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Understanding the development of advanced wound care in the UK: Interdisciplinary perspectives on care, cure and innovation

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Abstract

George Winter's 1962 paper in *Nature* reported his observation that wounds in young pigs healed more quickly if covered rather than being left open to the air. This has been widely regarded as the starting point for 'advanced wound care' because it established the idea that a wound dressing could influence outcomes. This paper argues that key to understanding innovation is placing technological advances within their broader historical and sociological context. As in other areas of healthcare, the development of innovation in wound care can be seen as a multifaceted, uneven and contested process, not the simple invention and introduction of 'advanced' products and services. Innovation in this field takes place at the intersection of historical changes in industry, scientific medicine, medical technologies, health care service delivery and the demographic and domestic spheres. Stemming from interdisciplinary exploration funded by the Arts and Humanities Research Council, this paper presents a provocative argument that contemporary wound care in the UK has become something of a partnership between elite nurses and industry marketing, with important consequences for science and service users. Current challenges in wound care stem in large part from an emphasis on a biomedical model focused on products (albeit one not led by medics) at the expense of considering service design and a social or public health model of patient care.

1 Introduction

Contemporary wound care in the UK has developed into two distinct complex wound care management spheres. The acute wound characterised by the contemporary, aggressive management of major trauma, and chronic wound care where there is widespread use of the term 'advanced' although, arguably its methods remain largely traditional [1]. Chronic wound care in the UK has now few connections with the more specialised systems that have developed for less prevalent burns and also for dermatological conditions [2,3]. Most management of people with complex wounds in the UK occurs in the community rather than in hospital with referral to a disparate range of health professionals including tissue viability nurses, vascular surgeons, podiatrists, physiotherapists, dermatologists, and occupational therapists. The bulk of the work is subsumed in community nursing.

The historical literature on wound care has tended to concentrate on hospital-based, acute clinical activity, even though wound care decision-making, prevention and treatment are often the preserve of nursing and of patients themselves in the domestic rather than, or in addition to, the clinical sphere. While there has been much research examining the historical context of acute surgical wounds and injuries sustained on the battlefield [4], or 'wounding' as a predominantly socio-cultural process before the modern period [5], the case of chronic wounds has yet to be investigated.

In 1962 George Winter published his observation that wounds in young pigs healed more quickly if covered rather than being left open to the air [6]. This has been widely seen as the starting point for 'advanced wound care' because it established the idea that a wound dressing could influence outcomes. It was followed by the introduction of occlusive and semi-occlusive dressings and various branded products such as Opsite from the 1980s. Wound care is now a multi-billion pound industry, yet there is a lack of recognition that products themselves are only a part of the story. As in other areas of healthcare, such as minimally-invasive surgery [7] and joint replacement [8], the development of innovation in this field can be seen as a multifaceted, uneven and contested process, not the simple invention and introduction of 'advanced' products and services.

Drawing on historical, sociological and health sciences research and recordings of a series of Arts and Humanities Research Council (AHRC) funded cross disciplinary workshops connecting academics from a wide range of disciplines with service users, professionals and carers [9], this paper explores advanced wound care in the UK as a specific exemplar with wider resonance for understanding the particular climates in which clinical judgement and innovation adoption take place. It argues that with the historical shift from dry to moist wound healing came a narrow product focus in wound care which is intimately connected with the history of the professional development of

nursing and its interaction with industry, marketing and evidence informed healthcare.

2 The development of a fractured and gendered field

Inevitably, those dealing with chronic wound care have faced the particular challenge of uncertainty about how (or, indeed, if) their efforts related to outcomes over time. This is not only a feature of contemporary or recent practice, but has long-since been recognised within the nursing profession. In December 1893, for example, Nurse Agnes addressed a query to the Nurses in Council column of *Nursing Notes*, seeking advice about treatments for leg ulcers where the patient could not tolerate then-standard treatment with terebene or iodoform. “District Nurse” replied in February 1894:

> I can sympathise with Nurse Agnes. I well know the sort of ulcers she speaks about. The cases I remember were too bad to hope to *cure.* One could only endeavour to keep them clean and comfortable and try and persuade the patients to go into hospital with the hope that amputation would be advised … I have no doubt Nurse Agnes has already tried these simple plans [vaseline or boracic fomentations and bathing in warm water with a little disinfectant added], but I felt much sympathy with a difficulty I have myself had experience of [10].

Aiding recovery was, and is, not necessarily about achieving cure but also about relieving symptoms, reducing severity and protecting against exacerbation or complication. Such care can however carry a sense of frustration at implicit failure or incomplete success if the desired goal is cure.

Historically, wounds were considered to be diagnostic markers indicative of the humoral constitution of the body; outward signs of internal disturbance. With the advent of significant levels of anatomico-clincal correlation from the mid-eighteenth century onwards, physicians began to try and cure as well as manage wounds [11]. The domain of wound care fell under the purview of surgeons who both created and treated wounds through a variety of means. This frequently involved amputation (for infection control), the practices of which were altered by the introduction of antisepsis and asepsis in the mid-nineteenth century. These still drew on Galenic conceptions of “laudable pus”, combining an appreciation for the “natural” progression of wounds with increasingly interventionist approaches through cautery, topical applications and debridement [12,13]. Germ theoretic approaches to disease causation provided renewed justification for such practices, rationalising surgical methods which had already become well-established [14].

Until the mid-nineteenth century, nursing was not an activity which was thought to demand particular skill or formal training. As recent historical research has shown, nurse education in wound sepsis remained largely determined by local factors – including the personal inclinations of individual instructors – at a time when the details of bacteriology and their implications for practice were in flux [15]. Against this backdrop, new dressings such as Elastoplast and ‘Gamgee Tissue’ - a preparation of cotton wool and surgical gauze developed in 1880 by J. Sampson Gamgee, a surgeon based at the Queen's Hospital, Birmingham - provided alternative ways of managing both acute and chronic wounds [16].

As well as development of specific surgical innovations, often during the context of warfare, relevant non-surgical ideas included both nursing and sanitary reform, in particular from the Crimea [17]. As Christine Hallett, Professor of Nursing at the University of Huddersfield, noted at the second AHRC workshop in a presentation which quoted her published work:

> Early twentieth century nurses - all of whom had been trained in an era of Lister and anti-sepsis - were accustomed to encountering and dealing with clean surgical wounds. Their training and experience had taught them that the tissue damage created by traumatic events such as severe industrial accidents could be complex and might be infected. But that infection could be countered with anti-septic treatment such as iodine and sodium hypochlorite. Nothing had prepared them for the horrific wound infections they encountered in the casualty clearing stations and base hospitals of Belgium and Northern France during the First World War [18].

The descriptions of some of the techniques adopted by nurses on the front line, were familiar to the Tissue Viability Nurses at the workshop:

> … apart from the use of the Carrel's tube which I've never come across myself, the rest of the care you [Christine Hallett] described was alive and well when I started in the trade in 1979 [19].

Whilst much of the historical focus to date has been on the development of wound care materials from World War One onwards, Hallett's work has shown that service reorganisations were arguably of far more significance. This is a critical aspect of contemporary wound care which is often neglected, highlighting how a focus only on innovation in technology can obscure more effective means of implementing measures to promote patient outcomes. Contemporary wound care is dominated by talk of products, and yet, the historical evidence demonstrates that the organisation of, what is done when, who is seen, and who becomes involved, is at least as important. The Lindsay Leg Club model of community-based leg ulcer care which provides nursing care in a non-medical, social environment is something of an exception to the contemporary predominantly product led focus [20]. Recent research in hospitals has shown that organisational context plays a significant role in severe pressure ulcer development and there have been calls for a step change to improve pressure ulcer prevention and management practice and training [21–23]. In addition, the National Wound Care Strategy Programme has been recently commissioned by NHS England to drive forward improvements in wound care and its remit includes drafting recommendations for workforce and service configuration, alongside other issues such as improving education and the supply and distribution of wound care products [24,25].

The historic emphasis on materials over systems is also reflected in the gender-driven power dynamics between surgeons and nurses. Historically, surgeons were far more likely to encounter and manage wounds directly, whilst nurses tended to prepare the necessary poultices but remained relatively isolated from wounds themselves. Instead they passed these preparations on to male "dressers" [26]. More recently, surgeons pack wounds in the context of the operating theatre but are both spatially and professionally at a distance from the consequences of their removal. As nurse-trainee Evelyn Matthias recorded in lectures delivered by a Miss Copeland in the early 1910s, nurses were schooled in deference. They were instructed to:

> Obey all orders given and never question orders given by a superior officer. Cultivate quietness and gentleness and be thorough with all your work. If asked a question, state facts without opinions and learn to control your own feelings. Be loyal to your superior officers and to those with whom you work. Always stand to receive orders and when a superior officer enters your ward … A nurse must never interfere with a patient's treatment, avoid amateur doctoring and never encroach on the doctor's province [27].

Nurses and surgeons at the AHRC workshops described this separation of spheres in more recent times. As Peter Vowden, a Senior Vascular surgeon and Honorary Visiting Professor of Wound Healing Research, noted:

> … the surgeon gets separated from the dressings nowadays. So we might put something on in theatre but we never see the consequences of it being removed elsewhere, because that's the only episode where we're involved with the wound … And we've drifted apart so that, the primary dressing, I can cause as much havoc as I like … pack it as tightly as possible, then the patient won't bleed until they're back on the ward and it's not my problem anymore [28].

Sue Bale OBE, R&D Director, Director of South East Wales Academic Health Science Partnership and Visiting Professor, recalled:

> I can remember a specific patient with a very complex large open wound and me negotiating with the registrar and saying you can take that packing out because I'm not going to take it out without an anaesthetic … I'm not doing it, it's too painful … once that registrar saw what it meant with the patient in a bath with blood and gauze packing everywhere, they soon realised the situation. So sometimes it was about not understanding the implications of instructing a nurse to do something [29].

Such perspectives are indicative of discontinuities of care identified also in service user and carers' accounts of their experiences of contemporary wound care, where there is no single clinical person in charge of a patient's therapy, and wounds are frequently left for a different individual or team to manage. Invariably, it is left to the patient to navigate/negotiate across different health professionals with potentially different views on how wounds should best be managed. This results in a chopping and changing of interventions. At the other extreme, Kay Walker, a service user and member of the Pressure Ulcer Research Service User Network (PURSUN UK) used the term "Sat-Nav wound care" at a workshop to describe nurses in the community almost abdicating responsibility for decision making as they continued to follow a hospital surgeon's instructions although it no longer made sense in the home context [30]. As Madeleine Flanagan, Principal Lecturer in Dermatology and Wound Management, noted: "There's really hardly any other area of clinical practice where nobody is in charge" [31]. This is in stark contrast with the managed, multidisciplinary, integrated approach which has developed in the UK treatment of burns [2].

The development of new technologies, medical techniques and pharmaceuticals in the twentieth century has been linked with a shift from care to "curing cultures" [32]. Caring, which may be understood simultaneously as concept, emotion, practice and moral exhortation, has long been associated with women and carries connotations of the non-technical, non-pharmaceutical and non-medicalised [33]. Caring and care work have until recently been regarded as a mundane, tedious practical necessity, rather than as an intellectually interesting area for study [34]. The practical and emotional responsibilities of caring have been disproportionately met by women domestically and professionally [35,36].

Although there is a long history of men in nursing, the profession was predominantly staffed by women for much of the twentieth century [37,38]. The General Nursing Council Register began in 1923, with male nurses permitted to join the register in 1951, three years after the establishment of the National Health Service in 1948 [26]. Nurses continue to be seen by some as predominantly "emotional labourers" associated with caring and nurturing [39,40], yet observational research has shown that much nursing work involves making decisions about, and administering therapies which require technical skills and critical decision-making capabilities [41,42]. Attending to the hygiene, nutrition and hydration needs of patients is increasingly delegated to non-nurse assistants.

More recently, 'Project 2000' in the late 1980s introduced a move away from apprentice style nurse training in hospital based schools to diploma level nurse training based in colleges/universities. Since 2013 all new UK nurses have to hold a degree-level qualification to enter the profession. This means that graduates are now a small but growing part of the workforce. Nurses with graduate or post graduate qualifications were very much in the minority in the 1980s, demonstrating the significant change in training expectations of those involved in managing complex, chronic wounds.

In the 1980s and 1990s the UK began to lead advances in wound care, which to a large extent, has developed as a nurse led sector. Since the emergence of the role of the specialist Tissue Viability Nurse (TVN) in the 1980s, there have been ongoing concerns about the legitimacy, complexity and diversity of the role within the changing demographic and health care landscape [43]. The TVN specialist nurse role calls for clinical expertise accompanied by management of services, lobbying for political attention, research and training roles. TVNs have felt the need to justify the relevance of the role and prove it as a nursing specialism, especially in the absence of formal qualification.

By 2004 there were approximately 500 TVNs in the UK, rising to around 800 in 2010 [44]. In the latter year, in the *Nursing Times*, Richard White identified wound care as an area, "widely perceived to be under threat" because, "with a few notable exceptions, the consultant nurse in wound care, the 'figurehead of tissue viability', and wound care services generally, were failing to provide evidence to justify their existence." The suggested solution was "to consider the amalgamation of tissue viability with related therapeutic areas for economy of scale, cost efficiency and improved delivery of care'" [45]. When the authors enquired, the Tissue Viability Society did not have figures on the current number of TVNs and were unsure how these figures might be found. It is therefore unclear whether the number of TVNs has kept pace with the rise in patients with contributory chronic conditions which lead to complex wounds.

3 Material relationships and marketing

Wound care has long moved from the use of materials readily at hand (at home) to mass produced materials (via the pharmacy and clinic). Building on the increasingly specialised medical landscape of the nineteenth century, the creation of national systems of healthcare produced mass markets for drugs and devices and expanded the earlier, more fractured, medical marketplace originally observed by Roy Porter and others for the eighteenth century [46,47]. The drug and device industry then assumed a major economic, social and political significance. The device side of the economy has not been as highly regulated as the pharmaceutical sector. Nurses have played a key role as pragmatic transformers of promising innovations from industry into workable and working processes.

Wound care management is currently one of the largest segments of the UK medical technology sector. It is the fourth of five segments which account for £7.4bn (43%) of the "Core Med Tech" turnover [48]. It has been estimated that the annual UK NHS cost of managing wounds and associated comorbidities was £5.3 billion in 2012/2013 [49]. The wound prevalence rates used in this estimate were considerably higher than those found in other recent studies trying to establish accurate figures for the prevalence of complex and/or chronic wounds [50]. Still, this indicates that the main cost drivers in the sector are not dressings and devices themselves but staff time and hospitalisation costs, reflecting the importance of appropriate care management structures.

Increasing industry investment in marketing in addition to mass production is intimately implicated in relationships with wound care processes and products. Since the findings of Winter's animal-based study of acute wounds began to be applied to the quite different context of chronic wounds in humans, the use of more expensive, quicker and easier-to-apply and remove wound dressings have featured heavily in the history of advanced wound care. Winter's work promised an 'advance' based on a fuller scientific understanding of wounds. Industry, starting with the company that funded his work, were keen to apply this through new technologies [51]. Manufacturers then took a lead in cultivating a new relationship with nurses in the UK by promoting and supplying new dressings. A new form of wound care expert with a supporting network of conferences and journals emerged. Nurses began to get involved in wound care research, much of it industry focused and on a relatively small scale. This was clearly reflected in the experiences of those TVNs at the AHRC workshops who were practising during this transformative period:

> ... there were suddenly dressings popping up all over the place. They were all new; we were being told they were all different. And we had to quickly run with it and learn. And really overnight we became key opinion leaders. We didn't know what a key opinion leader was ... [W]e kept focusing on dressings, more dressings, sticky edge dressings, different colour dressings. And it's only in the last 15 years where we thought ... it's more about the whole patient ... I think the average practitioner was just focusing on ... what dressing to use ... And we'd open the cupboard and we'd see what dropped out first ... All people did was stick dressings on wounds. They did not think about the patient or comorbidities. And that only came very much later and that's peculiar [31].

Arguably, dressings have been dominant in the UK because they are financially lucrative and nurses have been allowed, and are familiar and comfortable with, few other tools with which to interact with wounds. In addition, workshop accounts from World War One of causing pain to patients sparked practitioner memories of similar experiences [52]. This may explain why some nurses were so keen to embrace the new dressings that came with the paradigm shift to moist wound care. As two participants noted:

> ... probably all the practitioners here have literally chiselled off dry gauze from a screaming patient [31].

> ... much of our enthusiasm in those days was related to the usability, how easy it was to use these materials, how much more comfortable the patients were [29].

Yet, along with such benefits, increasing industry intervention in wound care education has effectively created a marketing feedback loop, where industry is the key provider of information and nurses and other practitioners are persuaded of the efficacy and novelty of products as a result of the perceived expertise located within industry [53].

In many cases, nurses cannot see the fundamental problem in a wound – or don't know whether it is there – but they are affected by the frustrations of a non-healing wound. Hyperbolic marketing claims offer a product 'solution' that provides hope of healing and confirmation for nurses of their professional status. From a business point of view, selective attention is given to certain hypotheses for which there is a profitable product market. The process of marketization has also been accompanied by a compartmentalisation of the wound as a site of multiple processes, each of which might be affected by the choice of dressing. Instead of being a product for a wound in its holistic sense, a dressing therefore becomes more and more a product for a very particular event in the wound. However, in many instances, the more basic technologies are easier to use than costlier dressings which are not

necessarily addressing the problem [54,55].

The ‘advanced’ in wound care signifies aspirations to move away from passive wound care using gauzes and sponges towards being able to manipulate the wound environment via moist wound healing. This has generated an environment which values actively promoting healing through interactive means such as tissue engineering and regenerative medicine. There is however a lack of clarity about the actual difference between a passive and active product [56]. “Interactive” dressing only makes sense if more is known about the biochemistry and physiology of the healing process of a chronic wound, and yet this is an area of medical science where there is still a lack of fundamental understanding. There are numerous biomolecular interactions in even the simplest of chronic wounds, which are poorly understood [57]. Wound bed preparation has more recently joined moist wound care as one of the prevailing theories underpinning early twenty first century wound care [58,59]. Despite the prevalence of wounds clearly related to underlying conditions including diabetes and cardiovascular disease, a focus on the surface of the wound, as if it is an acute injury, and not on underlying causes persists.

The language used in wound care plays a role in determining the way in which products are both perceived and used. The ‘advance’ claimed is often a development in ease of use and deliverability rather than a fundamental therapeutic innovation [56]. For example, honey is not spread from a jar onto a wound but now incorporated into a hydrocolloid or other platform to make it easier to use. Larval therapy is administered in bagged form. As a consequence the *Wound Care Handbook* – ‘the professional's guide to wound care selection’ produced by the *Journal of Wound Care* – has grown dramatically, not necessarily in terms of product types but the number of different products described in each of the categories, all of which are seeking a place in the market.

Terms like “critical colonisation” and “biofilms” are powerful as marketing terms but this terminology glosses over limitations in scientific understanding of the biology of wound healing, and, where there are advances in the science, there remains the challenge of how to translate basic science into clinical practice that actually makes a difference to outcomes in everyday wound care. “Critical colonisation” helped drive the widespread adoption of the use of silver dressings of unknown necessity on wounds that lacked full signs of infection. The concept is now no longer recognised due to a lack of robust evidence [60]. Bacteria form biofilms on surfaces rendering them harder to kill [61]. Biofilms are present in some, possibly all chronic wounds and it is hypothesised, but not yet proven, that this presence contributes to chronicity [62]. “Biofilms’” as a marketing term helps drive the adoption of antimicrobial dressings on wounds that lack full signs of infection. “Biomaterial” conveys the suggestion of novelty, yet simple gauze is a biomaterial: it interacts with a wound and is a biologically derived product. Other portmanteau terms, such as “hydrosorbative”, borrow from trends towards scientific jargon in mainstream advertising and create a sense of innovation. The accretion of scientistic terminology makes it more difficult for nurses and other user groups to evaluate in a meaningful way which products to trust.

Health professionals are intermediaries in the product supply chain between patients and industry. An industry led quest for a dressing with healing properties is communicated to patients via the people treating them. This was clear in service user and carer accounts of treatment problems at the AHRC workshops which attributed healing properties to dressings:

> It's fine if a dressing falls off in hospital, there's someone there to slap a new one on it. You don't feel confident to change stuff at home. You're worried waiting for someone to come to change it, you live with it 24 hours assuming “I'm not healing” while the dressing's not on [63].

While wound dressings play an important role in wound management, they do not heal wounds in isolation [54]. This translates directly into increasing frustration amongst more experienced TVNs when nurses and patients enquire about the details of the dressing itself as a solution:

> It's long been our mantra really, but it's not the dressing that heals the wound, it's the patient that heals the wound [64].

In general, there is still extensive use of passive wound care for chronic wounds in the UK, with an emphasis on covering the wound with absorbent material [54]. There is limited use of poorly-evidenced non-dressing treatments used extensively elsewhere, such as hyperbaric oxygen therapy [65]. The use of particular therapies is, however, not always as in step with the available evidence. For example, Pentoxifylline is not used in venous leg ulcer treatment although there is some evidence of efficacy through randomised controlled trials (RCTs) [66]. There is good evidence for compression in treating the most common chronic wound type, venous leg ulcers but this again is not always used and, where it is used, is often applied with ineffective pressure [49,50,67]. In contrast, negative pressure wound therapy, a dressing with suction, is regularly deployed (and considered to be effective) even though there is no good quality evidence to support it in chronic wounds [68–70]. The development and use of bioengineered artificial skin in treating acute and chronic wounds has advanced from a scientific concept to a series of commercially available products over the last 30 years. Plastic surgeons use these products to deal with complex burns as an alternative to skin grafts but they are not part of the ‘advance’ in chronic wound care [71]. Similarly, 3D-printing of an extra-cellular matrix is more likely to find use in the case of acute rather than chronic wounds [71].

In summary, whilst the market is suffused with a large number of poorly evidenced products, the intensive development of products is not matched by clear indications for their use. The lifecycle of a product is intimately connected with cultures of use, context and presentation [72], especially marketing. The context of linking tighter profit, commerce and medical practice is not a new feature of healthcare but there has been much less focus on the context of nursing, the assumed caring profession, than on medicine [73]. Research from the USA indicates that nurses view marketing activities as educational and beneficial. They perceive other providers, but not themselves as

being susceptible to influence [73,74]. Equivalent research has not yet been done in the UK. Transferring inferences to the UK wound care context of course would need to consider differences in professional cultures and training. For example, if levels of higher education are a factor, in the US, 13% of nurses hold a graduate degree but fewer than 1% have a doctoral degree [75]. Levels of postgraduate education are still relatively low amongst nurses in the UK. Best estimates are that only 0.1% of the nursing, midwifery and allied health professional workforce in the UK are clinical academics [76]. Some TVNs have higher degrees but, as noted above, data on current numbers and education levels of TVNs are not available. The extent to which higher levels of education alone might be indicative of how health professionals perceive and are influenced by marketing activities is problematised by the history showing doctors with prestige medical education to be susceptible to marketing influence [77–80].

4 Risk, regulation and the evidence base

The science of wound healing and prevention is variously informed by developments in physiology, epidemiology, bacteriology, cell theory, engineering and the rise of the evidence informed healthcare movement. Advanced wound care and evidence-informed healthcare both began to emerge in the 1980s. Since then the policy drive to modernise health care through continual innovation in medical technology and practice has continued alongside a radical science-based questioning of the evidence base on which decisions are made [74]. However, many of the plausible and persistent ideas in chronic wound care are not based on strong science, for example, debridement, critical colonisation (now rejected) or even moist wound healing in chronic wounds Plausibility is, of course, far from a sure indicator of efficacy and most wound care hypotheses are not robustly tested. A review of publicly-funded RCTs shows that the actual probability of a new treatment being better than an established treatment is roughly one in two. Even in those 50% of cases where the experimental treatment is better than current best practice, the review suggests that this will only be very marginally so [81]. As in other sectors of healthcare, where there are far more rigorous tests of ideas before RCT, those wound care hypotheses that are tested have a high failure rate despite the high level of confidence and investment to take the idea to trial. The corporate uncertainty associated with investment in research and development is one of the risks in the wound care field to be weighed against others, including: clinical risk associated with using a new product, service user risk borne by managing their own wound care, and innovation risk where new products are developed in order to increase margins and profitability despite the possibility that existing, less profitable, technologies may be superior.

Little is currently known about practices of knowledge acquisition and the use and culture of evidence in wound care [53,82]. There is, however, some evidence to suggest that other practitioners are the most frequently used source of information for nurses [83]. The wound care sector is flooded with products and marketing, and is dominated by clinical guidelines which state that clinical judgement must be used in the selection of an appropriate product. However, there is scant good quality evidence to support either the clinical guidelines or clinical choice. Many of the current ideas in wound care have not been tested thoroughly through robust clinical trials. There is therefore a limited, poor quality evidence base to underpin treatment choices [84].

At the root of this lies the classification of wound care products. Most wound care interventions are classified as devices rather than medicinal products and consequently are not automatically subject to clinical trial before entering the market. In order to access the market, the Medicines and Healthcare products Regulatory Agency (MHRA) requires the medical devices industry to demonstrate that its products meet the requirements in the Medical Devices Directive (MDD) by carrying out a conformity assessment. The assessment route depends on the classification of the device. Under the European regulatory framework for evaluating and regulating medical devices (CE marking), which at time of writing applies in the UK, the emphasis is on safety assessment, viability and competitiveness, not population effectiveness (i.e. health outcomes for patients). The MDD can require clinical evidence, depending on the level of risk involved and the claims being made about the device. The risk level for most wound care products has been deemed low enough for preclinical evidence (in vitro or animal studies) to be acceptable. The MDD is about to be replaced with the EU Regulations for medical devices (MDR) which may require clinical trial evidence for more types of products. At present there is no imperative for manufacturers to evidence the clinical effectiveness of their low risk devices. More clinical trials add costs to industry which gives rise to a “cost-evidence-risks-profits conundrum” for industry.

Clinical research in the field of wound care has mostly focused on products rather than services, with each company generating a clinical research agenda strongly focused on its own products and commercial return and little attention paid to the organisational context of product use. Ioannidis and others have identified the failure to take account of patient perspectives when designing research outcomes as a common flaw in most clinical research [85]. This is especially visible in the case of wound care where the patient voice is notably absent [86]. The James (not sure why these two words highlighted. If you want to hyperlink use this http://www.jla.nihr.ac.uk/priority-setting-partnerships/pressure-ulcers/) Lind Alliance Pressure Ulcer Priority Setting Partnership (JLAPUP) and the Pressure Ulcer Service Users Research Network (PURSUN UK) initiatives are rare recent exceptions initiated via publicly-funded UK research teams [21,50]. The JLAPUP does not engage with industry in its processes because commercial interests may not align with scientific or public interests. JLAPUP ceased to exist formally after its priority-setting task was completed. There is an ongoing lack of connection and dialogue between service users, researchers and manufacturers.

Historically, in the case of casualties in World War One, the outcome was either success (wound healing) or failure (death), with little variation and only a relatively small number of ongoing, chronic wounds. In contrast, contemporary outcomes for chronic wound healing or prevention are not always clear cut and binary, making them hard to measure; for example the level of frailty and other variability in the pressure ulcer patient population may make a huge difference to outcomes. Trials showing an outcome for a chronic wound have to be conducted over an appropriate period of time adding costs. The economics for industry therefore favour much less-financially-risky marketing which, in the UK, is targeted via the health professional rather than direct to patient and may include “corporate science” which falls somewhat short of best practice in the conduct of research but invests in ‘spinning’

outcomes in a positive light [87].

Research investigating a link between industry funding and methodological quality in wound care RCTs found that funding source was not reported for a quarter of studies and that RCTs in wound care were found to be lacking methodological quality across the board. Most did not meet international standards for conducting and reporting RCTs [84]. Many claims for wound care products are based on in vitro or animal studies, reflecting the historical developments in advanced wound care dating back to Winter's studies of the early 1960s. Concerns about scientific quality issues in the design and reporting of basic bioscience research have led to numerous guidelines [88]. It is not clear what proportion of wound care researchers consult these, however it is evident that there are no good animal models for chronic wounds which are associated with aging and underlying conditions [88].

Companies' ambitions are restricted by regulation and the law. Price wars within UK healthcare are rare, primarily because the government is paying, and is willing to pay a premium for specific essential products. The high costs of wound dressings to the NHS and variations in costs between and within dressings categories has led to the issuing of guidelines based on work investigating costs of dressings and evidence to support their use [89]. When faced with competitors producing similar products with similar benefits, manufacturers may be faced with a choice: either to lower prices or to differentiate their products from the competition. In the latter case, the strategy can be to add additional features and make small changes to existing products, which make them appear unique. If they are perceived as unique they may be able to command higher prices. This can result in a confusing plethora of slightly different products, all offering different features, though not necessarily giving additional benefits to the nurse or patient. Many facts and claims about products which are designed to highlight their indispensability may be largely irrelevant to the matter at hand. Despite a professional sense of immunity, clinicians are often just as susceptible to unwarranted marketing claims as patients or publics [78]. So, although, from one perspective, regulation can be seen as a barrier to potential innovation, from another it is a potential defence for patient and payer against inadequately tested intervention. Concerns about patient safety are in the balance against concerns about market access, because from the medical device technology industry point of view, existing quick-to-market European regulations encourage innovation through speedier regulatory approval and faster revenues. Although mostly regarded as low risk, a non-implantable/invasive, ‘benign’ device like a support surface to prevent pressure ulcers, may pose a significant risk to its user if it does not effectively perform the preventative medical function claimed for it.

The failure rate of RCTs which are embarked upon with the degree of confidence apparent in the investment placed in them, should serve to cast some doubt on the level of confidence individual practitioners place in their own observations and in small scale studies. However, in many cases, tacit, experiential knowledge on the part of practitioners tends to be privileged [90]:

> I think a lot of practice is based on the fact that you got used to using and handling something, you know when it's not working and you're getting a complication with it. You start a new product and you don't recognise when it's not working … if something covers the wound when you put it on, and you're not used to that, you suddenly think it's giving you a problem and you stop using it … [there is caution because it is] outside their normal experience [91].

Nurses in wound care who face the perceived gamble of choosing to adopt different techniques or products may err on the side of caution because there is low risk of doing harm, even at the risk of doing nothing at all. This means that practitioners can also be reluctant to make change even if there has been investment in the production of research which has resulted in good quality evidence. For example, many patients with venous leg ulcers are not receiving evidence-based care [49,92]. Many diagnostic judgements and treatment decisions in the management of leg ulcers are made by generalist community nurses rather than specialist TVNs [93]. Recent judgement analysis research shows variability and a lack of confidence from nurses working in an uncertain and complex clinical field [82]. Another means of avoiding risk or blame is to stick rigidly to guidelines, which are often based on poor evidence, without tailoring them to the person being treated [67]. From a patient perspective, the physical and social discomfort of wound care treatments can lead to ambivalence about their effectiveness [94].

5 Conclusion

The historical shift from dry to moist wound healing is key to understanding the wider social and technical context of advanced wound care in the UK. This is intimately connected with the history of the professional development of nursing and its interaction with industry, marketing, and evidence-informed healthcare. There has been much criticism that measures of success in UK health care have focused too much on health care activity rather than outcomes for patients. This is amplified in cases of complex, chronic conditions where links between inputs and outcomes are more challenging to measure. A biomedical model which addresses patients as aggregations of body parts and neglects social and economic determinants and contexts, relegates impact on everyday living as a secondary concern to what is happening physiologically. Physiological changes are judged predominantly by successions of health professionals looking at or measuring wound surface. In contrast, little attention is given to non-physiological matters of key interest to service users including the continuity, co-ordination and quality of care [50].

The impression amongst health professionals, and nurses in particular, is that if they do not use the best products then they are not giving good care. However, it is unclear exactly how one might determine the features of a product which might place it in the category of ‘best’. One of the most important factors is in distinguishing what we know from what we do not, and how these factors map onto deeply-entrenched beliefs within the healthcare sector. Lack of evidence of effectiveness is not the same as evidence of ineffectiveness, but uncertainty is exploitable. In this respect the role of nurse education has a crucial role to play in encouraging a critical engagement with the claims made about products marketed to nurses by corporate actors with vested interests for use with patients. Allied to this, research takes place in an accelerated culture of short-termism in both academia and clinical medicine, which promotes the continuous production of short-term, de-contextualised interventions as ‘solutions’ in the face of longer term systemic issues including reduced staffing levels and evidence uninformed service re-organisation. Rather than patients and their families being at the centre of wound care, the focus is currently on the de-contextualised wound at a de-contextualised point in time and what material should be applied. Recognising the necessarily complex and

multifaceted environment of chronic wound management is essential to move beyond a largely misplaced sole reliance on product innovation in the development of wound care.

Declarations of interest

None.

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Highlights