. By itself, it exonerates TVNs from the responsibilities of developing a better approach and allows them to justify their decisions should they be questioned. Furthermore, and controversially, this matrix allows TVNs to continue to exert and hold power, which will be discussed further in Chapter 7 (p166).

Having said that, the information gathered with this matrix does offer a valuable check list to ensure all those operational aspects have been considered. In fact, it is often small details that are missed in an evaluation and those details can make a big difference to whether a dressing becomes clinically acceptable or not. This matrix should be seen as a simple checklist rather than a comprehensive assessment and should become embedded in a mixed-methods evaluation process.

Reflexivity and Trustworthiness

Understanding my position within the region is critical to the trustworthiness of this analysis. I did approach the topic with each participant with extreme caution and maximum diplomacy. N7, N5 and N6 were active members of this group; P2 commissioned the Wound Management Formulary for the region, including my Trust.

It must be made clear that I did not belong to the Regional Tissue Viability Group for two reasons: first, my Trust did not participate to this model of procurement as they always had their own strong buying power. Secondly, I did not attend these Regional Tissue Viability Group meetings as I was openly critical of the 'table-top' evaluatory process.

The impact of this was some reserve at the beginning of each interview, but I approached the interviews with curiosity and openness, so each participant opened too. I wanted to understand how each participant aligned this 'table-top' evaluation to their publically-voiced beliefs that it provided a fair evaluation. But taken individually, outside the power dynamics of the Regional Tissue Viability Group, each participant voiced that the 'table-top' evaluation had strong limitations and was simply the best they could hope for as undertaking rigorous evaluation was too time-consuming and somewhat controversially, not really required to get what one wanted. Undertaking this thesis with its methodological challenges (see Chapter 1, p9), I have become more sympathetic and less critical.

Dressings are commercially sensitive products. The process of putting each dressing though this matrix allowed each participant-TVN to fend off unwanted pressure from industry. Furthermore, the Regional Tissue Viability Group offered an element of benchmarking, defined here as the process of comparing one's own organisation with its peers (Daniels 1996), enabling each participant to justify their decision-making within their organisation.

Reflexivity tells me that it is all too easy to be critical of such process when one sits in a powerful organisation that has strong buying powers. My Trust holds the knife by the handle. These interviews highlighted that dressing evaluations sit in a complex world of power struggles between many players and at this stage I was unsure if unpicking each piece of this large jigsaw would allow my final picture to be any clearer than what my colleagues had managed to achieve so far.

CONCLUSION

This chapter has explored the dressing evaluation process used in the region. Applying thematic analysis to the 'table-top' evaluation matrix, it appears that 'packaging' is the most valued part of the matrix, but with further analysis, one understands that this is the easiest aspect to quantify when sitting around a table; 'quality', measured at face value is the second aspect; 'education' in terms of

education available for patients and staff becomes the third aspect. The fourth and final aspect is a review of the 'evidence' that supports its use in clinical practice; surprisingly this takes a minor position, but this is possibly a most honest way to reflect the dearth of evidence available to select dressings. Costs of each dressing were not included in the 'table-top' evaluation but were examined individually as each organisation had different buying powers.

The interviews confirmed that a new dressing ought to be better than the old one for a change of practice to occur, therefore an element of comparison is required for a clinically acceptable evaluation; randomisation was not seen as necessary. Whilst the number of patients recruited was not seen to be important, a thorough description of standard care was seen as essential.

User involvement (patients and staff) was seen as central to the process, but not included in their process and therefore, the interviews did not assist to clarify how best to include the patients' voice in an evaluation. The interviewees agreed that nurses' skills and knowledge develop in practice with practice; therefore, it would seem sensible to assume that observing them while they work and dress wounds using new dressings should be central to a dressing evaluation. Observing nurses at work is an experience that is said to be rich of useful practical information (Street 1992). Undoubtedly, understanding costs associated with dressings has value in today's NHS and should be therefore be included, alongside 'packaging and availability' to complete the process.

This chapter clarified which elements were to be included, but left some of the *how* unanswered. The only way forward was to simply have a go. The next chapter describes how a new dressing was evaluated in clinical practice using a pragmatic, mixed-methods process of inquiry.

CHAPTER 6

How could a dressing evaluation be undertaken in clinical practice?

> *There is no automated protocol to follow: no cast-iron rules can be laid down.*
>
> *John Dewey (1911, p241)*

INTRODUCTION

Dewey's pragmatism is about solving problems through experiential learning within a structured process of inquiry. Emirbayer and Maynard (2010) highlight that whilst Dewey pointed the way, he did not conduct research and therefore he did not develop a methodology for his philosophy. This offers a great advantage as it enables to try new avenues, see if they work and with experiential learning, reflect on the outcomes.

This thesis is an exploration of the world of dressing evaluation, seen as multiple pieces of knowledge; little by little a full picture is constructed and this chapter offers a clinical application. Any dressing could have been evaluated at this point, but a PHMB foam disc was the dressing that required evaluation at the time and a mixed-methods approach was applied to the process.

Chapter Structure

This chapter is divided into sections, that will be familiar to the positivist reader but with a pragmatic element to it, that reflects this thesis journey (see Chapter 1, p9). An exploration of care of pin sites naturally commences with a review of the literature as it is important to understand what has come before as one "*cannot perform his own activities without taking the activities of others into account"* (Dewey 1916, p16), therefore the first section offers a literature review for the care of pin sites.

Then methods are discussed (with sampling and recruitment, data collection and data analysis) with a description of the eight methods used in this evaluation, namely medical histories and patients' stories (p128); participant observation and informal interviews (p130); a comparative study between the PHMB foam dressings versus standard care (p131); a patients' Likert satisfaction survey (p133); a staff survey (p133), a cost examination (p134); an evaluation of the packaging and procurement route (p134) and finally a consensus meeting (p134). Findings from each method are then discussed in the 'Evaluating PHMB discs in Clinical Practice' section (p137). All the data collected are then triangulated (p153) to gain a clearer understanding of whether this new dressing would offer a clinical solution to the problem of dressing pin sites. Finally, further discussions will be offered that includes limitations, recommendations and reflections on trustworthiness.

Pin sites Care: An Exploration of the Literature

An external fixator is a device used to stabilise bone fractures in adults and children after traumatic injury (Bernardo 2001) or to lengthen a shortened limb (Checketts 2000); the pin site is the area where the pin meets the skin (Bell et al. 2008). Pin sites are acute wounds that are not allowed to heal and through the hole in the skin, infection can travel alongside the metal pin, potentially all the way down to the bone (Brereton 1998). When the external fixator is removed, the small holes scab over and heal quickly if no infection is present.

In external fixation the major risk is from the spread of infection, which is extremely difficult to eradicate (Simms and Saleh 1996 and 2000; Brady et al. 2006). Any superficial infection in pin sites may track down the hole as far as the bone and medullary cavity, potentially leading to bone infection, called osteomyelitis (Ward 1998; Bibbo and Brueggeman 2010), which is an extremely severe complication. The condition often becomes chronic and prevents the bone from healing, leading to long term pain and disability. The prevention of infections is central of the care of patients who have been fitted with external fixator and pin site care is an essential aspect of the treatment until the external fixator is removed.

Over the years, a number of different protocols for the management of pin sites have been proposed and debated as pin sites care has been causing concern to trauma-orthopaedics teams all over the world in terms of achieving a balance between preventing infection and promoting healthy skin. Goldberger et al. (1987) identified a number of major clinical challenges involved in pin site care: type of cleansing agent, approach to crusts, use of clean versus sterile technique, post cleansing care, use of dressings versus no dressings and frequency of care. A review of the literature reveals that there is an absence of methodologically robust RCTs in this area of care.

Temple and Santy (2004) performed the first Cochrane Database Systematic Review and they uncovered only two research articles considered as providing evidence of sufficient quality to be included in their review. Lethaby et al. (2008) updated this review and six further trials were identified (Henry 1996; W-Dahl et al. 2003; Camillo and Bongiovanni 2005; Grant et al. 2005; Patterson 2005; Egol et al. 2006), however all these studies were shown to have problems with the lack of validity of the outcome measures used to measure infection as there is no uniformly accepted definition of pin site infection to compare infection rates. Furthermore, there are few studies that describe the bacterium found in their infected pin sites. Lerner et al. (2005) cultured *Staphylococcus aurous* in 80% of the cultures they took from infected femoral pin sites, whilst Schalamon et al. (2007) found the same bacteria in

33% of their infected pin sites. This variation of findings may corroborate the lack of a validated pin site infection assessment tool.

The Cochrane Database Systematic Review (Lethaby et al. 2008)

Henry's (1996) study was a trial of pin site care in the UK, where thirty patients (aged 11-18-year-old) with a total of 120 pin sites were randomised to either cleansing with 0.9% saline, with 70% alcohol or no cleansing. Crust removal, gently massage, spraying with dry Povidone iodine and dressing with dry gauze was undertaken at all sites. Infection occurred in 25% with the 0.9% saline group; 18% with the 70% alcohol group and in 8% of those in the control group who had no cleansing at all. They conclude that cleansing increases the infection risk. Of interest is that they all received dry Povidone iodine, which is an antimicrobial associated with a disruption of the healing process and disruption of the normal flora of the skin in previous studies (Olson 1996). Povidone-iodine has been reported to have a corrosive effect on the stainless steel of skeletal pins (Celeste et al. 1984). Povidone-iodine has historically been used in pin site care as there have been few choices in antimicrobial solutions that can be used in open wounds.

Grant et al.'s (2005) Australian study compared Povidone-iodine solution with soft white paraffin ointment. Data were analysed on 116 pins sites from 18 patients. They concluded that the use of this antibacterial agent reduces the likelihood of infection; white paraffin ointment is an uncommon product to be used in pin site care, no other study in the literature describes such practice and it is therefore a questionable comparative choice.

Camillo and Bongiovanni (2005) recruited 30 patients with external fixation in Brazil. Patients in both treatment arms of the study were instructed to apply the wound care protocol after a shower. In the control group, the skin around each pin site was cleaned with sterile gauze soaked in 0.9% saline solution. The sites were then dried with sterile gauze and each site was covered with folded gauze. The experimental group followed the same protocol except that gauze soaked in Polyvinylpyrrolidone-

iodine was applied to each site. The result did not yield significant difference between the two treatments, unfortunately the study was underpowered and therefore conclusions could not be drawn.

In this American pilot study, Patterson (2005) explored the differences in infection/reaction rate amongst seven different pin-care protocols that varied the cleansing agent (half strength peroxide cleansing, saline cleansing and antibacterial soap and water cleaning) and dressing type. They recruited 92 patients across two large trauma-orthopaedic hospitals over the course of twenty-four months: the control group had no cleansing and dry dressing which was only changed if it became wet or soiled. There was no significant difference in infection rates depending on each different treatment.

Egol et al. (2006) recruited 118 patients in the USA with 120 distal radial fractures (it is unclear over how many months this study took place) and allocated them to one of three treatments' groups one week after surgery: daily pin care with a solution of half 0.9% saline and half hydrogen peroxide; weekly application of Chlorhexidine impregnated dressings (Biopatch) or weekly dry dressing change without pin site care. They found that there were significantly more pin site infections with the first protocol (22.5% infection rate), rather than with no cleansing (2.5% infection rate).

Moving on to pin site dressings, only four of the studies included in the Lethaby et al.'s (2008) Cochrane Database Systematic Review compared the effects of different types of dressings. Egol et al. (2006) compared the weekly application of a dry dressing to the weekly application of a Chlorhexidine impregnated foam dressing (Biopatch). Grant et al. (2005) compared twice daily application of 10% Povidone-iodine solution with daily application of sterile, soft white paraffin ointment. Camillo and Bongiovanni (2005) compared daily topical application of 10% Polyvinylpyrrolidone-iodine solution on gauze dressing with dry gauze dressing. Patterson (2005) compared the effects of the application of gauze twice a day, the application of 3% bismuth Triromophenate and white petroleum emulsion

impregnated gauze (Xeroform/Xeroflo) twice a day (not available in the UK) and application of gauze, which remain *in situ* and only changed if wet or soiled.

Lethaby et al. (2008) did not consider the approach to whether crusts that form around pin sites should be removed or not and one suspects that no papers had been found that contain this important aspect of care. In fact, this issue is controversial. Some (dated) authors advocate removal of crusts (Celeste et al. 1984; Gunta et al. 1992), while others advocate leaving crusts in place (Sproles 1985). Celeste et al. (1984) and the Gunta et al. (1992) believe that removing crusted secretions allows the pin holes to drain freely to the outside, which maintains a relatively low bacterial concentration at the pin-skin interface, thereby reducing the risk of pin site infection and abscess formation. On the other hand, Sproles (1985) recommends leaving crust in place because they act as a natural barrier to infection. Clinical experience however, warns that crusts can form a lid for bacteria to reproduce underneath.

In terms of dressing regime, none of the six studies included in this Cochrane Database Systematic Review (Lethaby et al. 2008) compared sterile dressing compared with non-sterile techniques. Nevertheless, sterile technique for hospitalised patients has been recommended, due to an increased risk of infection in a compromised host and the high number of antibiotic resistant organism in the hospital environment (Olson 1996; McKenzie 1999). Jones-Walton (1991) reported that 55% of the respondents to her survey (n=795) managed patients with clean technique, whilst 43% used sterile technique.

W-Dahl et al. (2003) reported no differences between daily or weekly pin sites care. They undertook a RCT where they compared daily cleansing of pin sites with 0.9% saline solution and a dry dressing and bandage to the same procedure conducted weekly. This study was conducted in Sweden, with a sample of 50 patients, who had undergone elective surgery. They concluded that there was no evidence of a difference in pin site infection between the two arms of the study and suggested

that weekly pin site care would seem appropriate. The study was rejected by Lethaby et al. (2008) for errors in the analysis of infection rates and therefore they concluded that it was not possible to determine whether any particular dressing was more effective than any other, or which cleansing regime would be more appropriate.

The 2001 Consensus Document

In the absence of clear recommendations, the National Association of Orthopaedic Nurses decided to assess the available evidence and as they could not find valid and reliable guidance in the literature, they had to base their recommendations on a consensus of clinicians' experiences. This resulted in the National Association of Orthopaedic Nurses Guidelines in pin site care (Lee-Smith et al. 2001). In the UK, pin site care has been guided by these guidelines, which suggested daily showering, the leg being dried with a clean towel and no dressings applied. No studies have subsequently taken place to test the validity and reliability of these recommendations which have continued to be adopted as both Cochrane Database Systematic Reviews failed to make any recommendations.

The Kurgan Protocol

An alternative to the above protocol was proposed by Timms and Pugh (2010) and adopted by a number of trauma and orthopaedics centres stemming from the work of Davis et al. (2005) who demonstrated in a prospective, though not randomised (and therefore not included in the Cochrane Database Systematic Review) trial of one hundred and twenty patients that the use of alcoholic antiseptic, dressings and good surgical technique lowered the risk of infection compared with cleansing with normal saline.

Timms and Pugh (2010) make an analogy between pin site care and care of peripheral and central venous access devices. As these devices are widely used, clear guidelines are available, based on valid and reliable research. Epic2 (Pratt et al. 2007), recommend skin asepsis pre-insertion and in-between dressing changes with

a solution of 2% w/v Chlorhexidine gluconate in 70% alcohol. Weekly cleansing using this solution, the application of dressings has been termed the 'Kurgan Protocol' as it is the method used at the Ilizarov Scientific Centre for Restorative Traumatology and Orthopaedics in Kurgan, Russia (Timms and Pugh 2010), who advertise an (anecdotally) very low rate of infection rate. True Kurgan involves the use of 100% alcohol; however in the UK alcohol is only available as 70% in 2% w/v Chlorhexidine gluconate.

Timms and Pugh (2010) believe that pin sites should be considered similar to venous access devices and recommend the use of similar procedures for cleansing pin sites.

The 2011 Consensus

In 2011, the National Association of Orthopaedic Nurses in collaboration with the Royal College of Nursing updated the earlier consensus document. This protocol is based on the work of Timms (Timms and Pugh 2010) who is, incidentally the main contributor of the revised guidelines. Not surprisingly therefore, the new recommendation is that pin sites are should only be used if the patient is sensitive to Chlorhexidine. The new guidance also recommends that pin sites are cleaned and dressed every seven days unless exudate is present and the pin sites are covered with sterile dressing at all times (no recommendations are offered on what type of dressing should be used). The patient is allowed to shower once per week immediately before dressing changes. All these recommendations vary very little from the 2001 version, as in fact little research has taken place to further guide the updated consensus.

What happens locally?

In my establishment, some clinicians have stayed faithful to the 2001 Consensus whilst other have switched to the Kurgan method as they believe that it might potentially reduce their infection rates. No local infection rates have ever been collated for pin sites; however, the team that switched to Kurgan believed that this

method resulted in an (anecdotal) fall in infection. Unfortunately, they also started to see instances of contact dermatitis with the constant use of 2% w/v Chlorhexidine gluconate in 70% alcohol, especially when the external fixators had stayed *in situ* for a number of months. This had also been reported in the literature (Coulter et al. 2012).

Dressing Alternatives

A number of dressings were considered, all of which had antimicrobial properties. Antimicrobial is a term used to describe methods of eliminating or reducing bacterial load which may include the use of topical antibiotics and antiseptics[16].

Silver is a known antiseptic and has been manufactured within a dressing that has been used in pin sites with good results (Bhattacharyya and Bradley 2006). However, questions have been raised over the long-term consequences, with concern about silver toxicity, systemic uptake and deposition of silver in organs such as the liver and kidney (Wang et al. 2009). Dressings impregnated with honey, another powerful antimicrobial, could also offer an interesting option; however, honey is a messy, sticky medium to work with, and challenging to apply. Iodine-based dressings are corrosive to the metalwork and are not recommended in pin site care (Ward 1998).

A new foam disc, impregnated with polyhexamethelene biguanide (PHMB) was developed by industry. PHMB is a solution usually found in contact lenses solutions

[16] Antibiotics are substances that kill bacteria or inhibit their growth and/or duplications and are usually administer orally or intravenously and are no longer advocated as topical agents (Vowden et al. 2011) whilst antiseptics are chemicals which are used to eliminate or reduce bacterial numbers on hard surfaces, on the skin and within wounds. Some antiseptics can be toxic to human tissues (World Union of Wound Healing Societies 2008).

(Edwards-Jones et al. 2013). An antibacterial agent which is active against a wide numbers of microorganisms found in wounds, PHMB is bacteriostatic (prevents bacteria from growing or reproducing) at low concentrations (1-32mg/l), but bactericidal (kills bacteria) at higher concentrations (8-208mg/l) depending upon the microorganisms tested (Moore et al. 2008). Laboratory studies demonstrated that PHMB is effective against wound-colonising bacterial including *staphylococcus aureus* (Kirker et al. 2009). PHMB provides an alternative antiseptic agent to silver, honey or iodine (Vowden et al. 2011); it offers broad-spectrum antimicrobial activity in both acute and chronic wounds (Lee et al. 2004) and reduces wound pain/malodour (Daeschlein et al. 2007).

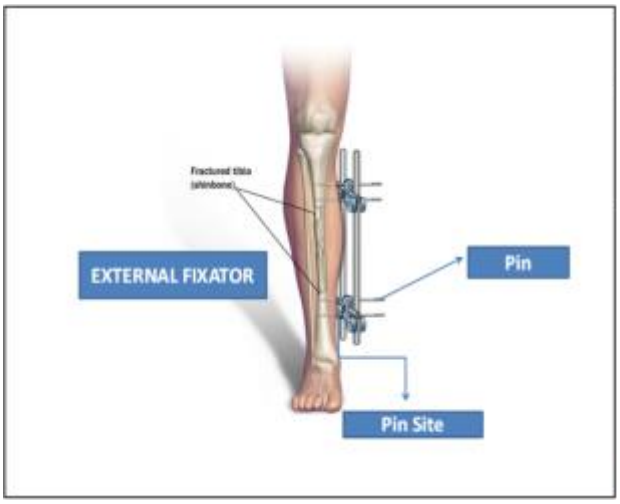

Figure 6.1 External Fixator

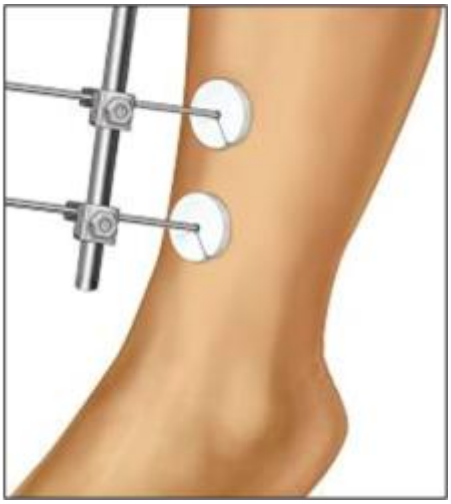

Figure 6.2 PHMB discs

Sibbald et al. (2011) undertook a study to determine the antimicrobial abilities of PHMB foam dressings in chronic wound care. This Canadian study recruited forty-five patients with chronic wounds. They were stratified to either foot or leg ulcers and were followed for five weeks. A multicentre, prospective, double-blind, pilot randomized controlled clinical trial with three study visits (week 0,2 and 4) was set out to evaluate the effectiveness of PHMB foam dressing compared with a similar non-antimicrobial foam for the treatment of superficial bacterial burden, wound

associated pain and a reduction in wound size. The results were very promising, they concluded that the use of PHMB foam dressing was a significant predictor of reduced wound superficial bacterial burden (p=0.016) at week 4 as compared with the foam alone, with a statistical significant pain reduction and wound reduction.

After reviewing the available literature and all possible alternative dressings, a product containing PHMB[17] seemed a product worthy of evaluation. The manufacturers had just developed a foam dressing with a slit on one side for the dressing to fit around any medical devices such as tubes, catheter or pins (see Figure 6.1 and 6.2, p124) and this is the product that was evaluated in this study.

METHODS

Sampling and Recruitment

Ten patients, thirty-one nurses (ward and out-patients' generalists), one orthopaedic surgeon and five trauma sisters were recruited to different elements of the study, which are described below.

Participants (Patients)

Ten patients (Oliver, Jacky, Noelle, Jacob, Charlotte, Harry, Josh, James, Thomasina and Wilhelmina[18]) were recruited to the study.

Inclusion criteria were for all patients who had been fitted with an external fixator to the upper or lower limb; who were older than eighteen years of age and had capacity. This occurred whilst the patient was still in hospital, 24-48h hours after

[17] Kendall™ AMD Antimicrobial Foam Disc (2.54 cm), 4mm hole.

[18] All names are fictitious to preserve their identities.

surgery. All the patients who were approached were given a participant information sheet[19] and subsequently agreed to participate to the study and provided written consent.

Exclusions criteria were set for those patients who had been fitted with an external fixator as a temporary measure and those who lived outside our catchment area[20] and were to be repatriated on discharge. One patient was excluded as lacked capacity to consent.

Participants' medical records were scrutinised to understand how these patients arrived at being fitted with an external fixator and their journey to its removal. Each individual patient had a different story of how they sustained their injuries. Accidents in life occur on a regular basis with falls from horses (Jacky) and motorbikes (Oliver, Jacob); falls from ladders and stairs whilst at work (Harry; Wilhelmina) but also injuries where it is unclear if it was the bone that had given way and caused the fall (Charlotte; Thomasina).

Some patients had advanced osteoporosis (Thomasina), some had cancer, some both (Noelle; Charlotte) and therefore their bones were more brittle than should be. In these instances, the medical history for the patient was as complex as the fracture.

Some patients sustained comminuted fractures, which meant that at time of the injury, the broken bone had come through the skin, exponentially increasing the risk of osteomyelitis (infection in the bone). Many photographs were taken over the

[19] A copy of the participant information sheets for patients can be found in Appendix III.

[20] The study is set in large city in the north of England, a NHS Foundation Trust which provides tertiary care to its region and primary care to its city centre community. The trauma/orthopaedic unit consist of two wards with sixty-five beds and an out-patient department.

course of these ten patients' treatment, some by the ambulance crew (Thomasina), too graphic to be included in this thesis.

Participants (Nurses)

In order to capture as many registered nurses opinions and engage with them as a valued source of information, a short questionnaire (see Appendix IV, p232) was distributed to all registered nursing staff from both trauma wards and the out-patients department. This was a non-probability and purposive sampling (Plowright 2011). Its selectivity is due to knowing that whilst this particular group of nurses do not represent the wider population, they represent 'themselves' (Cohen et al. 2007), a group of nurses who had the potentiality of having been exposed to the new PHMB dressing. Thirty-one generalist nurses were recruited in this way; twenty-seven were generalist nurses (twenty-one generalist nurses worked on the two trauma wards whilst six worked in the out-patient department).

Additionally, a further four nurses (Anna, Lisa, Georgia and Esme) were recruited because they were on duty when a pin site dressing on one of the ten recruited patients was due (convenience sampling, Plowright 2011). They also worked within the orthopaedic department. Anna and Lisa were ward nurses; Georgia worked in the out-patient department and Esme was the junior sister of one of the two trauma wards.

Participant information sheets[21] were issued to all the wards and out-patients before the commencement of the study, so a copy was easily obtainable to refresh staff on the day. Anna, Lisa, Georgia and Esme had informed me when a patient required pin site care; (verbal) consent was obtained for recruitment to the study.

[21] A copy of the participant information sheets for nurses can be found in Appendix III, p232.

The staff survey was handed to the ward managers as a paper format but also electronically, through a group email.

Participant (Orthopaedic surgeon and Senior Trauma Sisters)

One orthopaedic surgeon and five senior trauma sisters were recruited. The orthopaedic surgeon was the same colleague who had approached me at the right beginning of this journey (see Chapter 1, p9) to discuss the issue of contact dermatitis with the Kurgan regime and was looking for an alternative. Their role was to give the data collected *trustworthiness*, defined as credible, dependable, confirmable and transferable (Lincoln and Guba 1985), because they were a specialist group of staff, with many years' experience in the field. These clinicians were key decision-makers in the organisation (purposive sample, Plowright 2011).

Data Collection

In the spirit of Dewey's experimentalism, this study borrowed techniques from a variety of research traditions, in order to develop a bespoke evaluation framework. Techniques were borrowed from rapid ethnography which differs from classical ethnography. Classic ethnography is known to be time-consuming (Handwerker 2001), which is a luxury that is simply unavailable in clinical practice.

Ethnographies that focus on a distinct problem within a specific context among a small group of people are labelled focused ethnography (Morse 1987), mini-ethnography (Leininger 1985); micro-ethnography (Werner and Schoepfle 1987) or rapid ethnography (Millen 2000; Handwerker 2001; McNall and Foster-Fishman 2007), the latter originates from humanitarian aid relief (Sandison 2003). I have chosen the term 'rapid' because it is a term already used in health and therefore known to our setting; for example, rapid assessment is undertaken in the early recognition and assessment of patients showing signs of acute deterioration (Adam et al. 2013).

As the term implies, rapid ethnography is a collection of field methods which intends to provide a reasonable understanding of users and their activities given significant time pressures and limited time in the field. Lack of time does not have to mean poor quality (Handwerker 2001) but it is about making the most of the available time. The techniques are easy to use and their straightforwardness and lack of pretence add to their attraction (Wolcott 1999).

Rapid ethnography techniques are focused, cost effective, technically eclectic and pragmatic (Vincent et al. 2000) as the primary purpose is to quickly generate information to assist decision-making. Not designed to contribute to an existing body of theory, this technique provides information of sufficient quality at key decision points to improve the quality of decision-making by collecting data from a variety of sources. This study collected data from the following sources:

a. Medical histories and patients' histories to include photographs
b. Participant observations of nurses with patients; informal interviews with nurses and patients, at the same time
c. Comparative study – PHMB versus standard care
d. Patients Likert survey
e. Ward and out-patient staff survey
f. An examination of costs
g. An evaluation of the packaging and availability of the product
h. Consensus meeting with an orthopaedic surgeon and five senior trauma nurses

a. Medical Histories and Patients Stories

In November 2014, the patients' medical notes were reviewed to report on their journey since completing the study and were written in a story-telling format as recommended by Goodall (2012). The review of medical and nursing records provided additional information, namely the patient medical history and process of injury. These were added to the previously collected field notes, taken during my participant observation and informal interviews. The aim of this section was to

convey the complexity of each patient's journey; patients were not simply the 'recruited sample'; they provided a deeper understanding of the issue of dressing pin sites. This is important because each journey had an impact on the dressing used and therefore outcome. Photographs of the pin sites were also collated and descriptions were written up as field notes.

Digital photography

Digital photography is advocated as best practice in wound care (Hayes 2003). As more wards purchase digital camera, this practice has increased and is now considered standard practice. However, one must be mindful that cameras can distort reality. In the hands of a nurse, not usually trained in using a digital camera, a wound can be misrepresented as depth and colour, indicative of infection and inflammation, may not necessary 'come out' well. Furthermore, taken out of context, photographs, like words can be misleading.

Photographs were helpful as they allowed for better documentation and labelling of pin sites, so to be clear to staff which pin was which. Each patient's limb was photographed a number of times, from different angles; the photograph was then printed and each pin site numbered. Photographs were also used for those patients who developed infection (see Noelle's story, p138) in order to compare wound healing progress. Photographic records provided information that was not noticed at the time and enhanced my understanding of how complex the system of external fixator can be and how tight the access to each pin site was on these patients. Not all clinicians had the ability for such fine hand-movements and pin sites care definitely required high levels of eye-hand coordination and dexterity. A photograph of a pin site *in situ* can be found in Appendix V (p232) to give the reader a better understanding of the technical problems faced by clinicians when redressing pin sites.

b. Participant Observation and Informal Interviews

Participant observation was central to this dressing evaluation. It is critical that the things that people say about their own activities and about the activities of others are supplemented with first hand observation and behaviour in the setting in which they habitually occur (Blomberg 1995). Patients and nurses were observed whilst undertaking the task of re-dressing pin sites, as the use of direct observation of situated activities allows to grasp the lived reality of the target population (ten Have 2004). Discussing dressing issues with staff and patients at the same time elicited information of the 'now and here' issues (Handwerker 2001), fresh in their mind as they were working. Staff felt they had participated to the study, and they hoped that the final protocol would take into consideration their opinions, experiences and recommendations.

Six participant observations were made, when the nurses delivered pin site care to five of the ten recruited patients. Esme was observed three times on two different patients as there are only a few nurses in out-patients and Esme was the dedicated pin site nurse.

Both nurses and patients were informally interviewed during the same episode of care. Informal interviews are the most common in ethnographic work and they seem casual conversations (Fetterman 2010), forming a mixture of conversation and embedded question, where open and closed ended questions helped with discovering and confirming the participants' experiences and perceptions (Brewer 2000). The questions emerged from the conversation. Informal interviews offered the most natural situation format for data collection and analysis. Each patient had a story to tell, fragments of their experiences that might not have been documented in the medical notes, fragments that added to my understanding of the problem.

Field notes were taken after each event and expanded to a more comprehensive description later, on the same day, to ensure memory remained as fresh as possible.

c. Comparative Study

One of the challenges already discussed in Chapter 2 (p23) is the issue of sufficiently powering a study. If using the same power calculation as Egol et al. (2005) (see 'Pin site care: exploration of the literature' section, p115), which was based on 5% difference in complication rates between two treatment groups and computed for 80% statistical power with a Type I error of 0.05, a sample of eighty patients would have been required, with forty patients in each group. In our establishment, it would have taken eight years to complete recruitment; had resources been available to engage in a multi-centre study, a further eight to ten centres would have needed to join the evaluation. There appears little value in engaging in such endeavour, with all the effort, cost and time for a study that looks at the dressing effectiveness of one dressing versus a very variable and ill-defined standard practice.

The ten patients recruited were allocated to either PHBM or Kurgan protocol (inclusion/exclusion criteria has been previously explained on p124), looking for occurrence of contact dermatitis or infection. It was decided that even if not required, randomisation would offer the opportunity to include the comparative element deemed essential for a dressing evaluation (see Chapter 5, p95), but also for reasons explained in Chapter 1 (p9) and the 'Ethical approval' section in this chapter (see p135). Patients were randomised using computer generated allocation, printed and placed into individual envelopes which had been prepared by an independent colleague.

A data sheet was used to collect relevant data, which include patient demographics, medical history of patient, details of the surgical procedure, site of pin (upper or lower limb), details of antibiotic therapy, pin-site observation and when

inflammation or infection occurs, this was qualified using the Checketts-Otterburn grading system (Checketts 2000). Signs of contact dermatitis were also recorded (see Table 6.1, p132).

The Checketts-Otterburn grading system is a commonly used tool, but it is not been validated (Timms and Pugh 2010) therefore its reliability and validity remains purely descriptive.

	GRADE	APPEARANCE
MINOR INFECTION	1	Slight redness, little discharge
	2	Redness of skin, discharge, pain and tenderness in the soft tissue
	3	Grade 2, but not improved with antibiotics
MAJOR INFECTION	4	Severe soft tissue infection involving several pins, sometimes with associated loosening of the pin
	5	Grade 4 but also involvement of the bone, also visible on X-ray
	6	This infection occurs after fixator removal. The pin track heals initially but will break down and discharge at intervals. X-ray shows no bone formation and sometimes sequestra

Table 6.1: *Checketts-Otterburn pin site infection grading system*

d. Patients' Likert Survey

Data were collected from each patient, with the Likert scale (see Figure 6.3, p133), where a '0' score was given for 'don't like it at all' and '5' for 'like it very much'. Patients were asked the simple question: 'do you like this dressing?'

Figure 6.3*:* *Likert Scale used to gage patient satisfaction*

e. Ward and Out-patient Staff Survey

The survey was developed as to ask clear questions, limiting the possibility of misunderstanding, with one open ended question to allow staff the freedom to discuss any issues they wished. This high degree of structure gives greater predictability on the data (Plowright 2011).The questionnaire (presented in full in Appendix IV, p232) was piloted by two nursing colleagues, both experienced in questionnaire development.

It included four questions: the first asked if they had had the opportunity to use the PHMB discs; if not they did not have to answer the other three questions. They were asked to rate (Excellent, Good, Fair or Poor) the ease of application; the ease of removing dressing from the packaging; the (perceived) comfort for the patient and the ease of keeping the disc *in situ*. In order to give each respondent a counting voice, the final question was whether they would like the product to be available for patients with external fixators. These questions had arisen from the findings

described in Chapter 5 (p95), these were the elements that had been considered essential to be included in a dressing evaluation.

f. Cost Examination

Costs for the dressing regimes of both arms of the comparative study were ascertained.

g. Evaluation of Packaging and Product Availability

As described in Chapter 5 (p95), packaging was deemed to be important to a dressing evaluation. The packaging was evaluated by FP[22] as clinician-researcher. An assurance was sought that the product was available both in acute (via NHS Supplies) and community setting (via FP10). This data collection method is appropriate for this thesis, being a Professional Doctorate (see p153 for further details).

h. Consensus Meeting with Orthopaedic Surgeon and Five Senior Trauma Nurses

A consensus meeting between senior decision-makers was set up to review the data collected and after triangulation had taken place (see p153) and to agree a protocol for pin sites. They were contacted via Trust e-mail. Minutes for this consensus meeting were taken, written up as standard procedure in our organisation and circulated for approval (email traceability).

This meeting took place in January 2015.

[22] FP = Author of this thesis.

Data Analysis

All the data collected were triangulated, which has been defined as the "*act of bringing more than one source of data to bear on a single point"* (Marshall and Rossman 2011, p252). Data analysis was based on triangulation that checked results of one method against the other as well as during the final stages of writing after a firm knowledge base has been built (Crang and Cook 2007). This dressing evaluation was based on gaining knowledge of various key aspects, asking questions, listening, probing, observing, comparing and contrasting with other dressings and finally synthesising, bringing it altogether to offer a fuller picture of the problem and its temporary solution.

The data are presented in such a way that the findings are interlaced with elements from the literature and from my own field notes. This is because the aim for the study isn't to gain a deep understanding of participants' experience or to develop a theory, but to compare and contrast my own experience with the participants' experience (patients and staff) and the literature in order to advance this area of practice. Non-parametric statistics were used when appropriate because of the small samples used; an assumption was made that normality would not be met and outcomes would be of the categorical or ordinal variable (Handwerker 2001).

Ethical Approval

Seeking ethical approval commenced at the very beginning of my personal, philosophical and literary journey (see Chapter 1, p9). Ethical approval to undertake a pilot study was sought and approved by Northumbria University (June 2012) and from the NHS Ethic Committee (December 2012) for the recruitment of up to

twenty patients to a mixed-methods study, which included a pilot RCT with randomisation of patients to either PHMB or standard care[23].

This approach however met two big challenges: firstly, became the realisation that a pilot study came with the moral promise to undertake a larger study at a later date. This was not going to take place for the reasons mentioned in Chapter 2 (p23). The second problem was deeper than the methodology problem; dressing evaluation had a philosophical perspective problem (see Chapter 3, p38). These realisations came well after the request for ethical approval.

As ethical approval for staff observation/informal interviews was not required for research involving NHS or social care staff recruited as research participants by virtue of their professional role (HRA 2015), this was not sought. However, all nursing and medical staff involved in this study gave verbal consent. Staff participant information leaflets were given to each ward and out-patient department.

The same document explains that ethical approval is not required for the use of medical documents, as long as all information remains confidential and is information collected in the course of normal care.

To ensure full compliance, I completed the online course: *An introduction to good clinical practice: a practical guide to ethical and scientific quality standards in clinical research module* (8th February 2013, certificate available on request).

Digital photographs were also taken with verbal consent as per Trust policy. This is standard practice with wound care, where verbal consent is taken for clinical,

[23] Letters of approval can be provided on request; they are not submitted with this thesis to maintain participants' anonymity.

educational and/or publication reasons. This was made possible within the remit of the *researcher- in-clinical practice,* undertaking a Professional Doctorate.

EVALUATING PHMB DISCS IN CLINICAL PRACTICE

This section offers an account of the analysis of the data collected, element by element.

a. Medical Histories and Patient Stories to Include Photographs

The following medical histories and patient stories were collated. Photographs were included to inform the final analysis.

Patient 1 (Oliver): *Oliver was forty-five years old. Four years previously he was involved in a velocity trauma (motorbike accident) which shattered his fibula and tibia on his left leg. For the first two years, he was treated with an external fixator, a piece of his rib was used to make the tibia (the loading bone) and bone grafting was used to 'glue' it all together. However, this did not work, the external fixator was very loose with numerous pins site infections and wound abscesses. He returned to theatre in August 2013 where a new external fixator was applied. Following this surgery, the new frame was solidly implanted in the bones. After sixteen weeks of the study, he had no infections; pin sites remained clean and dry throughout the treatment. He was very satisfied with the dressing regime, scoring 5 on the Likert scale. I observed Georgia perform his dressings a couple of times.*

At the time of medical notes review, Oliver's external fixator was still in situ*; no incidence of infection recorded this time and no contact dermatitis. However, he was no longer using strict Kurgan. At the end of the sixteen weeks' study participation, Oliver started to use normal saline to clean his pin sites and only occasionally the solution of 2% w/v Chlorhexidine gluconate in 70% alcohol. Removal of the external fixator was reported to be imminent but the orthopaedic consultant was doubtful that the bones had actually healed well enough for this patient to walk without aid.*

Patient 2 (Jacky): *Jacky was a sixty-four years old woman who fell off her horse. She sustained a complex fracture to her left wrist. The external fixator was applied and remained in situ for a period of eight weeks. She stayed in hospital for three days and was then discharged home, care of the district nurses as was unable to self-care. District nurses adhered to plan of care very consistently and Jacky did not*

develop any infections, her pin sites remained clean and dry throughout the treatment.

Patient 3 (Noelle): *Noelle was sixty-one year of age. She fell in the house in a low impact trauma and sustained a very complex open fracture to her left tibia and fibula bones. Noelle had been diagnosed with bilateral breast cancer with lymphoedema and osteoporosis. At the time of recruitment to the study, she had had an external fixator for two years and amputation had been mentioned to her numerous times.*

She was recruited to the study when a new external fixator had to be reapplied. There was a large wound on the shin of her left leg, where the tendon was exposed; therefore, wound care for this lady was very complex. Noelle was nursed in hospital for over one year.

She received numerous courses of antibiotics as her lower pin sites got infected, Checkett grade 4. Furthermore, she developed contact dermatitis with the regime. The external fixator had to be repositioned many times but was finally removed in September 2014. At the time of the medical notes review (November 2014), Noelle could walk with a supportive brace but it was reported that it was unlikely that the bone was stable enough and re-break was expected at any time.

Patient 4 (Jacob): *This forty-three-year-old man was riding his motorbike in a local town, was stationary and waiting to turn right at a junction, when a large car run into him. He sustained a high impact trauma which resulted into a complex fracture to his left wrist and a fracture to his mandibular bone (jaw). He was nursed in intensive care for two days. Jacob lived fifty miles from the facility; he therefore was unable to attend weekly fracture clinic appointments. Jacob needed a course of antibiotics for infection. The external fixator was removed after five weeks, bone and wounds fully healed.*

I was never able to review Jacob. He only sporadically returned to our centre, therefore not technically lost to follow up. Telephone contact with the nurses in fracture clinic enabled me to report outcome as well as the review of his medical notes.

Patient 5 (Charlotte): *This eighty-four-year-old lady fell whilst shopping. She sustained a low impact trauma but sustained very important injuries: a complex fracture of her left radius and fractured left femur. She arrested a few times in Accident and Emergency and needed to have an urgent pacemaker inserted. This lady had been diagnosed with terminal cancer with bone metastasis a few months*

prior to this event. She was looked after by ward nurses on two different wards. As her rehabilitation took time, she was discharged home nearly three weeks after the external fixator had been removed.

Charlotte had an uneventful time with her external fixator, no infections; her pin sites remained clean and dry throughout the treatment. The external fixator was removed after five weeks, bone and wounds fully healed.

Patient 6 (Harry): *Harry was a fifty-six-year-old gentleman, who collapsed whilst he was on a ladder. This patient had 'fainted' three times previously for unknown reasons. Unfortunately, this time, he sustained a complex fracture to his left radius, with the broken bone actually protruding from the skin. On admission he was found to have arrhythmias and required cardiac investigation. On discharge he was looked after by the practice nurses at his GP surgery. They followed the regime. He reported that the practice nurses were very slow with doing his dressing and he was concerned with their skills and abilities. The external fixator was removed after five weeks, bone and wounds fully healed, no infection present throughout and the pin sites remained clean and dry.*

Patient 7 (Josh): *Josh was a forty-five years old gentleman who was admitted after stepping out in front of a car. He sustained a complex fracture to the proximal tibia; a fractured knee and required ligament reconstruction. Three surgeons were involved with his surgery and subsequent follow-up. He was looked after post-discharge by his practice nurse, in a neighbouring Trust. At the time of the medical notes review, he still had his frame in situ, over six months' post-injury. Whilst he had consented to taking part of this study, he had a number of non-attendances to the fracture clinic, which meant that I was not able to follow him up personally, but simply via telephone with the nursing staff. They reported no infection and no contact dermatitis, however it is unclear if true Kurgan was followed once discharged. I observed Esme perform this dressing.*

Patient 8 (James): *James was admitted electively for application of external fixator to fix his elbow in position. He was a thirty-eight-years-old gentleman who had a fall in town and sustained a fracture and dislocation of his elbow. This was a complex fracture with large soft tissue damage associated with it. He was subsequently readmitted a number of times for dislocation of his elbow. The application of the external fixator was to allow his elbow to heal and hopefully become more stable. James very keen to participate in this study but he was also very anxious and required much input in terms of explanation and emotional support. His external fixator was removed seven weeks later after an uneventful period of care and at*

time of review, his elbow was fairly stable. He reported his practice nurses being slow in the application of the dressing and had concerns about their proficiency in wound care.

Patient 9 (Thomasina): *Thomasina was an elderly eighty-six-year-old who had a fall at home. She had a history of osteoporosis, fairly sedentary lady who was overweight. She was walking with the Zimmer frame and felt her leg giving way; she fell and sustained a compound fracture of the tibia. Photographic evidence taken by the paramedics is very graphic indeed and show the bone split in half with the foot right underneath. I spent much time with this lady as I observed Anna undertaking the dressing. A few weeks later the patient was transferred to another hospital for rehabilitation, and therefore technically lost to follow-up.*

Thomasina was readmitted a few weeks later with infected pin sites but reported that the rehabilitation hospital did not undertake pin site care regularly or as proficiently and did not continue with the PHMB discs.

Patient 10 (Wilhelmina): *Wilhelmina was a fifty-eight-year-old lady slipped all the way down a staircase. There was initial concern that she had hurt her back, but in fact she sustained a complex fracture of the ankle. Open reduction and internal fixation was performed but the screws in her ankle were not stable and she had to return to theatre for application of an external fixator. I observed Lisa perform this dressing.*

Two weeks later, this patient was seen in out-patient but stated that the discs had been discontinued by the practice nurses because this was 'not allowed'. Full written explanation had been given to the practice nurses as well as a supply of dressings; it is unclear what the problem was. At the time of the medical notes review, this patient continued to have the external fixator, dressed by the practice nurses with normal saline only and staff reported inflammation (redness) and crusty, unclean pin sites but no infection.

b. Participant Observation and Informal Interviews

Observing nurses working yielded some interesting and surprising results. Despite my background of trauma-orthopaedics and the numerous times I have undertaken pin sites care, my role of *participant as observant* allowed me to take a step back and *really* look at what was happening in front of my eyes. The following is taken from my field notes,

Anna seems to be very dextrous nurse but struggles to apply the discs. They do not stay in place. With the static they seem to bend upwards and to secure them down, much tape is necessary. There is little room between pin sites. Anna does not clean the pin sites enough and I have to intervene. Eleven discs are required for this procedure; this is the biggest frame I have seen so far. The dressing is redone weekly; after I leave the ward, Anna writes me an email and explains that in her mind tape does not work well to secure the discs but if gauze is applied on top, tape can be successful.

Dry blood is very noxious for wound healing and ensuring wound cleanliness is essential. From theatre, sponges are used, these stick to the skin and the frame, making the pin sites bleed when removed. Quoting again from my field notes,

Esme is an experienced senior nurse; she cleanses the whole frame with normal saline and applies the dressings with expertise and dexterity. Cleaning the frame is important; this is the first nurse that I observe doing this task; however normal saline is not a solution that will kill bacteria. Esme keeps the dressings in situ with clips rather than tape.

Nursing staff demonstrated involvement, commitment and concerns. Attree (2001) describes how 'good care' is characterised by an individualised, patient-focused, humanistic relationship. 'Not so good' is routine and delivered in an impersonal manner by distant staff who do not not want to be involved with patients. I only observed good care: nurses got to know their patients well over the course of their treatment, Oliver and Noelle had been in the system for years with two to three weekly visits to the out-patient department, so they have had ample time to get to know each other. In fact, all patients were welcomed with warmth and friendliness.

Dressing Techniques

The nurses dressing techniques varied significantly and whilst all did try to use non-touch techniques (Rowley and Sinclair 2004) only the most dextrous were able to do

that. Pin sites care was very time-consuming is in the hand of an inexperienced nurse.

Use of clean versus aseptic technique is one of the variables identified in pin site care (Goldberger et al. 1987) and it is usual practice that aseptic technique is used when the pin sites are still exuding. Once dry and once the patient has been discharged home, they are allowed to shower, therefore using a clean technique. Most patients said that they tried to keep the frame dry and did not shower the limb, even after months of wear.

The PHMB dressing was difficult to remove from its packet as it statically stuck to the wrapper. This made it even more difficult for nurses to adhere to the principles of non-touch techniques advocated by Rowley and Sinclair (2004) and established protocol in our establishment. Some nurses used more tape than others to secure the PHMB dressings. Tape, even medical tape, is adhesive and with long term use, is known to cause skin reaction.

The bottle of 2% w/v Chlorhexidine gluconate in 70% alcohol is a spray for multi-use. Most nurses sprayed it directly onto the pin sites, rather than onto a piece of gauze and use that to clean the pin site.

The wounds should be cleansed rigorously (Carr 2006), however most nurses were far too gentle in cleaning the patient's skin and left too many debris such as crusts and dried blood. Quoting from my field notes, "*the wounds are dirty; the skin around the pins is also dirty. The nurse struggles to clean it all; she is worried that this may cause pain. I have to explain that good skin hygiene is necessary to keep the pin sites clean. I cannot help wondering how often pin sites are not cleaned properly".* Patients also struggled with this aspect when self-caring; Oliver had not cleaned his pin sites since discharge from hospital four days previously, five days since his operation. The bloody exudate had dried and the gauze was stuck to the pin sites and skin, making removal of the old dressing a painful procedure.

One nurse cleaned the whole frame before she started on the pin sites and this was the first time I had observed this practice. Some nurses were very dextrous and patients noticed, commented and appreciated their expertise especially when they had been subjected to less experienced hands.

Dressings Regime

Whilst we[24] thought that standard protocol was Kurgan, it became very clear that each nurse and patient did a bit as they saw fit. Oliver explained that with his old frame, he cleaned his pin sites sometimes with the 2% w/v Chlorhexidine gluconate in 70% alcohol solution but mostly he used saline. He reported having numerous infections. Whilst we talked, Oliver regularly put his fingers in his wounds to point to a specific pin site that had caused him problems.

Removal of External Fixation

Georgia was observed removing the pins, this was undertaken with a corkscrew type of tool, the patient (Jacky) was in a lot of pain throughout the procedure. No local anaesthetic was given, as the treatment was undertaken by a nurse. Entonox (gas and air) was administered and provided some relief but the brutality of the treatment was a surprise to me. Interestingly it was explained to me that when a doctor undertakes the same procedure, local anaesthetic is injected to numb the skin. The effectiveness of this procedure is however limited, as pain is still felt in the bone.

[24] Senior medical staff and senior nurses and FP (author of this thesis).

Crusts Removal

Approach to crusts is another variable listed by Goldberger et al. (1987). The literature is unclear on whether we should advise patients to remove crusts or not. Some earlier authors advocate removal of crusts (Celeste et al. 1984; Gunta et al. 1992), as they believe that removing crusted secretions allows the pin holes to drain freely to the outside, which maintains a relatively low bacterial concentration at the pin-skin interface, thereby reducing the risk of pin site infection and abscess formation.

On the other hand, Sproles (1985) recommended leaving crusts in place because they act as a natural barrier to infection. Oliver did however make some very clear recommendations: he believes that there are different types of crusts. Hard, dry scabs that are solid around the pin sites should be left in place, whilst wet crusts that move when cleaned should be removed. This is in line with what the Royal College of Nursing Professional Consensus (2011) recommends.

With Kurgan, gauze is applied to the pin sites. Oliver made the very interesting point that this gauze should be applied neatly folded flat to the skin to prevent pressure and tissue deformation which can cause localised pain.

Treatment Consistency

Patients reported concerns about treatment consistency. My participant observations raised this issue too, as it seemed that every nurse interpreted the Kurgan regime differently. This was also reinforced by inconsistent medical prescription for differing regimes that they all called Kurgan.

It was also nearly impossible to anticipate where patients would end up after discharge. Jacky, for example, had one episode of extreme pain within a few hours of discharge and attended A&E in another Trust where they were not aware of the study. Despite having a letter in her hand describing the study, Jacky did not bring the supplied dressings or show the letter to the team in A&E. They dressed her pin

sites with 'another' type of dressing which was not comfortable to the patient. The following day, the district nurses re-applied the PHMB. The patient therefore was able to state that she found the PHMB very comfortable and that the district nurses had been impressed with the dressing as they had not seen it before.

Harry reported some difficulties as practice nurses were not very competent in pin sites care and found the application of the PHMB foam fiddly. He reported that it took his practice nurse over fifty minutes to clean and re-dress four pin sites. They did learn with practice and found it easier to apply after a few dressing changes.

What Does an External Fixator Mean for a Patient?

This aspect of care was not approached during the informal interviewing, but during their treatment, in conversation, most patients appeared resilient to the external fixator. Oliver was *living with it,* which to him meant driving his car and riding his bike in an attempt of normalise his life. He drove himself for all the out-patient appointments as he could not afford the cost of bus or inconvenience of public transport. To drive with a frame *in situ* is certainly skilful but also incredibly dangerous to other road users, demonstrating however the necessity for patients with long term frames to live a normal life as possible. Jacky relayed how frustrating it was to live with an arm fitted with external fixator; she was *"fed up having to ask for help from her husband"*.

Managing Patients' Expectations

Noelle, a highly qualified nurse by background was very aware of her diagnosis and prognosis (see p138). She had already had a number of external fixators and was disappointed to have been randomised to Kurgan as she had hoped that a new dressing would help with the healing and as she developed further infection, she expressed her dissatisfaction.

Charlotte, another retired nurse, was very aware of the risk of infection and wanted her pin sites covered at all times. She therefore liked the idea of a PHMB foam dressing as she thought that gauze would allow germs in.

Dressing Provision

Patients reported that once discharged, dressing provision was challenging and often community teams stated that they were not able to source recommended dressings. For the purpose of the study, all PHMB dressings were given to the patient. Interestingly, the solution of 2% w/v Chlorhexidine gluconate in 70% alcohol required for Kurgan was also not freely available in community and that was one of the reason that protocols were not adhered to, leaving patients concerned about the continuity of care. Quoting from my field notes, *"Oliver tells me that he needs the solutions and some pack of gauze as his practice nurse cannot get anything".*

c. Comparative Study

Four patients were allocated to standard care (Kurgan) and six to the PHMB foam disc. Table 6.2 (see p147) describes data collected for the ten recruited patients and each aspect was explored in turn in the paragraphs below.

Patient	Gender	Age	Randomised to	Limb affected	Pins	Length of pin treatment	Contact Dermatitis	Infection	Antibiotic
OLIVER	M	45	Kurgan	Lower Limb	6	>16 weeks	No	No	No
JACKY	F	58	PHMB	Upper Limb	4	6	No	No	No
NOELLE	F	61	Kurgan	Lower Limb	8	>16 weeks	**Yes**	**Yes**	Yes
JACOB	M	46	Kurgan	Upper Limb	4	5	No	**Yes**	Yes
CHARLOTTE	F	85	PHMB	Upper Limb	4	5	No	No	No
HARRY	M	58	PHMB	Upper Limb	4	6	No	No	No
JOSH	M	47	Kurgan	Upper Limb	6	6	No	No	No
JAMES	M	38	PHMB	Upper Limb	4	6	No	No	No
THOMASINA	F	86	PHMB	Lower Limb	11	>16 weeks	No*	No*	No*
WILHELMINA	F	58	PHMB	Lower Limb	8	>16 weeks	No	No	No

*lost to follow up after three weeks

Table 6.2: *Data collected for ten patients*

Age and Gender

The participants' mean age was fifty-eight years with an equal spit between women and men (Table 6.3, p148). Two patients were older than eighty-five-year-old; interestingly the mean age for men was 39 and female was 70 years. Complex fractures tend to be due to high impact trauma in men (car and motorbike incidents; high impact sport injuries) and low impact trauma in elderly women, due to co-morbidity such as osteoporosis (Checkett 2000). The sample reflected such clinical experience.

AGE	18-60	>60	GENDER	M	F
Kurgan	3	1	Kurgan	3	1
PHMB	4	2	PHMB	2	4

Table 6.3: *Age and Gender*

External Fixator Site and Duration of Treatment

The length of time that patients were fitted with the external fixator varied greatly depending on the site of the fracture. Upper limb fractures were treated with the external fixator for an average of five to six weeks, whilst lower limb fractures were all very complex and all the patients had the external fixator for over six months (see Table 6.4, p149). One patient had the external fixator *in situ* for over two years.

	Upper Limb	Lower Limb
Treatment duration	5-6 Weeks	>6 months
Number of patients	6 patients	4 patients

Table 6.4: *External Fixator Site and Duration of Treatment*

Development of Contact Dermatitis

Contact dermatitis is a skin inflammation that occurs when the skin surface comes in contact with a substance. There are no tools in the literature to measure contact dermatitis, which is diagnosed by observation of the skin (English 2004). There are two kinds of contact dermatitis, irritant and allergic, irritant contact dermatitis is the more commonly reported of the two kinds of contact dermatitis. With the Kurgan method, it is the irritant kind that has raised concern, due to the presence of Chlorhexidine rather than the alcohol. The symptoms can take many forms such as redness, itching, crusting, swelling, blistering, oozing, dryness, scaliness, thickening of the skin, and a feeling of warmth at the site of contact (English 2004). During the study period, one patient developed contact dermatitis with Kurgan, nobody with PHMB (see Table 6.2, p147).

Development of Infection

Two classification systems are used to grade the level of pin site infection (Simms and Saleh 2000; Checketts 2000) but neither system has published validity or reliability results. In addition, pin sites infections have been categorised as either major or minor (Ward 1998) where minor infections are considered benign, easily treatable with antibiotics and are characterised by prolonged drainage, cruising,

swelling and erythema. Major infection requires removal of one or more of the pins before any infection can be resolved. Furthermore, there is the difficulty in telling the difference between an inflamed and infected wound (Santy et al. 2009). Debate also exists as to when a colonised wound becomes an infected wound (Lee-Smith et al. 2001), all of which impacts on the validity and reliability of any study aiming to compare different methods of pin site care.

Two patients developed an infection during the time under observation, both with the Kurgan method. One was qualified as grade 4 (= severe soft tissue infection involving several pins, sometimes with associated loosening of the pin) on the Checketts-Otterburn grading system; the other was given antibiotics from his GP for 'redness' (grade 1, slight infection).

d. Patient Survey

All recruited patients gave 4 to 5 points ('Like it' or 'Like it very much') to whatever regime they had been randomised to, as patients would only know their own regime and they did not have anything to compare it with.

This survey had very little to add to the evaluation and was not included in the final triangulation of data. The value and challenges of including this method within a dressing evaluation will be debated further in the 'Reflection' section of this chapter (see p155).

e. Ward and Out-patient Staff Survey

There are about fifty-five registered nurses working on the two trauma wards and out-patients; some work part-time, some full-time. Sickness level had been running at 11% over the year of the study, therefore a response from forty-eight staff was hoped for. It is known that questionnaire return rates can vary substantially (Plowright 2011), therefore a 100% return rate may reflect unrealistic expectations for a survey. Nevertheless, this level of return has often been achieved in my organisation.

However, initially, eighteen replies were received. A couple of reminders were then sent, which yielded a further nine responses. A total of twenty-seven replies were received (56% response rate). The responses were counted and percentages calculated. Interestingly most nurses had not used the PHMB dressing (n=17; 63%). The nurses who had seen and used the dressing (n=10; 37%) rated 'the ease of application'; 'the ease of removing dressing from the package' and 'their perceived comfort for the patient' as *excellent/good*. Most were slightly disappointed with the ease of keeping the disc *in situ* (rated as *fair/poor*). Tape was predominantly used to secure the discs, but one nurse used clips. All recommended that the product was made available for all patients with external fixator.

The value and challenges of including this method within a dressing evaluation will be debated further in the 'Reflection' section of this chapter (see p155).

f. Cost Examination

Methods and Working Assumptions

Table 6.4 (see p149) lists the products used in each comparator. A number of assumptions were made: firstly, each patient was fitted with an average of six pins. Usual practice, but not always, as it depends on the level of exudate, is that the dressing is reapplied weekly once the pin sites become dry.

As participants were not followed at each dressing change over the course of their treatment, it was not possible to establish what dressing routine they received. Whilst we recommended weekly dressings changes once the pin sites were dry, great variations did occur. For example, Oliver undertook his own pin sites cleaning whenever he felt it was required, usually more often than weekly, whist Jacky received weekly dressing changes for six weeks. Therefore, this cost examination study offers an average based on an expected treatment regime, rather than being based on the ten recruited patients.

The cost of each treatment (see Table 6.5, p152) for one patient, for six pins per dressing change per week is more expensive with PHMB rather than Kurgan. As one 250mls bottle of the 2% w/v Chlorhexidine gluconate in 70% alcohol solution would last for six weeks, it substantially reduces the cost for Kurgan. PHMB becomes more expensive the more dressing changes a patient requires. The value and challenges of including this method within a dressing evaluation will be debated further in the 'Reflection' section of this chapter (see p155).

MATERIALS	**KURGAN**	**PHMB**
Dressings pack	0.49p	0.49p
A 250mls bottle of 2% w/v Chlorhexidine gluconate in 70% alcohol	*£3.45*	N/A
PHMB disc (each)	N/A	*£1.14*
Saline solution sachet (to clean)	N/A	0.20
Tape to secure	£2.05	£2.05
Gauze used to wrap around pin site	£1.50	N/A
Cost for one pin site per treatment	£7.49	£3.68
Cost for six pin sites per treatment	£7.49	£9.58
Cost for six pin sites for 6 weeks* **weekly dressings*	**£15.39**	**£42.78**
Assumptions:	1 bottle and 1 roll of tape are sufficient for 6 weeks	1 roll of tape is sufficient for 6 weeks

Table 6.5: *Average treatment cost per treatment for six pin sites for a full six weeks' treatment*

g. Evaluation of Packaging and Product Availability

The packaging was sturdy, without being bulky, with ten small PHMB dressings in each box. When opened the static prevented the little discs to fall on the sterile dressing field, which can cause problems in maintaining asepsis when dressing pin sites. Writing on the packaging was clear. The information leaflet was clear and concise. These dressings were available on NHS Supply Chain and on FP10.

TRIANGULATING THE DATA

Triangulation of the data determined that staff liked the dressing but found it 'fiddly' to use. They found it challenging to secure, but were in favour of having this product listed in the Wound Management Formulary for use with external fixators. Patients were less interested in what dressing was used but expressed a wish for a seamless transition between hospital and community. They were concerned with the nurses' ability to dress their pin sites with competence, confidence and consistency. Observation of nurses highlighted differing dressing techniques, especially with regards to effective cleansing.

Reviewing medical notes and writing each patient's story highlighted their individual trauma stories. External fixators applied to the lower limb are definitely more complex than those applied to upper limbs and are kept *in situ* for longer, some even for 3-4 years. Those patients with long term lower limb external fixator were more likely to develop contact dermatitis and infection. Standardisation of care was poor, with every clinician applying their own interpretation to the protocol. The cost examination highlighted that the new PHMB foam was costlier than standard care.

Consensus Meeting and Clinical Application of Findings

The data collected were presented to the group, starting from the medical histories and patients' stories; then the comparative data was presented, followed by the

learning from the participant observations and informal interviews. Listed below are the aspects of care that were not understood when the study commenced:

- Standard care was not set out clearly prior to the commencement of the study. There were wide variations in both surgeons' and nurses' interpretation of standard care.

- Core wound care techniques were not consistent.

- Patients were concerned about lack of continuity in dressing regime.

- Frame, pin sites and surrounding skin were not cleansed sufficiently.

- Upper limb external fixators were *in situ* for considerably less time than lower limb external fixator.

- Contact dermatitis was more likely to occur with long term contact with the 2% w/v Chlorhexidine gluconate in 70% alcohol solution.

- PHMB dressings were problematic to keep in place.

- PHMB dressings were costlier than standard care.

A Protocol for Pin Sites Care

A protocol was first proposed that saw a different regime from upper limb than lower limb; however, the senior nurses in the consensus group explained that this would be far too confusing for their nursing teams, therefore a simple one-fits-all protocol was agreed. The protocol was agreed as follows,

a) Redress pin sites on strikethrough – consider using haemostatic dressing to wrap the pin sites if they are bleeding during the first few hours post-operatively. Do not use sponges or caps.

b) Frame must be kept extremely clean at all times: consider using antiseptic wipes to clean the frame but not the skin.

c) Clean pin sites and surrounding skin with PHMB solution.

d) Wrap dry gauze around the pin sites until exudate stops (expected to be within 5-7 days).

e) Secure with clips.

f) Dress daily until dry.

g) Once the pin sites are dry, the patient can shower; then clean pin sites with PHMB solution and leave exposed.

h) If any exudate, inflammation or infection develops, switch to PHMB discs aand secure with clips.

i) On discharge from the ward, the patient will be given a pack of antiseptic wipes; a bottle of PHMB solution; gauze; clips and tape for one-week treatment and clear instructions for use. It is then the responsibly of the community staff to provide further dressings, the exception to this will be for clips, as community will be unable to source these.

j) If external fixator is to remain for longer than eight weeks, the patient or the carer can be taught how to dress pin sites.

The protocol was sent for wide review internally; no changes were recommended, therefore the protocol was endorsed and made available on the Trust's official intranet site. Subsequently it was circulated across the region.

REFLECTIONS

Participant observation was the most valuable of the techniques used as it revealed that each nurse performed pin site care differently. The comparative study protocol that was given to all staff at the beginning of the evaluation set out clearly Kurgan, which was to be compared to PHMB. This provided clear direction for staff on how to dress pin sites. Unfortunately, PHMB was therefore not compared to 'standard practice'.

Core dressing techniques varied between nurses. Dexterity played an integral part in pin site dressing as the work is very fiddly. Those nurses who were dextrous were consequently able to maintain better asepsis (working in a sterile way). Taking this further, correct dressing technique recommends cleaning the wound and the peri-skin effectively (Carr 2006).

Participant observation allowed to understand that this practice was not followed, most nurses did not clean the pin sites appropriately or the surrounding skin. Furthermore, some nurses cleaned the external fixators' frames whilst others did not. Dry blood or other contaminants left on the external fixator are a source of infection as bacteria thrives in this medium. This is especially important in the long term external fixator where the mechanisms of the frame are like a Meccano set, intricate, with tight spaces which are challenging to clean (see Appendix V, p240 for an image of an external fixator *in situ*).

Participant observation discovered that when external fixators were removed, the experience could be traumatic for some patients and analgesia provision differed when a nurse undertook this procedure from when a doctor did it. Whilst this was not part of the study objectives, this observation led to a change of protocol, whereby patients are now offered the procedure under local anaesthetic by an anaesthetist as a day case.

There was also an expectation that all staff knew how to dress pin sites. The trauma wards had a relatively high turnover of staff and the necessity to teach this skill had been lost amongst many other ward priorities. When one considers that external fixators are very rare indeed, it is unsurprising that this knowledge had been diluted to such an extent that Kurgan had become a shadowy entity.

The patient survey did not yield valuable data. Whilst Likert scales are simple to construct, easy to read and complete, they have 'central tendency bias', participants may avoid extreme response categories; 'acquiescence bias', participants may agree with statements as presented in order to please the

researcher (Bertram 2007). Lack of reproducibility is also a problem with Likert but the most problematic issue is that it did not measure what it was meant to measure (i.e. lacked validity). Patients would rate the dressing as 'very good' but this was unhelpful as one cannot rate a dressing regime when a comparator has not been offered (i.e. I like regime A better than B).

Instead, the patient's voice came from the informal interviews, undertaken at the time of their wound care, when both the nurse and the participant observer were giving their full attention to the patient and their pin sites. Patients have experiences to tell and ought to be taken as valuable informers; their involvement is recommended by the National Institute for Health Research (2012). Patients added clarity to the issue of crust management in pin site care; others voiced concerns about leaving pin sites exposed for infection prevention point of view. This informal interviewing approach made for a very different type of involvement, one that offered richer data and a better understanding of the problem.

Patients were clear that their biggest concern was the lack of continuity with their pin site care between professionals. Some of the patient stories highlighted that communication was not straight forward between the hospital and the community setting. Care in the community was an unregulated entity where at times staff did not follow instruction letters sent at time of discharge. Patients consistently reported a lack of proficiency and dexterity in the application of pin sites' dressings and in their eyes this was a significant of lack of knowledge. It increased their anxiety at a time where they felt very vulnerable due to the traumatic event itself (Breslau 2009) and the living with an external fixator *in situ* (Lopez et al. 2013).

The sheer number of healthcare professionals involved in the care of these ten patients was astounding, each patient saw an average of twenty to twenty-five different nursing staff. Unsurprisingly, the aspect these patients struggled with most, was accepting the differing dressing techniques of the many nurses who cared for their pin sites throughout their treatment. Whilst some reported good

experiences with community colleagues, others expressed concerns and made strong recommendations to improve communication between settings.

The staff survey offered some interesting data, but it was surprising how difficult it appeared to be for staff to complete and return a simple questionnaire; poor staff participation and the reluctance to be part of the decision-making process had not been anticipated.

The review of documents provided data from a number of different sources. Medical records offered a clearer picture of each recruited patient across the full spectrum of their treatment. The mechanism for their injuries highlighted how different each patient story can be. Furthermore, the patient stories gave an alternative insight to their journey and added to the body of knowledge.

The data yielded from the comparative study highlighted that there was a difference in length of treatment between patients with external fixators to the upper limb versus those to the lower limb. This was not clear at the onset of the study. As contact dermatitis appeared to be more likely to develop with the continued use of the 2% w/v Chlorhexidine gluconate in 70% alcohol, it would follow that lower limbs fitted with an external fixator were more likely to develop this skin condition. In fact, the only patient who developed contact dermatitis in this study was a long term lower limb external fixator (see Noelle's story, p138).

Two patients developed infection with Kurgan; however, in the case of one of them, this was unlikely to be due to the dressing regime and more likely to be due to the patient's low bone density and poor stability of the frame. The movement of the pin in the bone increased exudates and the pin became more prone to infection. The second patient developed a minor infection to one of the proximal pins, too many variables were at play to even hazard a guess to why this infection developed (see Jacob's story, p138).

The PHMB discs were not as simple to use as first thought: I observed that the discs stuck to the packet with static. Interestingly the staff survey did not highlight this as being a problem. What they did consider an issue was that these PHMB discs required to be fixed to the pin site. Tape was used by most nurses but the adhesive of the tape is known to be unkind to the skin after repetitive use.

PHMB discs were more expensive than standard care and they were probably not good value for money when used prophylactically. Nevertheless, a review of more recent literature revealed that PHMB has increasingly been used in clinical practice on acute and chronic wounds to treat infection (Eberlein and Assadian 2010). It is said to be well tolerated and having a low-risk profile (Kaehn 2010) which means that it is unlikely to cause contact dermatitis with long term use. Furthermore, since the beginning of this study, PHMB has become available in a solution, used to cleanse wounds (Dissemond et al. 2011). And this confirms that, with such rapid changes in practice, dressing evaluations must strike the right balance between rigour and practicality. Evaluation must therefore become embedded in routine practice.

Reflexivity and Trustworthiness

Reflexivity is the reflexion on subjectivity, a critical attitude towards the data, its representation (writing up the data) and the data's status, standing and authority (legitimisation, Brewer 2000). The findings of this evaluation presented a number of limitations to the data produced. The main problems were due to logistics. First of all the number of patients recruited could have been higher, a handful were lost to recruitment due to unavoidable circumstances.

Another problem was that despite all the advertising, explaining, emails and letter sent to staff at times they forgot to inform me that patients with external fixator were present on the ward. Not many patients were lost to recruitment for this reason, but when there were so few patients fitted with external fixators, everyone

counted. With the benefit of hindsight, I should have enlisted other staff to help me with the recruitment and follow-up.

The observations one makes of informant responses and behaviour will embody two sources of error (Brewer 2000). The first kind of error consists of either random (sampling error) or systematic (selection of informant bias). In terms of sampling error, all patients that could be recruited were recruited, but if we had recruited at a different time, a different set of people would have been selected; the participants would be different and have different stories to tell. This could mean that the protocol that was agreed might have made different recommendations. Nevertheless, issues with staff training, consistency in practice and continuity between secondary and primary care would have been highlighted regardless of the sample. The same goes with the difficulty in sampling large numbers and the natural heterogeneity of each sample.

Field notes were the most identifiable feature in this technique where thick description and verbatim quotation offered strong face validity (Fetterman 2010). However, field notes engendered the second kind of error, measurement error, comes from the means by which one transforms sensory information into intelligible mental constructions, whether in text or number or both. This is somewhat involuntary, due to one's capability to write and express thoughts in the written format.

At work, I have always relied on my own memory. Gobo (2008) voices that one's memory is often not as reliable as we would like to admit and over time, we end up making up our own reality of events. Barnes's (2011, p4) poses: *"a few incidents that grow into anecdotes, to some approximate memories which time further deforms into certainly"*. Therefore, for this inquiry I diligently wrote field notes and utilised these as data.

Copious field notes were kept throughout the course of this evaluation, written as soon as possible after each moment of data collection. These were not written as

an outsider looking in with fresh eyes, but as a clinician embedded in the process. Routine practice was not described, only what 'hit' me as being different from my preconceived ideas found its way to paper. Partial field notes (Roper and Shapira 2000, p84) were then completed to provide the evidence for this evaluation; for example when combining patients' medical histories with their stories to present them as participants (see p137) or to understand key findings of my observant participation.

I found the action of writing field notes quite challenging. We are trained to make entries in patients' medical records that are clear and accurate (Nursing and Midwifery Council 2015) but also succinct. Writing impressions, feeling, thoughts mixed with facts was alien to me; I had never kept a personal diary for example. Furthermore, my handwriting had always been illegible (I am often unable to read my own writing) and for this reason, I felt discouraged to write more than the most succinct entries. However, writing notes for this inquiry I did, and interestingly, it became easier to do as time progressed. Furthermore, once I re-read them, it became clear that the recollection of my memory was not as reliable as I once thought, exactly as Gobo (2008) had stated.

I undertook my participant observation 'on the job', defined as *"pure observant participation"* (Brewer 2000, p61), or "*participant-as-observer"* (Roper and Shapira 2000, p17), in effect using my existing role of TVN to research a familiar setting (Holdaway 1982). This role increased the likelihood to obtain key insider information. There were however times where I had to cross over from researcher to nurse, from observer to participant, namely when nurses failed to clean pin sites accurately. This could not be left unsaid and I had to intervene as per our code of conduct (Nursing and Midwifery Council 2014). I was conscious that I was no longer simple observer and I felt at times frustrated that I could not be more objective.

Participant observation was also challenging in terms of planning the time with the ward nurse or the out-patient nurse. Ward routines were such that dressings were

undertaken between the many other clinical priorities, such as washing patients, giving medication, dishing meals, visiting times, rest periods and so on. Out-patients' clinics are notorious for not being on time and timing a room for the nurse and the patient and the observer to meet all at the same time became very difficult indeed. Considering the value that participant observation had to this evaluation, more time should have been invested for this method.

Prior to becoming a TVN, I had ten years clinical experience working in the trauma-orthopaedic department and this undoubtedly gave me credibility in that setting; my background of wound care expert facilitated entry to the field; it allowed nurses to feel comfortable and open in my presence, especially once they knew that I was not assessing their aseptic techniques[25]. Nurses on the wards were used to work with me as I was the wound care specialist for the Trust, however in my day-to-day job, either I dressed the wounds (in complex wounds) or I would leave instructions on how to re-dress the wounds for the nurses on the ward to undertake at a later time. Observing nurses undertaking dressings was rather challenging for me as I had to literally sit on my hands to prevent taking over the task.

I had worked with most staff involved in this study. It gave me access to their clinical practices and their candour and openness was testimony to our relationships. They were all willing to be part of this journey of discovery. Patients liked having the 'expert' there; it provided reassurance but also a hope that concerns raised would find a solution. I never observed incorrect practices but some were surprising, things that even with my background I did not know were happening.

[25] Nurses are assessed periodically on their aseptic techniques, namely their ability to keep the dressing trolley and all the dressings sterile. This assessment can be source of anxiety.

Leadership was intrinsic to my role as a clinician and emerged through my role as a researcher in practice. This thesis is the result of a Professional Doctorate, where the primary goal is to advance professional practice (Brown and Cooke 2010) and therefore the element of objectivity becomes secondary to the ability to decision-making and leading a team towards a clinical solution. Reflexivity is about being part and parcel of the setting, context and culture that one tries to understand (Altheide and Johnson 1998). This study was not a positivist piece of work; I *was* part of the study but so were the nurses, the ward managers, the surgeons and the patients, each voice was given an equal weight, each bit of information found a place in this evaluation. Nurses are often not educated or cultured to be leaders, but followers of superior medical knowledge; in engaging them in the research, they were forced to adopt a critical stance over their previous practice. My research was an act of leadership, where research is used as a means to engage participants in solving a practice problem.

Familiarity with the sector requires a heightened awareness regarding any preconceived awareness (Fetterman 2010). Goodall (1989) however, argues that all representations are partisan, because they generally represent only the point of view of the teller and only reveal or capture what which the teller of the tale wishes to focus on. Indeed, this was *my* study and throughout the text, the value given to each bit of information represented *my* beliefs, knowledge and experience. The reflexivity process allowed for this partisan-ness to be aired and was somewhat balanced by the peer-review process undertaken during the consensus meeting, from which the protocol emerged.

CONCLUSION

So far, this thesis has collected a number of pieces of knowledge to understand the jigsaw that is dressing evaluation. The first two chapters were about understanding the challenges of evaluating dressing in clinical practice. Chapter 4 (p51) explored the professional milieu dressings are evaluated within; Chapter 5 (p95) explored the

elements that an evaluation should include and this chapter has been about the practical application of using a pragmatic inquiry to evaluate dressings.

The techniques used were simple: look and see; hear and listen with rigorous recording of every event. Participant observation was the most valuable aspect of this technique as it offered some clarity of what actually happens in clinical practice. Key to this study was the discrepancy between how practice was undertaken and what was reported by the nurses. It highlighted the necessity to capture the voices of nurses with expertise, replicate and therefore standardise, examples of good practices.

Undertaking informal interviews with patients at the time of dressing changes offered an intimate time between patient, nurse and participant observer. The data that were released during those times was precious; speaking as a researcher-in-practice, I cherished these data and acted upon them, because patients and nurses had great insights and willingness to solve problems.

The review of medical records, photographs, costs and any other available documents such as the data from the comparative study rounded off this evaluation. The findings were full of rich data with this multi-methods approach. The findings did not tell if PHMB was better than Kurgan, but they allowed for the development of a protocol that has been guided by real, clinical knowledge.

The outcome of this evaluation is a standard care protocol. It is expected that new dressings or solutions will be developed in the future and a new cycle of experimentalism will inevitably ensue. The main recommendation is to work to this newly developed standard care protocol and report any adverse findings. Data should be collected, even if anecdotal, as this will provide the trigger for a future evaluation with a new cycle of experimentalism. Time will tell if this protocol works in practice, or if it needs further refining, which is perfectly acceptable in Dewey's pragmatism.

It is now time to reflect upon the journey and the final chapter offers further reflections on all those little fragments of knowledge that makes the world of dressing evaluation.

CHAPTER 7

Further reflections

> *We do not learn from experience. We learn from reflecting on experience.*
>
> *John Dewey (1933, p78)*

INTRODUCTION

This thesis offers an insight into the world of dressings and how best to evaluate them. We have established that taking an empirical approach is challenging for a number of reasons, namely a difficulty to control the variables associated with co-morbidities; calculating sample sizes to achieve statistical significance; recruiting enough patients that meet the inclusion criteria; challenges with validating infection, inflammation and wound sizes and challenges with validating subjective assessments such as comforts and user friendliness. Furthermore, there are issues with funding such studies, especially when dressings are considered medical devices and efficacy studies are not required to sell the product.

An alternative perspective, pragmatism, was suggested and the previous chapter implemented it in clinical practice. This approach yielded some helpful data which was analysed and a new protocol was created but it also highlighted that the world of dressing evaluation is complex and merits further reflections to gather all the pieces of the jigsaw together.

Chapter Structure

This chapter explores further the value of pragmatism as a method, as a methodology and as a philosophical perspective when applied to dressing evaluations.

REFLECTIONS ON PRAGMATISM

In the everyday sense of the term, pragmatism is associated with a matter of fact approach to problem-solving (Bacon 2012). The related word pragmatist is sometimes used as a compliment, describing the person who gets results. It is also employed pejoratively, especially in the case of politicians, where the pragmatist does not stand on principles but will do whatever it takes to succeed. These connotations carry over, often in misleading ways into pragmatist research, to mean 'second best' and authors feel that they have to justify their decisions for adopting a pragmatic methodology rather than positivist trial methodology. For example, Ward (2010, p22) describes the evaluation of a new mattress as a pragmatic evaluation and writes in her abstract,

> *Although ideal, RCTs are difficult to control in wound care and seldom reflect the natural challenges encountered in a busy hospital. By contrast the data arising from this pragmatic evaluation showed the mattress to be compatible with the care setting ... etc.*

I have shown in this thesis that pragmatism offers so much more. Johnson and Onwuegbuzie (2004) explain how pragmatism views inquiry as a construction of reality by rejecting the traditional mind and matter dualism. There is recognition that knowledge is fallible because we can never be certain that our current knowledge will be appropriate for future inquiries, rather than believing that it is fallible because we have not doing the job properly. There is a belief that truth comes from experience and the absolute truth will only be determined at the end of times; our assertions are only real in specific inquiry contexts. Their value must be

continuously re-established. Finally but significantly, pragmatism is a commitment to the value of democracy, freedom, equality and progress. Dewey points out that it lies in the nature of pragmatism to "*be applied as widely as possible and to things as diverse as controversies, belief, truths ideas and objects"* (Dewey 1908, p101).

Reflections of Pragmatism as a mixed-methods methodology

A number of methods were used through the thesis, from interviews and focus group in Chapter 4 (p51) and Chapter 5 (p95) to techniques borrowed from rapid ethnography to evaluate a dressing in clinical practice in Chapter 6 (p114). Whilst an empirical stance would be impossible to implement in practice, a purely qualitative approach would not answer the questions raised in a clinical setting. Instead, a pragmatic mixture of methods appeared to be the way forward. Reflecting on each of the methods used and how they might have been improved allows for a further learning experience, so central to Dewey's pragmatism.

Chapter 4 (p51) describes the focus group that was undertaken with staff working within my organisation. Reflecting on the experience allows me to critically evaluate the worth of this methodology in this field. Interviewing our peers can engender questions of positive bias as the data may not appear to say what it says to a non-TVN. This is where Goodall's (2000) recommendation to describe the data before they are analysed has proved invaluable to maintain credibility (see Chapter 4, p56Understanding Each Individual Contexts).

A running digital tape recorder in the middle of the room does not make for a natural environment, especially with colleagues one knows well. Asking questions about their understanding of what evidence should be considered to select dressings for a Wound Management Formulary forced the team to confront their knowledge in front of their colleagues, their manager (me) but also in front of a senior pharmacist, whom none of them knew that well. They might have taken this as intense scrutiny.

The ability to run a focus group requires listening skills, personal interaction, question framing and gentle probing for elaboration (Marshall and Rossman 2011, p145); the process became easier as the discussion grew into a debate. I concluded the focus group before the participants started to 'chat' rather than debate the issues put on the table; minutes were also taken and circulated as this focus group was more than an academic endeavour. In fact, this was also a meeting of clinicians agreeing that they would no longer 'have a try' with boxes of dressings given to them by company representatives. On reflection, a follow-up questionnaire might have been valuable, to ensure that the salient points had not been misinterpreted; some of participants were more vocal than others, which does not mean that they would not have been less knowledgeable or that their contribution to the discussion been less valued. The pragmatic methodology would have allowed for such additional data to be collected.

The interviews with the three TVNs and the regional pharmacists were an interesting learning experience. I prepared carefully the questions. I was, to my surprise, good at interviewing, despite being very nervous.

Throughout the interviews, the differences in the understanding of the complexities of dressing evaluation vary from the new experts (N5) versus the long-time experts (N6 and N7). Both have to make decisions with regards to what dressings to list on their Wound Management Formularies, undertaken in the face of uncertainty where there is missing, unreliable, conflicting or complex information (Schmitt and Klein 1996).

Uncertainty exists at different levels: the level of data; the level of knowledge that is inferred from the data; the level of understanding in which the inferences are synthesised into projections of the future events. Klein (1998) explains that experts can perceive things that are invisible to novices: fine discriminations, patterns, alternate perspectives, missing events, the past and the future and the process of managing decision-making activities. Often experts do not realise that the rest are

unable to detect what seems obvious to them and therefore there is a real requirement to become more explicit in the description of the process that is followed with each dressing evaluation.

Research is described as a messy enterprise (Brewer 2000) and on reflection, how did I know what questions to ask when I did not know what direction this thesis would take? Fortunately, I did ask the right questions, as the interviews yielded wonderfully rich data that allowed me to develop those professional, philosophical and literary skills described right at the beginning of this thesis. The data analysis carried me towards understanding the context of dressing evaluation, and at its epicentre, the issue of power, which will be discussed in the following section.

Pragmatism offers a workable, fit for purpose solution to capture data from a variety of participants. Rapid ethnographic techniques focus on observing and interacting with participants in their natural environment, giving a voice to people in their own context (Handwerker 2001). However, nurse participants appeared to be reluctant to engage in research and thereby having a voice in setting protocols. It has been recognised that nurses show apathy when decision-making opportunities come along (Brinkman 2012). Clarkson (1993) describes the attitude of the 'bystander', where staff are aware that something is not working but do not take responsibility in changing it and do not see that in effect, by doing so they are maintaining the problem. In dressing evaluations, like in many other fields of nursing, the continuum between apathy and full research integration must be recognised; different ways of engaging with staff need to be thought off. Use of on-line survey, tablets and apps are appealing to our younger nurses, whilst it would be fair to say, that pen and paper remains a solid option for many of the other (older) nurses. Undertaking a focus group prior to the study is known to increase participant engagement (Roxburgh 2006) and this could be easily adopted in a pragmatic dressing evaluation.

Nurses tend to overestimate patients' willingness to assume an active role in decision-making (Kujala 2003; Florin et al. 2006). When I was recruiting patients to the comparative study (Chapter 6, p114), it was very clear that they did not like deciding whether to participate in the study or not. The formality of signing a consent form and the opening of the sealed envelope increased their stress levels at the very time when they felt highly vulnerable. Taking written consent makes the whole process so formal; it is seen as a necessary part of research but also a great barrier.

Understanding the debate between what is defined as research, clinical audit and service development may aid with understanding the issue of consent in dressing evaluation. Research is an attempt to derive new knowledge through studies that involve intervention or collection to data additional to routine care (National Research Ethics Service 2015); research is about obtaining new and generalisable knowledge (Healthcare Quality Improvement Partnership 2015). Clinical audit observes and evaluates practices compared to predetermined standards (National Research Ethics Service 2015); clinical audit is about quality and finding out if best practice is being practised (Healthcare Quality Improvement Partnership 2015). Research tells us what we should be doing, whilst clinical audit is about whether we are doing what we should be doing and how well we are doing it (Casarett et al. 2000). Service evaluation observes practices solely to define or judge current care (National Research Ethics Service 2015). Research requires full governance in terms of seeking ethical approval; service development is fundamentally an improvement project and as such they do not require ethical approval (National Research Ethics Service 2015).

Dressing evaluation flows through the currents of this debate. In Chapter 6 (p114) we saw that the evaluation developed new knowledge and the process fits the definition of research (ethical approval required); standard care was however not understood and that falls under the umbrella of service evaluation (ethical approval not required).

The literature highlights a similar example. Kinzella et al. (2012) undertook a study to evaluate how one CE-marked spinal needle in four hundred patients evaluated compared to another CE-marked spinal needle in 100 patients (standard practice). Before starting the study, the author sought advice from the local Research Ethical Committee which judged it to be a service evaluation and not requiring patient consent. The issue is vehemently debated by Cook (2013) who believes that those patients should have been consented. He acknowledges that whilst there may be a wider responsibility to future patients with an ongoing imperative to evaluate new products, this should not erode standards of ethics, consent or patient care.

A pragmatic inquiry in dressing evaluation is based on finding something that works in practice. If dressing evaluation falls under service development, by definition, taking written consent is not required. Nevertheless, if we decide that seeking written consent is not necessary, this does not imply that a full explanation of the available choices is not given to our patients, so to seek their informed verbal consent. In fact, in the action of seeking written consent and randomising patients, the impartial stance I needed to maintain prevented me from disclosing my experience to the participants.

The centrality of experience in inquiry is fundamental to pragmatism and will be discussed in more depth later in this chapter. Suffice to say at this point, that the lengthy process of seeking ethical approval may be actually stifling the development of dressing evaluation into a branch of research in its own right. Conversely the formality of requesting ethical approval would most definitely prevent the 'have a try' approach to dressing evaluation. The answer is likely to lie somewhere in the middle.

It must be pointed out that whilst these debates are central to my thesis, these are old debates (Feinstein and Horowitz 1997; Hofmeijer 2014) and it is outside the scope of this thesis to go beyond acknowledging their existence. Instead, I have

limited myself to finding workable solutions in practice rather than engage in a broader ethical debate.

It is clear that nurses have the skill to elicit information from patients during care (Sellman 2011). Staff who regularly recruit patients to trials develop better communication skills and learn to minimise distress, akin to nurses who request organs from bereaved relatives (Ranhawa 2014). To me, it remains a very uncomfortable process, possibly because I believe that randomisation is not necessary for dressing evaluation and patients do not need to be subjected to this additional stress. Randomisation is akin to asking patients to gamble with the care they will receive. Comparison can be achieved with longitudinal studies: data are collected with standard care and *then* with a new dressing. It must be pointed out that data recording practices in relation to standard care is patchy at present and would need considerable enhancement before comparative studies can be routinely undertaken.

Staff observation allows for interaction with patients within an informal approach and is a technique that should be undertaken to understand standard care. This immersive and informal data collection is undertaken by nurses all the time (Watson and Rebair 2014), but it could perhaps be undertaken more consistently, more thoroughly and also be recorded.

Ethnographic techniques also require the analysis of available documents. Mixing medical histories (traditional positivistic approach) and patient stories (constructivist approach) is the practical application of Dewey's vision of pragmatism, the experimental and naturalistic conception of inquiry (Hildebrand 2008). Mixing the two approaches offers a more humanistic view of the patient's clinical journey.

The examination of costs related to adopting a dressing within a set protocol remains challenging; as true cost-effectiveness cannot be established without RCT (Robinson 1993), a different approach has to be sought to establish how much a

dressing regime costs. One has to accept that a less-than-perfect solution may be the answer in light of the challenges related to knowing exactly how many dressings are used for each single dressing change. Nurses' documentation is known to be unreliable (Prideaux 2011). Whilst this process is common practice in countries that charge health insurances for care (Kaplan and Porter 2011), in the UK this process is unfamiliar in NHS funded care (Department of Health 2012). Dressing evaluations that bridge across settings increase the vagueness of the exercise. Whilst one can quite easily find out how many boxes of dressings have been used, it may not be clear what those dressings have been used for, as dressings are often used for more than one regime. Therefore it would be fair to say that in dressing evaluations undertaken in complex and relatively rare procedures, such as what was undertaken in Chapter 6 (p114), cost examination becomes quite an irrelevant exercise, the difference in price being minimal in the great scheme of the dressing spent in the NHS (1bn, Department of Business, Innovation and Skills 2014). An examination of costs becomes much more relevant for those evaluations that use a significant amount of dressings on a significant number of wounds, such as, for example, post-operative dressings.

Anderson (2006) explains that the richness of using ethnographic techniques is the close symbiosis between the researcher and his/her context. Conversely, the position of the researcher must be firmly stated as familiarity with the sector requires a heightened awareness of how much our past experiences influence our ways of thinking. Having a background of ten years trauma-orthopaedic experience prior to becoming a TVN, allowed for deeper insights into the challenges faced by staff and patients during the dressing evaluation described in Chapter 6 (p114). The role of the *insider-outsider* researcher has been described before and does bring many benefits to a study: Cassidy (2002) undertook a study of horses which would have been a very different study, had she not been an accomplished horse-woman and capable of riding a thoroughbred. Her vivid account of the experience of riding a horse at the gallops is qualitatively different from the account possible from a mere observer. Another example is Kondo's ethnography of family life and labour in

Japan which would have been a very different experience had she not had an American-Japanese identity (Kondo 1990).

There are challenges associated with working within one's own practice setting that should be acknowledged, namely becoming 'captured', when the capacity to explain, theorise and critique is reduced or even lost (Jules-Rossette 1978, cited in Baines and Cunningham 2011, p75). Buraway (1991, p5) advocates, *"participation but not immersion; observation but not marginality*", in order to avoid the dangers of too much distance or over identification. Therefore, in any evaluatory group, there must be someone that has enough understanding of the problem without being blinded by routine.

TVNs are ideally placed to play the role of insider-outsider researcher. The TVN is the specialist that is called when wound healing problems arise and is well known to many different contexts (i.e. different wards). This professional relationship aids dressing evaluation in finding a solution that works within that all-important context. Understanding what staff are doing in their own environment becomes critical if we want to understand how a dressing will perform. Undertaking participation and observation, I uncovered non-standardised clinical practices or "*contradictions between intent, meaning and action"* (Street 1992, p11).

Ethnographic techniques are useful in dressing evaluation: mainly qualitative methods are used in a field where traditionally, quantitative methods have been favoured. The strength of this method is not in collecting qualitative data instead of quantitative data, it is in accepting that a number of different methods are required to conduct the inquiry and that the decision-making process is based on a variate and variable set of findings. The challenge with this multi-method inquiry is to document the process in a way that offers trustworthiness. Clinicians struggle to find the time to write reports; they think that they can rely on their memory to relate their experiences; however, one's memory is often not as reliable as we would like to admit (Gobo 2008).

Ultimately, the value of using a set of methods in dressing evaluation rests in the triangulation of all the data collected. Decisions on whether to adopt a new dressing or not, has necessarily to be based on small nuggets of knowledge gained from clinical practice, clinical expertise, patient opinion, costs and consensus between participants rather than from one single method. The process is inevitably lengthy and time-consuming and would be best be undertaken as a team activity.

A workable, realistic and impactful model would involve some of the clinicians to become participant-observer or participant-researcher and the data analysis and subsequent decision-making to be fully set within its clinical context.

Trustworthiness in a pragmatic mixed-methods inquiry

Ethnographic techniques are shared with other methodologies, mainly with phenomenology, which aims to capture the essence of experience (Brewer 2000); with grounded theory, which generates concepts leading to theory development (Glaser and Strauss 2009). However, used within pragmatism, these techniques assist with a comprehensive inquiry of all those clinical experiences associated with a dressing performance within its environmental context.

Mixing methods is not an excuse for poor research (Greene and Caracelli 1997). Dewey argues that carefully designed experiments (as in *experiential* learning, see Chapter 3, p38) produce objective truths. Even though such truths may change over time, they are valid at the time that the experiments are completed and one can proceed with confidence until faced with new and conflicting data. In his view, truth is constructed as a by-product of the process of solving problems (Campbell 1995).

The first element of trustworthiness is *credibility* (Guba 1981) and ethnographic techniques call for the intentional use of the self, called reflexivity. This involves being deliberately aware of oneself, one's responses and one's internal state in relation to a specific situation and at the same time attempting to understand the patient and the situation (Roper and Shapira 2000, p26). Using reflexivity allowed

me to become aware of my role in dressing evaluation and to identify bias and their potential influence on the data and its interpretation.

Ethnography is often criticised for lack of replication (Johnson 1990); the fact that it focuses on local specificity renders any replication effort useless. Pelto and Pelto (1979, cited in Johnson 1990, p17) explain that instead of hearing applause for a replication of observation, an ethnographer more often hears a scornful 'that's already been done by X ten years ago' which is unheard of in the positivist approach where meta-analysis studies are considered the pinnacle of all evidence. When adopting ethnographic techniques to evaluate dressing, one needs to be aware that it is unlikely that the same dressing protocol will be studied again in the same depth for a number of years.

The nature of field research makes it next to impossible to ever duplicate exactly the methods and experiences of another researcher because each individual has a set of skills that is brought to each study added to a good dose of luck, serendipity, opportunism, chance and fortune (Johnson 1990). These elements play an important role in the selection of the moment that is studied. The set of patients studied in the dressing evaluation in Chapter 6 (p114) was unique to that moment and time. Nevertheless, the strength of using mixed-methods techniques is in the variety of the data collected and the triangulation of the analysis that gives such study *dependability*, the second the four measures of trustworthiness (Guba 1981).

Defining the context of the study gives the study *transferability*, the third of the four measures of trustworthiness (Guba 1981). Understanding the context of each dressing is crucial for its evaluation. Firstly, each nursing context is different and nurses are socialised differently depending on where they work: a surgical nurse has a different attitude towards wound care than a medical nurse, due of course, amongst other things, to the exposure to wounds that each group has had.

Harper (2006) illustrates this point well. He undertook a study that explored the concept of post-operative pain assessment and how this assessment was influenced

by military nurses' cultural background. In the context of this study, military culture refers to the socialisation in the armed forces through basic military training, the wearing of uniform and the development of military ethos, such as integrity and honour, military professionalism, loyalty, commitment and cohesion (Mileham 1995). One consequence of this socialisation in relation to pain behaviour is the expectation that service personnel will be stoic and not express pain. Ethnography was used to explore the assumptions that this socialisation has indeed occurred in that setting. Harper (2006) sent a questionnaire to over two hundred military nurses and collected mixed quantitative and qualitative data on their attitudes towards pain management. The second phase of the study was based on interviews with twenty-nine military nurses, working within civilian hospitals to see if differing attitudes arose. He concluded that military nurses' cultural background did indeed influence their post-operative pain assessment, where less analgesia was offered to patients.

Generally, nurses are socialised into the profession and they learn accepted and expected attitudes, not just those relating to the levels of pains associated with different surgical procedures, as in Harper (2008) but also in changes to clinical observations (Smith et al. 2013) or dressing selection in wound care. These attitudes will influence how they organise their work and as their practice becomes more repetitive and routine, it can become deeply ingrained (Harper 2008). In hospital, each ward offers differing elements of 'sub-culture' where nursing staff organise their work and have differing attitudes and values to clinical skills, such as wound care. Hutchinson (1984) seconds this belief and in her study, she conceptualises a new-born intensive care unit as a cultural system, a unit where nurses have certain traits not found on other wards.

Lincoln and Guba (1985) and Firestone (1993) suggest that researchers should ensure that sufficient contextual information about the field is provided to enable the reader to make a case for transferability. Contextuality in dressing evaluation

requires a description of standard care. Chapter 6 (p137) highlighted clearly the issues surrounding standard care in the case of pin site care.

Shenton (2004) questions whether the notion of producing transferable results from a single study is a realistic aim. Dressing evaluation should be based on the concept that every practitioner generates his/her own evidence in the unique context in which they practice and with the unique individuals for whom they care, as recommended by Nolan and Bradley (2008). Therefore, I would argue that the responsibility to decide if a study has transferability is with the reader who understands his/her own clinical context, rather than the researcher.

The final measure of trustworthiness is *confirmability* (Guba 1981), the concept which is comparable to objectivity in positivistic research. Achieving objectivity is challenging. Goldring (2010) recounts how he undertook a study on the 'married gay man'; participants were recruited from a self-help group of men who were married to women but who were sexually attracted to other men. When the leader of this group quit, Goldring decided to take the role on but he had to declare his interest to this group, as he was also a married gay man. He concluded that objectivity is an illusion and that one must declare one's interest when undertaking a pragmatic study that uses ethnographic techniques.

Likewise, in dressing evaluation, it is almost impossible to be 'the detached and impartial scientist who seeks the ultimate truth'; instead one has to acknowledge the subjectivity of the researcher (Crang and Cook 2007). The way I see my professional life, my work in clinical practice and the approach to this study have been completely entwined and the beauty of pragmatism is that these aspects did not require disentangling or be put aside in the name of objectivity. In fact, being an insider gives a richer account of the experience in this philosophical perspective (Atkinson et al. 2008). The extent to which my own predispositions influenced the dressing evaluation in Chapter 6 is made explicit with the process of reflexivity (see p159).

Shenton (2004) recommends describing a data-oriented trail: the data collected leads to the formulation of recommendations (and protocols) but most importantly, it also leads to a more theoretical trail, the understanding of a world, populated by different powers that hold a stake in dressing evaluation.

Pragmatism as a methodology enabled the research questions to be answered for it allowed for a number of methods to be used. The focus group and interviews were the appropriate methods to understand the context of dressing evaluation, namely to understand how TVNs select dressings to be listed on their Wound Management Formulary in the absence of empirical evidence. The (same) interviews yielded further data that were triangulated with a thematic analysis of the 'table-top' evaluation to produce a list of elements that would require investigation if a clinical dressing evaluation was undertaken. The study made a further pragmatic choice in borrowing techniques from ethnography; these techniques are a mix of methods which have enabled for a structured approach to develop; their strengths are in the ability to be tailored to any dressing evaluation with fluidity and imagination, to suit its context.

Reflections on pragmatism as a philosophical perspective

The TVNs and pharmacists interviewed agreed that staff and patient participation were essential to a comprehensive dressing evaluation but it appears that they did not practice what they preached (see Chapter 4, p51 and Chapter 5, p95). Understanding the reasons for this involves a threefold discussion: firstly, there seems to be some reluctance for staff to be involved in research and this has already been discussed in the above section.

Secondly, there is a risk of patronisation towards our patients. Healthcare is a social milieu that is characterised by technical terminology and conventions of communication amongst professionals and with patients. Debating whether the jargon used by healthcare professionals is exclusionary, Marshall and Rossman (2011) undertook semi-structured interviews with a variety of healthcare

professionals (n=10). They conclude that using jargon excludes the patient from working with healthcare professionals in the management of their own health. Power relationships between healthcare professionals as well as within each individual profession generate an unwillingness to modify the language used to become more inclusive. In addition, patients are not necessarily comfortable in a healthcare environment, which can interfere with their ability to function assertively (Trede and Higgs 2008). Many patients have not been enculturated to act as contributing members of a healthcare team and are not treated as such by many healthcare professionals, thereby interfering further with their ability to function as collaborators in research. Involving patients in dressing evaluation is mere tokenism if the wrong approach is undertaken.

Thirdly there is an issue of maintaining control and power. To understand this 'power dance' in the context of dressing evaluation (alluded to in Chapter 4, p51 and Chapter 5, p95), is where pragmatism becomes more than a mixed-methods methodology, it becomes a philosophical perspective.

The Power Dance

With reflexivity, as a researcher within my own professional world, I see throughout the interviews the undertone of power that weaves in the conversation. *"Oh no, that is not good enough. Go way and do it again"* says one of the participants to industry (p79); another states that she has always been able to get the products *she* wanted onto *her* formulary (p83). But more than what was said and transcribed in hard data, it is the unspoken words, the pauses in speech that illustrate the dances we undertake to maintain power. We understand each other without words; we speak the same language; we live similar professional lives; issues can be left unsaid but clearly understood.

Power is translated into authority, the ability to control or influence other people (Duffy 1998); power is defined as 'power to' and 'power over' (Hokanson Hawks 1991). The concept of 'power to' relates to effectiveness and includes the ability or

capacity to achieve objectives. 'Power over' refers to the ability or capacity to influence the behaviour and decision of others. Power is the ability to get things done (Kanter 2001) and powerless nurses are said to be ineffective (Manojlovich 2007).

Power is created out of hidden or special knowledge within professional relationships that have positive or negative impacts on other people (Buchmann 1997). Maintaining authority (the power of decision-making) and autonomy (the power of being allowed to make decision) is expressed in how Wound Management Formularies are produced. TVNs are the gate keepers of each Trust, controlling the industry's activities within the organisation but also controlling staff and patients, allowing them to contribute when asked, but not to lead on decision-making processes.

Austin et al. (2006a) undertook an ethnographic study, where a number of TVNs were interviewed (amongst other specialists). They observed how TVNs were limited within their clinical practice, unless they had good relationships with individual medical consultants; for example, some were able to order investigations without having to ask permission. TVNs have to cultivate relationships with more powerful allies to get what they want because the role itself does not give them the level of autonomy and authority required to practice most effectively (Austin et al. 2006a).

In the UK, wound care is developing to a speciality in its own right. The transition of wound care responsibility from doctors to nurses described in Chapter 2 (p23), offers one of the best examples of the work that has been undertaken by nursing to become a profession, with autonomy, authority and accountability at its core (Liaschenko and Peter 2004). Specialist roles have developed (nurse specialist or

nurse consultants[26]) with the four elements at its core (clinical expertise practice, service development, education and research) and in the field of tissue viability these roles are mostly nursing-led, with no direct supervision by medical staff (Pagnamenta 2014). It is unsurprising that few doctors have embraced wound care as their speciality (Harding and Queen 2012) considering the challenges associated in developing evidence that would satisfy medicine, the most loyal exponent of evidence-based practice.

Historically, TVNs have had to fight to get resources for quality improvement projects, such as to purchase therapy surfaces for pressure ulcers prevention; to set up leg ulcer care clinics and also to develop Wound Management Formularies (Austin et al. 2006a). Generally educated at Master Level (White 2008), which reflects the participants studied in Chapter 4 (p51) and Chapter 5 (p95), (senior) TVNs are knowledgeable nurses with expertise that varies with each context; significantly, a core job description for TVNs does not exist in the NHS.

Under TVN leadership, local wound care practices have developed with an individual vision of how each area of practice should be run (Austin et al. 2006a); the stronger the personality, the more autonomy they gained and with this, authority and power. Senior TVNs have experience which allows them to trade accuracy for speed (Klein 1998) and are powerful enough to minimise the effects of their errors (Haag-Heitman 2008).

The relationship between doctors and nurses has never been simple. Status, education, pay, class and in particular gender have by tradition differentiated the groups (Davies et al. 1999). Stereotypical patterns of interaction between doctors

[26] The differences between nurse specialist and nurse consultant are being currently debated (Gerrish et al. 2013) and are outside the remit of this thesis.

and nurses were first described by Stein (1967), who observed that nurses when engaging with doctors did not make bold recommendations but used verbal prompts, offering advice in such a way that both parties could act as if the idea was initiated by doctors. Despite some developments in this area, as nurses strive towards greater equality (Stein et al. 1990), power imbalances continue. Kohr (2007) believed that wound care had been an area where the doctor-nurse relationship had a traditionally paternalistic pattern; the doctor would dictate to the nurse what dressing was to be used. A decade later, Pijl-Zieber (2013, p142) quotes from her field notes, her ethnographical study taking place in a Canadian hospital,

> *My experienced nurse colleague put down the patient's chart and looked at me, her face contorted with concern. "I can't do this. I just cannot do this". I glanced down and saw the chart lying open to the Physician's Order Sheet. He'd ordered a wet-to-dry[27] dressing. "That's ridiculous. I won't do it."*

Nurses, like other groups throughout history, have been described as an oppressed group having mostly female members (Peltomaa et al. 2013). Oppression theory suggests that powerlessness, lack of control over the working environment, and subsequent low self-esteem contribute to the development of horizontal violence within the nursing profession (St-Pierre and Holmes, 2008) and, as in other professions, it encompasses individual, social, and organizational characteristics (Wilson et al. 2011). Horizontal violence embodies an understanding of how oppressed groups direct their frustrations and dissatisfactions towards each other as a response to a system that excludes them from power (Leap 1997).

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[27] Wet-to-dry dressings: wet gauze is applied to a wound, allowed to dry and then energetically pulled to remove any dread tissue that has stuck to the gauze. This procedure can be extremely painful, is no longer recommended and has never been practiced in the UK.

The definition of horizontal violence stems from the work of Freire (1972); within nursing, it is contended that nurses are dominated (and by implication, oppressed) by a patriarchal system headed by administrators, nurse managers and doctors, nurses lower down the hierarchy of power resort to aggression amongst themselves (Street 1992; Peltomaa et al. 2013). Skillings (1992), in defining horizontal violence in relation to nursing, argues that nurses adopt the adaptive strategies of oppressed groups, directing their dissatisfaction inward towards each other, towards themselves and towards those less powerful than themselves (often the patients). Nurses control time for medicine, for food, for wash, for getting out of bed and back to bed, what dressing to use and how often it is done (Palviainen et al. 2003) and when patients express an opinion or chose not to adhere to these shows of authority, they are labelled as non-concordant (Morgan and Moffatt 2008).

TVNs are constrained in their ability to be autonomous in their *clinical* practice (Austin et al. 2006a); therefore, in their *service development* practice, they fight for the power to decide what dressing to list on a Wound Management Formulary. They play the role of the gatekeeper, which allows them to exert authority and power over staff on the wards, disempowering them (Scales and Toogood 2000; Castledine 2000; Austin et al. 2006b) with the ultimate consequence of disengaging staff from the opportunity and responsibility of contributing to the decision-making process. TVNs, in so doing, can perpetuate oppression within nursing.

Changing the way we undertake dressing evaluations will not be an easy transition, as TVNs are caught up in this circle of power and manipulation in order to keep control of practice, control over the context of practice and control over competences. Using a mix of methods was necessary to yield data that would bring attention to the power dance; the focus group and interviews got the debate started which was contra-balanced with the thematic analysis of the 'table-top' evaluation.

Arguably the difficulties of producing evidence for dressing selection have heightened TVN's power, as their expertise is based on intuition, the ability of quick thinking (seeing the past and the future); seeing what is invisible to the novice and the ability to analyse rationally challenging situation (Klein 1998). Generalist nurses often see TVNs as having mystical knowledge to the question of 'what dressings should be applied where' as if dressings were a magical potion that heals wounds (Pagnamenta 2015). The reality is that we only do what Paré (c. 1510 –1590) so eloquently wrote about his ability to heal wounds: "*Je le pansai, Dieu le guérit.*" [28]

Nevertheless, as experts, we see things differently than novices and we should therefore recognise that our expertise is grown from experience rather than evidence. Empirical evidence has been said to challenge the clinical tradition of professional autonomy (Timmermans and Berg 2003), where common sense is no longer valued (Smith and Pell 2003). Klein (1998, p287) tells that "*experience does count"* and pragmatism as a methodology gives value to this expertise and may assist TVNs to refrain from engaging in these power dances.

Critical to this discussion, is the issue of morality and professional conduct when conducting dressing evaluations as they are thrown in the turbulences of clever marketing forces, consumerism at its best and easy criticisms. TVNs are concerned about the delicate relationship with industry; they expressed a need to *"cover yourself"* (N6, p84) as they have been being accused of *"underhand dealing"* (N5, p84). They recognise that selling dressings is a *"cut-throat business"* (N6, p65).

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[28] Translation: "I dressed his wounds, God healed him."

Ambroise Paré (c. 1510 –1590) was a French barber surgeon who served in that role for kings Henry II, Francis II, Charles IX and Henry III. He is considered one of the fathers of surgery and battlefield medicine, especially in the treatment of wounds. He was also an anatomist and invented several surgical instruments (Thurston 2007).

There is a desire to treat industry fairly *"to have a structure that is transparent"* (N7, p86) but also to be treated fairly in terms of being told the truth about the healing ability of the dressings they are selling, *"honest answers"* to our questions (N5, p85).

Godson (2009) explains that personal and social networks drive customer relationships and therefore business. Industry trains their staff in marketing, strategies for selling and the importance of developing customer relationship; most TVNs do not receive any formal business training but are expected to negotiate deals that can be worth hundreds of thousand pounds. TVNs do not receive any formal training on morality, ethical conduct or trustworthiness but are expected to demonstrate those traits of good character (Sellman 2011). All we have is our Code to guide our conduct, "a*ct with honesty and integrity in any financial dealings you have with everyone you have a professional relationship with ..."* (Nursing and Midwifery Council 2015, p7) but that may mean different things to different TVNs.

Adding to this testing arena is the issue of education. Whilst industry should offer training on the equipment they sell, within wound care there is a further requirement, in so far that industry is expected to offer widespread training to generalist nurses (explored in Chapter 5, p109). In fact, TVNs rely on the training delivered by industry, as the NHS is unable to offer consistent and ongoing training to staff on wards and community. One has to trust industry to deliver training without bias, further complicating the relationships between company representatives and TVNs; dressing evaluations will never be able to focus simply on the product as the relationships that exist with its manufacturer must be appraised. For some companies, the relationship smoothes the path of doing business; for others, it can be a formidable barrier that effectively locks some industry out of the market (Godson 2009).

The Department of Health (2013) recognises that the challenges faced by TVNs in business relationships stems to the fact that there are no effective national

community that develops, owns, promotes and reinforces high, professional standards of best practice in procurement and supply chain management. Madden (2012, p2050) arguably states that "*rather than filling the evidence gap with evidence, industry markets the promise of solutions through launching endless wound management products*". Fletcher (2015) questions whether we have reached the point of oversaturation in dressing choice and recommends a consolidation of our existing knowledge. I would add that if the market was to be controlled centrally, there would be fewer dressings to 'have a try' with; less need to undertake evaluations that are quite meaningless just to protect each individual TVN from criticisms from industry and at the same time attracting more criticisms for a process that is seen as worthless by academia.

TVNs would have the time to develop alternative dressing evaluation methodologies; to conduct evaluations as research; have transparent knowledge that will offer value to our expertise; break this dance of power that is ultimately failing the speciality and this is where reflecting on pragmatism as a philosophical perspective becomes important.

Dewey's Pragmatism for Emancipation

Whilst other branches of healthcare have embraced more readily a broader range of evidence, the world of dressings is largely dominated by a traditionally hierarchy of evidence that values trial methodologies above all. This has stifled the development of novel approaches that seek to understand the complexity of clinical practice, rather than control it. Governing bodies are unable to make recommendations precisely because they limit the kind of evidence that can be taken into account, for example, Chapter 6 (p114) appraised two Cochrane Database Systematic Reviews where the authors could not make any recommendations to guide clinicians in pin site care (Temple and Santy 2004; Lethaby et al. 2008).

As explored in Chapter 1 (p13), I acknowledge the emergence of Improvement Science and other such concepts as new fields of inquiry; they have a translational focus and aim to transform what is learned from research into common practice to improve care processes and outcomes (Stevens 2013). Set within an agenda of quality, safety and efficacy, a number of authors have developed cyclical models for developing and integrating research findings to practice (Mitchell et al. 2010). The Medical Research Council (Graig et al. 2008) offers a framework for developing and evaluating complex interventions. The authors assert that randomisation should always be considered and offer some alternatives to the classical RCT design (Graig et al. 2008, p10). However, evaluating dressings is not a 'complex intervention' as defined by Graig et al. (2008, p7); it is the context of these evaluations that is complex where so many conflicting forces affect the ability to conduct trial methodology research. As explained in Chapter 2 (p24), the practice of wound care is immersed in a context that lacks resources (time and money), legislative clarity (medical devices versus pharmaceutical products) and freedom to choose methodological alternatives.

Within the world of wound care, governing bodies continue to have influence in the way we care for patients and there is undoubtedly limited understanding of the issues highlighted in this thesis. For example, the National Institute for Clinical Excellence has produced a number of wound care guidelines that are seen as the bastion of clinical knowledge. Since the beginning of this study, I have been on the panel of one National Institute for Clinical Excellence Guideline Committees (co-opted expert, NICE 2013); I have been asked to review another Guideline draft (NICE 2014) and very recently, I have been asked to comment on the update for the Guideline on Wound Care Products (NICE 2016) before publication. Thee bear witness to my immersion and voice in the field of wound care. However, despite my vehement opposition, the National Institute for Clinical Excellence proceeded to recommend that "*in the absence of any robust clinical evidence to guide choice, prescribers should routinely choose the dressing with the lowest acquisition cost and the performance characteristics appropriate for the wound and its stage of healing.*"

This single statement will have untold implication for clinical practice and this because trials as methods for 'robust clinical evidence' remain the foundation for wound care practice (see Chapter 2, p28). This thesis has been about challenging this prevailing view by governing bodies and returning to the original thinking of Sackett: to base our practice on the best available evidence, from a range of methodologies, selected for their appropriateness to answer to a clinical problem. So much like the participants in my study, I am embedded within a context, which limits the potential of my research to impact practice at a national level. This thesis is, however, the first of its kind and it, as well as the publications that will follow, will hopefully begin a movement of change not dissimilar to some of the cyclical practice improvement models discussed earlier (p13).

It is understandable that there will always be authors who believe that the only worth-while evidence sits with the well-designed and properly executed RCT (Al-Benna 2012; Weller and McNeil 2010 and Jeffcoate 2013). Nevertheless, the RCT should only be used when it is the right tool for the right job (Nolan and Bradley 2008).

Times may be slowly changing. The literary journey that I have made in this thesis has given me the confidence to introduce the possibility of Cochrane accepting other forms of evidence than that produced by trial methodology (Forster and Pagnamenta 2015). Dewey's pragmatism helps with this overall slow movement. Dewey (1919, p181) explains how the goal of pragmatic inquiry is "*the active process of transforming the existing situation. Not perfection as a final goal, but the ever-enduring process of perfecting, maturing, refining is the aim in living".*

One of the most famous versions of the fable of the blind men and the elephant is the poem by John Godfrey Saxe (1816–1887) (see Appendix VI, p241). It describes six blind men who touch an elephant and describe it as being either a wall; or a spear; a snake; a tree or a fan depending on which part they touch; each blind man is convinced to hold the truth. The poem illustrates that one's subjective

experience can be true, but that such experience is inherently limited by its failure to account for other truths or a totality of truth. Dewey (1949, p183) recommends tolerance in inquiry,

> *Genuine toleration does not mean merely putting up with what we dislike, it does not mean indifference…. It includes active sympathy with the struggles and trials of those of other faiths than ours and a desire to cooperate with them in the give-and-take process off search for more light… There may be, there will be differences on many points, but we may learn to make these difference a means of learning.*

Hildebrand (2008) explains that Dewey's views are valuable today not only because he exhorts compassion but because tolerance enables cooperation that over time yields results that are more satisfactory, and in the world of dressing evaluation, more clinically acceptable. Experience and inquiry are ongoing processes and if one assumes a pragmatic stance, absolute values have no place. The way forward is to slowly develop tolerance towards different methodologies, not because 'best' cannot be achieved, but because it provides good work on its own merit.

Liberty, freedom and rights are especially important to Dewey. He defines liberty as a "*release from the impact of particular oppressive"* (Dewey 1935, p35). Liberty is seen as a social question, not an individual one; *"it is a matter of distribution of power that exists [in each context]"* (Dewey 1935, p361-362). The struggle for freedom is a struggle for conditions which will enable an individual to make his own special contribution. Dewey's concept is thus not "*freedom from involvement"* but "*free and full participation"* (Campbell 1995, p169). Pragmatism aims to liberate and enrich human experience and may have the ability to liberate (tissue viability) nurses and enrich the experience of evaluating dressings. Bridging the concept of empowerment and freedom with experience is art. Central to Dewey's philosophy is the role of art and aesthetics in experience. Dewey believes that art is liberating in so forth that it creates experiences. The purpose of art is not to build upon

someone's knowledge but to provoke and shape whole experiences (Hildebrand 2008). Dewey (1934, p70) writes,

> *The product of art (temple, painting, statue, poem) is not the work of art. The real work of art is the building up of an integral experience out of the interaction of organic and environmental conditions and energies...The work takes place when a human being cooperates with the product so that the outcome is an experience that is enjoyed because of its liberating and ordered properties.*

Nursing is said to be both science and art (Sellman 2011). The discussion of whether nursing is more of a science or more of an art remains contentious and outside the remit of this thesis. However, if we take the pragmatic approach where absolute values have no place, nursing is indeed a science and an art; where the science of nursing is a combination of performance, skills and knowledge and the art pertains to those attitudes of care, compassion and communication (Palos 2014); dressing evaluation exemplifies this view.

Art is in the being creative with each evaluation as a number of mixed-methods have to be selected, as each dressing evaluation requires adaptation to its context; art is in the bringing care, compassion and communication to our staff and our patients and is in ensuring we include them in the research process. Science is in that each method selected follows the rigorous principles of that research technique.

An artist starts from where she is, fully embedded in her history, culture and passions fully embedded in her context just like a nurse. Dressing evaluation should be seen as a transformative process, each product that is evaluated merits the creation of a tailored inquiry to shape new experiences and offers capacity for disciplined expression. The creativity, flexibility and humanistic aspects in the art of dressing evaluation may offer an expression of freedom to nurses. *"Art is the most effective mode of communication that exists"* says Dewey (1934, p291) but possibly,

not all (tissue viability) nurses have creative abilities; maybe this ability does indeed come from experience.

Dewey (1925, p392) adds,

> *Respect for experience is respect for its possibilities in thought and knowledge as well as an enforced attention to its joys and sorrows. Intellectual piety toward experience is a precondition of the direction of life and of tolerant and generous cooperation among men. Respect for the things of experience alone brings with it such a respect for others, the centres of experience as it is free from patronage, domination and the will to impose.*

I tentatively propose that Dewey's experimentalism is renamed experiencialism as this would be a better term to describe the incorporation of experience in the inquiry process, which offers respect and freedom from domination of others.

CONCLUSION

This chapter has offered further reflections on the world of dressings and how to best evaluate them. This thesis is underpinned by a pragmatist approach. Using a mixed-methods approach borrowed from ethnography, it has opened the door for an evaluation of dressings that allows for data to be collected from a variety of sources, all equally important in the construction of a clinically sound picture. Nevertheless, there are considerations to be taken in the practical undertaking of such evaluation: namely the difficulties in engaging staff and patients with research; the fact that in the NHS we are not set out to list the equipment we use for each dressing change and therefore the ability to examine costs can never be an exact quantity and finally, the fact that the whole process is time-consuming. Furthermore, central to this approach is to fully understand current practice with participant observation. Street (1992, p15) says that *"to experience the awesome complexity of clinical nursing practice, one has to spend time in the swamp"*;

subsequently, the context must be described clearly so that other clinicians can understand it and decide for themselves if it is applicable to their organisation.

Pragmatism as a methodology quietens the debate of whether dressing evaluation is research or service improvement. With pragmatism, dressing evaluation should be firmly set in the research camp, as, with its inquiry process, one seeks new knowledge. With pragmatism, one can give value to the experience of experts, some of whom may lack appreciation of just how specialist their knowledge is. This means that we can call an end to the power dance; TVNs can be valued for what they know, for the transparent processes they take to evaluate dressings; for the flexibility and the creativity in devising context-bound evaluations, with findings that can guide clinical practice.

Pragmatism as a philosophical perspective calls for tolerance, for the acceptance of new ways of conducting inquiries. It is about finding out what is happening and finding a workable solution. Through e*xperiencialism*, the aim of all endeavours is melioristic, looking for an improvement in the condition that may be temporary and that may need further inquiry. Through e*xperiencialism*, the aim of inquiry is empowerment. It is about offering freedom and rights to the process of inquiry; it is about understanding the problem first and then find a practical, workable solution.

Dewey's hopes for a wide adoption of his philosophy has been fulfilled as it has already been applied to many other disciplines (bioethics, McGee 1999; psychiatry, Brendel 2006; engineer education, Omidvar and Mani 2012; marketing, Hatch 2012; medicine, Shelton 2013; education, Maki 2014 and so on). Through the work I have undertaken in this thesis, dressing evaluation has been added to the list.

CHAPTER 8

Concluding thoughts

> *A being connected with other beings cannot perform his own activities without taking the activities of others into account.*
>
> *John Dewey (1916, p16)*

ORIGINAL CONTRIBUTIONS

As a Professional Doctorate this work has had to make equal original contribution to knowledge and to clinical practice.

Contribution to Knowledge

Placed within the general movement of critique of EBP[29], my thesis brings the debate to the world of dressing evaluation by considering the issues from a clinical perspective and offering an alternative.

This thesis offers a new understanding to the world of dressing evaluation, namely that the world of dressing evaluation is complex. The unique contribution to knowledge that this work makes is using Dewey's experimentalism to find new methods to evaluate dressings, where experience is valued and recognised in the

[29] Evidence-based Practice.

data collected, in the analysis and in the recommendations made for clinical practice. It is experience that enabled me to unpick the context of dressing evaluation, where the issue of power amongst stakeholders takes central stage in the decisions that are made. In order to reflect this, I coined the term '*experience-alism*' or experiencialism, which makes more explicit the key contribution of practitioners' experiences in practice improvement and clinical decision-making. Through experiencialism, this work has emancipatory intents, as with the development of a new kind of evidence, TVNs free themselves from the 'Power Dance' (see Chapter 7, p181).

Contribution to Practice

This thesis has offered a contribution to practice in terms of developing a new protocol for pin sites (Chapter 6, p153). The pragmatic methodology allowed for an 'experiencialist' data collection which was well received by colleagues within the Trust. Regionally, the protocol is expanding and more centres are now considering its adoption. Nurses specialised in pin site care within paediatrics (patients younger than eighteen-years-old were excluded from the study) have reported that the Chlorhexidine in alcohol solution causes stinging pain in the initial phases and dressing changes become a traumatic experience for their young patients; they have recently adopted my protocol with good results.

In the clinical world, new practices can expand like oil over water, in an informal way, as clinicians move from one centre to another and share information. New practices can spread faster than academia can spread the word as writing and publishing articles is time-consuming and slow to reach clinicians.

In fact, this protocol is a true testimony to Dewey's pragmatism, as if it works in practice, it will be adopted widely, on its own merit.

A JOURNEY OR A DESTINATION?

The journey started with Madden's (2012) strong criticisms to our ways of working when evaluating dressings, accusing wound care clinicians of having an antagonistic relationship towards evidence based medicine, which is positioned in opposition to clinical knowledge and seen as an obstacle to innovation and a remover of solutions. There are certainly some truths in her observations when one looks at the world of dressing evaluation with positivist eyes; but what about if we look at the same world from a different perspective? I make a case using pragmatism, more specifically Dewey's pragmatism. Through experiencialism, structure is given to our experiences so to make sense of the world of dressing evaluation.

Madden (2012), but also governing bodies such as NICE and Cochrane, fail to understand the competing priorities that power the world of dressing evaluation. It is complex, and the antagonism by wound care clinicians expressed towards EBP is only the tip of iceberg, it is just the eruption of the volcano. This thesis has given me the opportunity to look at our world and be honest in the reporting of our problems. Despite being well educated nurses, TVNs have limited clinical autonomy and authority. Welcomed when our advice is requested but rebuffed if we recommend changes when not invited to do so, we remain oppressed within NHS structures. We therefore engage in power dances to get what we want for our patients. My study is offering TVNs a way to reconquer dressing evaluation as a nursing field to be proud of.

This thesis has been a journey towards gaining an understanding of the world of dressing evaluation. It has been a personal journey, in the understanding of the role I play in this world. It has been a philosophical journey, as I have come to realise that my beliefs are intrinsic to the way I have understood this world and it has been a literary journey, in the way I have painted this world.

This is a subjective piece of work, for which I make no apologies as every effort has been made to offer a detailed and honest view. A connected being cannot work

well in isolation (Dewey 1916). *"Every new idea*", Dewey writes, *"Every conception of things that differ from the traditional belief, must have its origin in an individual"* (1916, p305). But it is because I am a TVN and work with other TVNs that I am able to see our strengths and weaknesses. I gained a deeper understanding of my professional world and my philosophical ethos which has given me the confidence to gently gnaw at conventional bodies of evidence-appraisers (Forster and Pagnamenta 2015) and to gently publicise the realities of the role of the TVN (Pagnamenta 2014, 2015). Dewey also says that only in social groups, does a person have a chance to develop individuality (1924, p176), which I hope to have conveyed in this thesis.

Chapter 2 (p23) illustrated how dressings are mainly in the nursing domain and have suggested that a positivist approach to dressing evaluation does not offer a useful method in clinical practice. Chapter 3 (p38) introduced the concept of pragmatism as a philosophical perspective, as a methodology using mixed-methods, some borrowed from ethnography. Chapter 4 (p51) explored the world of dressing evaluation as pragmatism believes in a full understanding of the context of inquiry. Regional TVNs were interviewed and it became clearer that there is a dichotomy between what we say we want and what we accept in terms of evidence to support our clinical practice.

Chapter 5 (p95) explored the key elements that regional TVNs believe are important to be evaluated to yield clinically valuable data, because pragmatism is about doing whatever works in practice. Chapter 6 (p114) was a first attempt to produce a pragmatic dressing evaluation in a clinical setting. A dressing evaluation needs to have a comparative element between what was used before to what has been tried. Nevertheless, the most valuable data was obtained through qualitative techniques (i.e. participant observation; patients' stories) which yielded more clinically informative data than the quantitative ones (i.e. staff survey, patient survey and an examination of costs). In effect, this approach puts meat on the bone; offered humanistic meaning to the comparative element of the study and after all,

dressing evaluations are about human beings and how best to dress their wounds. In Chapter 7 (p166), I indulge in further reflections, namely on the successes and limitations of pragmatism as a mixed-methods methodology and as a philosophical perspective.

I have argued that the difficulties with evaluating dressings with the traditional method and the reluctance of the 'System' to accept a different approach have resulted in TVNs becoming complicit in the oppression of generalist nurses and patients. The solution is in the understanding that the world of dressing evaluation is not perfect; that we will not strive to find perfection as our final goal. Dewey (1919, p181) writes,

> *The end is the active process of transforming the existent situation. Not perfection as a final goal, but the ever-enduing process of perfecting, maturing, refining is the aim in living. Honesty, industry, temperance, justice, like health, wealth and learning are not goods to be possessed as they would be if they expressed fixed ends to be attained. They are directions of change in the quality of experience. Growth itself is the only end.*

Whilst significant progress has been achieved through this thesis, this is only the beginning; the aim of adopting a pragmatic approach was not to find the perfect, finite, dressing evaluation method. Rather it has been about perfecting, maturing and refining *and* valuing our experiences. Thus this is about a journey in experiencialism which is set to continue beyond the completion of this thesis, rather than as assertion of a new and undisputable truth.

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APPENDIX I

JOHN DEWEY

John Dewey (1859-1952) was an American psychologist, philosopher, educator, social critic and political activist. He was a prolific writer with a career spanning some 65 years.

Dewey was born on the 20th of October 1859 in Burlington, Vermont USA. Dewey graduated from the University of Vermont in 1879, and received his PhD from Johns Hopkins University in 1884. He started his career at the University of Michigan, teaching there from 1884 to 1894. In 1894 he became the chairman of the department of philosophy, psychology, and pedagogy at the University of Chicago.

Dewey taught at Columbia University from 1905 until he retired in 1929, and occasionally taught as professor emeritus until 1939. During his years at Columbia he traveled the world as a philosopher, social and political theorist, and educational consultant. Among his major journeys are his lectures in Japan and China from 1919 to 1921, his visit to Turkey in 1924 to recommend educational policy, and a tour of schools in the USSR in 1928. He was outspoken on education, domestic and international politics, and numerous social movements. Among the many concerns that attracted Dewey's support were women's suffrage, progressive education, educator's rights, the Humanistic movement, and world peace. Dewey died in New York City on the 1st June 1952 (Hildebrand 2008).

His Lasting Influence

Dewey made seminal contributions to nearly every field and topic in philosophy and psychology. Besides his role as a primary originator of both functionalist and behaviorist psychology, Dewey was a major inspiration for several allied movements

that have shaped 20th century thought, including empiricism, humanism, naturalism, contextualism, and process philosophy. For over 50 years Dewey was the voice for a liberal and progressive democracy that has shaped the destiny of America and the world (Campbell 1995; Hildebrand 2008; Hickman et al. 2009). Dewey ranks with the greatest thinkers of this or any age on the subjects of pedagogy, philosophy of mind, epistemology, logic, philosophy of science, and social and political theory. His pragmatic approaches to ethics, aesthetics, and religion have also remained influential (http://dewey.pragmatism.org accessed 14/07/2015).

Dewey's Work

The full list of his published work is available http://dewey.pragmatism.org.

The critical edition by Southern Illinois University Press, edited by Jo Ann Boydston (Boydston 2008) was used throughout the thesis, where Dewey's work is divided in three sections: his *Early Work* (1882-1898); his *Middle Works* (1899-1924) and his *Later Work* (1925-1953).

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APPENDIX II

'TABLE-TOP' EVALUATION MATRIX FOR WOUND DRESSINGS

QUESTIONS	MARKS	MARKING CRITERIA
Quality of the outer packaging (sturdiness)		Strong box=2. Boxed=1 No box=0
How much packaging is used		Dressing package is just right=2. There is a little too much/too little packaging=1. There is far too much/little packaging=0
Ease of opening the inner packaging, does it easily rip/tear or require excessive force to open. Is opening the product difficult.		Dressing package is easy to open and does not rip/tear=3. Dressing package is more difficult to open and sometimes rips/tears=2. Dressing package is difficult to open and frequently rips/tears or is technically challenging=1
Does the packaging contain any latex?		No latex =2. Some latex=1.
Is the size of any labelling acceptable on outer packaging?		The labelling can be easily read-2. The labelling is difficult to read=1

Is the product information clear (quality, size of text) on IFU sheet?		The clarity, quality and size of the text is Good=3. Average=2. Poor=1.
Does the clarity of the label on inner and outer packaging allow the user to clearly identify the product brand, size and type?		The labelling ensures the right size, type and brand is identified=3. The information is too small and/or unclear to safely select the right product=2. Information is missing from the labelling=1.
What is the level of risk of contaminating the dressing surface when removing the backing sheet or breaking seal of product or opening the sachet/tube?		It is easy to avoid contaminating the dressing surface when opening=4. It is possible to avoid contaminating the dressing surface when opening =3. It is difficult to avoid contaminating the dressing surface when opening =1.
Clinical evidence		RCT = 3, Case Control = 2, Case Study / Review = 1, None = 0
Ease of application		Easy = 3, Some difficulty = 2, Difficult = 1
Available on FP10		Yes = 1 No = 0
Wear time		Up to 7 days = 1 Less than 7 days = 0

Easy to remove in one piece		Yes = 1 No = 0
Bioresorbable		Yes = 1 No = 0
No fibre shedding		Yes = 1 No = 0
Welded seams if applicable		Yes = 1 No = 0
Overall fluid handling in 24 hrs		Exceeds standard = 2 Acceptable = 1 Poor = 0
MVTR data		Exceeds standard = 2 Acceptable = 1 Poor = 0
Fluid handling data		Exceeds standard = 2 Acceptable = 1 Poor = 0
Indications clearly stated on application		Yes = 1 No = 0
Contraindications clearly listed on application		Yes = 1 No = 0
Side effects clearly labelled		Yes = 1 No = 0

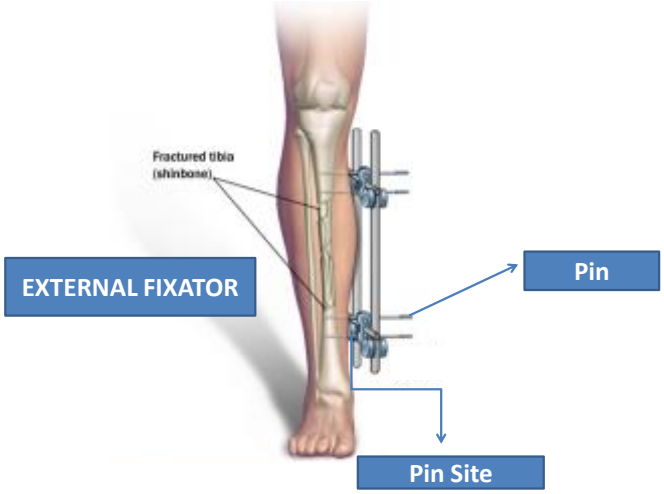
Congruent with other application techniques		Yes = 1 No = 0
Patient Information		Good = 2 Average = 1 Poor = 0
Staff Education		Good = 2 Average = 1 Poor = 0
Marketing Information		Good = 2 Average = 1 Poor = 0
Range of sizes		Good = 2 Average = 1 Poor = 0
Proof of quality standards		Yes = 1 No = 0
TOTALS		

APPENDIX III

A) PATIENTS INFORMATION SHEET

Dressing Selection in The Care of Pin Sites

This information sheet is for men and women who will soon be fitted with an external fixator to their limb (arm or leg) or that have just been fitted with an external fixator to their arm or leg.



We are inviting you to participate in research on the selection of a dressing regime for the pin sites. One of our team will go through the information sheet with you and answer any questions you have. We suggest this should take about 10 minutes. Before you decide if you want to participate in this research, we would like you to understand why the research is being done and what it would involve for you. Ask us if there is anything that is not clear.

Study researcher

Fania Pagnamenta – Nurse Consultant (Tissue Viability)

Title of the study

Dressing selection in the care of pin sites.

Introduction

I am a Nurse Consultant working in Tissue Viability. I am doing research on the best protocol to dress pin sites. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will

participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me or you can contact the doctor or the nursing staff.

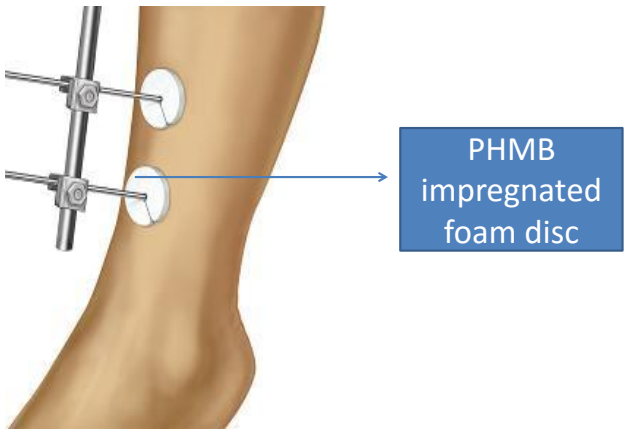
Purpose of the research
There are different ways to dress pin sites, but we are unsure which is the best way. We have typically two regimes:

The Kurgan method: cleaning the pin site with 2% w/v chlorhexidine gluconate in 70% alcohol, dressing the pin site with gauze. Same regime before and after you leave hospital.

The Disc method:
While you are in hospital: clean pin sites with Sterile 0.9 Sodium Chloride, apply PHMB* foam disc and secure with tape. Remove crusts if necessary using sterile gauze. Daily dressings if pin site oozes, weekly if dry.

After you leave hospital: wash the limb under the shower, towel dry, remove crusts if necessary using sterile gauze, apply PHMB* and secure with tape. Daily dressings if pin site oozes, weekly if dry.

**PHMB is a product that is known to kill bacteria*



Participant selection
We are inviting all patients who are about to be fitted with an external fixator or have just been fitted with an external fixator to participate in this research.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital.

You may change your mind later and stop participating even if you agreed earlier.

We are looking to recruit 16-20 patients to this study: this is the average numbers of patients who have an external fixator in one year in Newcastle.

How are we going to do it?
Because we do not know which protocol is better, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin. If you agree to participate in this research, I will use a computer program to put you in one or the other group. I have no way to know which group the computer will put you in.

If you don't wish to take part in this research, you will automatically follow the Kurgan method.

Whilst you have the external fixator, you will come to clinic most weeks anyways, but I will review you 6 times.

Week 0	Start of the research
Week 2	Review
Week 4	Review
Week 8	Review
Week 16	Review
After 6 month or at fixator removal	Review

I will be looking after you and the other participants very carefully during the study. I will be looking for signs of infection, inflammation or any other skin reactions. If there is anything you are concerned about or that is bothering you about the research please feel free to talk to me at any time.

Risks and side effects
Any risks are mainly associated with the having an external fixator rather than to the research. Infection is the most common risk associated with the external fixator.

This proposal has been reviewed and approved by the NHS Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm.

Benefits
If you participate in this research, you will be receiving care by an expert wound care specialist whom you would not usually see unless you have a serious wound problem.

Confidentiality
We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be stored in a safe and secure way and no-one but the researchers will be able to see it.

Sharing the Results
The knowledge that we get from doing this research will be shared with you in writing if would like. Confidential information will not be shared. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment in any way. You will still have all the benefits that you would otherwise receive. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here.

Who is organising and funding the research?
This research is to evaluate a new type of dressing and is organised by the Newcastle upon Tyne Hospital NHS Foundation Trust. There is no company involvement in funding the research.

What happens when the study is finished?
If you still need pin site dressing and you have been selected to have the foam discs, these will be made available to you until the external fixator is removed.

Payment
There will be no payment given to you for participating to this study.

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact:
Fania Pagnamenta – Nurse Consultant (Tissue Viability) - *Address supplied*

If you wish to contact someone independent about this research, please contact:
Mrs X – Assistant Matron - *Address supplied*

Complaining: If you are unsatisfied and wish to complain about any aspects of the study, you can do so by writing to: Chief Executive Office - *Address supplied.*

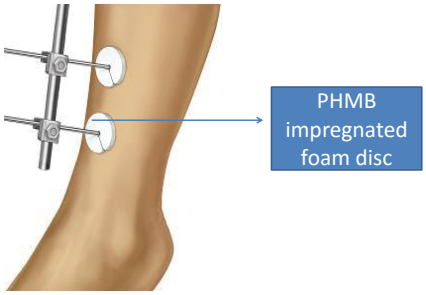
B) STAFF INFORMATION SHEET

Dressing Selection in The Care of Pin Sites
We are inviting you to participate in research on the selection of a dressing regime for the pin sites. We would like your opinion on the dressing you have been using and on your experiences of living with an external fixator. *One of our team will go through the information sheet with you and answer any questions you have. We suggest this should take about 10 minutes. Before you decide if you want to participate in this research, we would like you to understand why the research is being done and what it would involve for you. Ask us if there is anything that is not clear.*

Title of the study: Dressing selection in the care of pin sites.
The primary purpose of the study is to select an appropriate dressing for pin sites.

The aims of the study are:
To establish the full extent of the available body of knowledge by including studies of all methodologies in a comprehensive literature review.
To determine themes that are key to patients living with external fixator.
To establish if the PHMB* foam disc is a good dressing for pin sites, in terms of preventing infection, patient satisfaction, staff satisfaction and costs.

**PHMB is an antibacterial*



The study consists of a mixed method design which incorporates four key elements:

1. Pilot RCT to assess performance of a new antimicrobial impregnated foam disc compared to standard care (up to 20 patients with radial or below knee external fixators)
2. Semi-structured interviews on up to 75% of the patients recruited to the pilot RCT to explore the patient experience of dressing own pin sites and self-management
3. Survey of staff to establish clinicians' preference and experience

4. Economic evaluation to compare the cost the new foam disc to standard care.

A copy of the research protocol is available if you wish to see it.

Your participation in this research is entirely voluntary. If you agree to participate, the survey will be sent to you via an email (your work email address). The survey will take a maximum of 10 minutes to complete and is totally anonymous.

Benefits: If you participate in this research, you will be able to voice your preferences from a clinician point of view and direct future dressing protocols.

Sharing the Results: The knowledge that we get from doing this research will be disseminated across the Trust shared with you in writing if would like.

Who is organising and funding the research? This research is to evaluate a new type of dressing and is organised by the Newcastle upon Tyne Hospital NHS Foundation Trust. There is no company involvement in funding the research.

Risks and side effects: This proposal has been reviewed and approved by the NHS Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm.

Right to Refuse or Withdraw: You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your rights in any way.

Payment: There will be no payment given to you for participating to this study.

Who to Contact
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact:
Fania Pagnamenta – Nurse Consultant (Tissue Viability) - *Address supplied*

If you wish to contact someone independent about this research, please contact:
Mrs X – Assistant Matron - *Address supplied*

Complaining: If you are unsatisfied and wish to complain about any aspects of the study, you can do so by writing to: Chief Executive Office - *Address supplied.*

APPENDIX IV

STAFF QUESTIONNAIRE

PHMB disc evaluation - Staff Feedback

Please complete:

□ I have not used them: *"Thank you that is all I need from you. No need to continue answering questions".*

□ I have used PHMB discs on patients with external fixators. Please answer these few questions:

How do you rate PHMB disc?

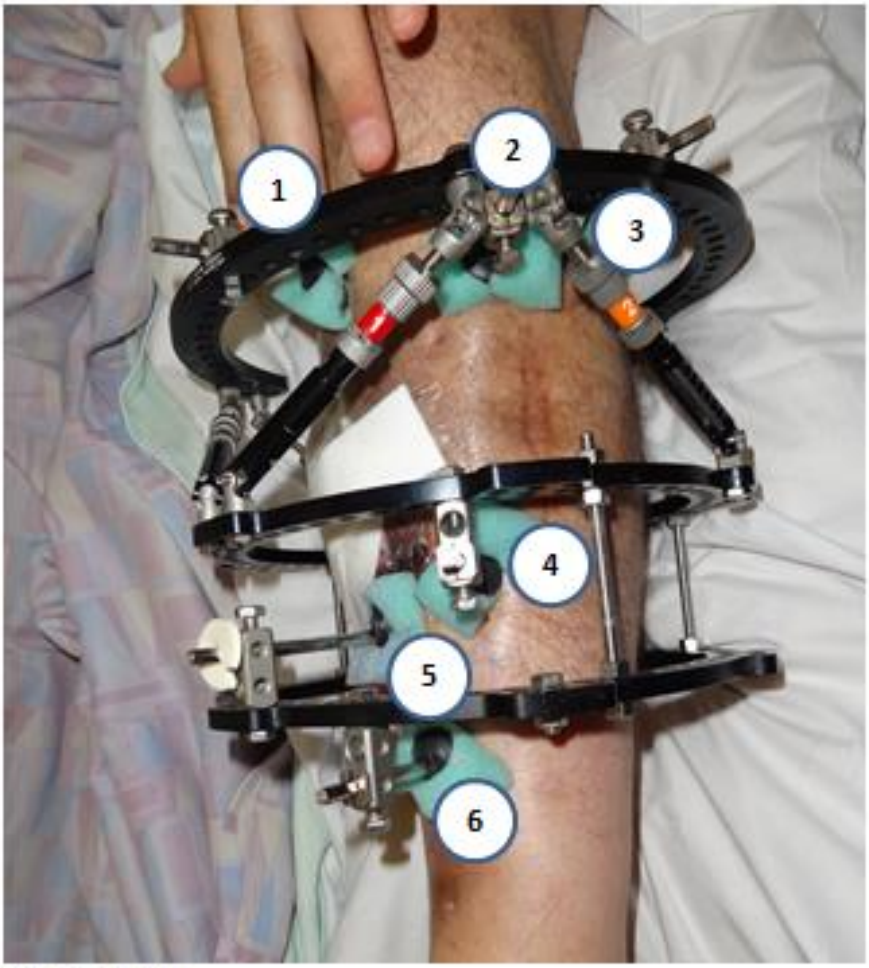
	Excellent	**Good**	**Fair**	**Poor**
Ease of application				
Ease of removing dressing from packaging				
Comfort for the patient				
Ease of keeping the disc in situ				

How did you secure the PHMB to the skin? (ie tape, hyperfix, or other): _____

Would you like this product to be available for patients with external fixators? Yes/No

APPENDIX V

AN EXAMPLE OF A PIN SITE PHOTOGRAPH WITH FIELD NOTES



Observation
Sponges applied.
Little space between pins.
Wound in between pin sites, difficult to access.
Patient's hands close to wounds

APPENDIX VI

THE BLIND MEN AND THE ELEPHANT

It was six men of Indostan
To learning much inclined,
Who went to see the Elephant
(Though all of them were blind),
That each by observation
Might satisfy his mind

The First approached the Elephant,
And happening to fall
Against his broad and sturdy side,
At once began to bawl:
God bless me! but the Elephant
Is very like a wall!

The Second, feeling of the tusk,
Cried, Ho! what have we here
So very round and smooth and sharp?
To me tis mighty clear
This wonder of an Elephant
Is very like a spear!

The Third approached the animal,
And happening to take
The squirming trunk within his hands,
Thus boldly up and spoke:
I see, quoth he, the Elephant
Is very like a snake!

The Fourth reached out an eager hand,
And felt about the knee.
What most this wondrous beast is like
Is mighty plain, quoth he;
'Tis clear enough the Elephant
Is very like a tree!

The Fifth, who chanced to touch the ear,

Said: Even the blindest man
Can tell what this resembles most;
Deny the fact who can
This marvel of an Elephant
Is very like a fan!?

The Sixth no sooner had begun
About the beast to grope,
Than, seizing on the swinging tail
That fell within his scope,
I see, quoth he, the Elephant
Is very like a rope!

And so these men of Indostan
Disputed loud and long,
Each in his own opinion
Exceeding stiff and strong,
Though each was partly in the right,
And all were in the wrong!

Moral:

So oft in theologic wars,
The disputants, I ween,
Rail on in utter ignorance
Of what each other mean,
And prate about an Elephant
Not one of them has seen!

Available at: http://www.constitution.org/col/blind_men.htm (Last accessed: 20/01/2016).