

REIMBURSEMENT OF DRESSINGS: A WUWHS STATEMENT

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Introduction

The treatment of wounds has undergone a technical revolution since the pioneering work on moist wound healing by Winter in 1962. Since that time, a number of different classes of wound dressings and devices have been developed, facilitating patient comfort, optimising local wound management and improving the outcome of care. More complex wounds can be treated earlier, with improved outcomes, as demonstrated by a fall in the rate of amputations associated with diabetic neurotrophic foot ulcers. However, most of modern dressings and devices have not yet brought about a significant level of improvement in wound healing or patient care. The problem arises with regard to the method of approval of dressings and devices in many countries, where statisticians working for country-specific health authorities require evidence from randomised clinical trials. These randomised clinical trials should reflect the efficacy and efficiency of devices while taking into account the multifactorial nature of many chronic wounds and associated comorbidities.

Currently, the only gold standard criterion used by health authorities to assess different devices is complete wound healing. However, some countries – influenced by panels of experts – may adopt another strategy for reimbursement, based on what are known as ‘secondary’ criteria or surrogate endpoints. Some of these alternative endpoints are adapted in peer-reviewed published studies and include an improvement in pain or other quality of life indicator, an improvement in wound surface debris, a 4-week reduction of at least 30% from baseline in wound size and an increased presence of healthy granulation tissue in the wound base.

The WUWHS panel members are advocating for a minimal set of reimbursed devices in all countries worldwide. It is currently acknowledged that reimbursement exists for dressings and devices in a limited number of geographical areas, whereas in other countries, no reimbursement is available or partial coverage may disadvantage outpatients.

Education is another important component to improve patient outcomes. Teaching of the basic principles of wound management, including evidence-based treatment of the cause and how to manage patient needs should be offered as tools for changing practices. An International Consensus approach was investigated during the first and second WUWHS reimbursement in Paris in 2005 and 2006, leading to this statement.

Reimbursement of nursing care

Nurses are increasingly recognised in their own right as professionals in wound healing (e.g., Tissue Viability Nurses in the UK, University Diplomas in France, Wound Ostomy and Continence Nurses in the USA and Enterostomal Therapists in Canada). These specialised nurses usually undertake the holistic care of the patient and have responsibility – along with the physicians (GPs or specialists) – for the general health of the patients, in addition to the prevention and care of wounds. In some countries, these nurses are entitled to prescribe local wound care dressings and other treatments.

Nursing services are reimbursed by different health care systems that vary, depending on the country. Reimbursement systems may include the expenses involved when the nurse travels to the patient's home, but in the majority of countries, the patient has to travel to a Wound Healing Centre (WHC). Regional WHCs are available in the USA, the UK, Denmark and Germany. In other countries, however, where the distance from a patient's home to the WHC can be an issue, a network of professionals will visit via home care systems to attend to the patient's needs. Nurses may be reliant on a health department – part of a city's organisation (under the authority of the mayor) – and their contribution to a specific task is decided by the administrative authorities (e.g., as in Denmark). This service is free of charge for the patient. In Spain, care centres are distributed throughout a region and patients are compelled to attend their local centre, although travelling expenses are not always covered.

Private health care systems have also been developed. Groups of private insurance companies offer different care packages, including nursing care. A large range of coverage plans are offered, depending on the level of payment. These systems are usually offered by private companies to their employees as part of their professional contract. Risks and coverage are clearly defined on the contract. In general, a broad package covers all diseases and medical conditions, including wounds. The armed services and some national companies (e.g. those responsible for mining, transport and metallurgy) offer this type of package and will, in some cases, have their own physicians, teams of nurses, or even entire hospitals. Small companies may establish an association with private or public hospitals. There are other specialised coverage arrangements that may have resulted from political need (e.g. as in Alsace Lorraine after the Second World War).

For the patient with no available resources, general hospitals exist virtually everywhere in the world. Wounds are often poorly managed owing to the lack of knowledge and clinical skill in the modern care of wounds and also because of a lack of available funds for wound prevention and treatment, including the cost of supplies and professional expertise.

Reimbursement of medical devices and dressings

Reimbursement systems surrounding medical devices are poorly developed even in advanced medical systems in the Western world. In most countries, there is no reimbursement of medical devices for outpatients. The devices are paid for by the patient and the price is fixed according to the market (e.g. Australia, the USA, Singapore, Spain, certain regions of Italy, North Africa, the Middle East and Australia). In other countries, medical devices are not available, as a relevant commercial company is absent or not represented (such as in India and Africa). In the UK, France, Denmark and Germany, the reimbursement of medical devices is partially covered by the general social insurance system, with the remaining cost being paid for by private insurers. The reimbursement is – depending on the Ministry of Health involved – awarded by a commission and is based on the evidence level of the device's efficacy and its cost. Private pharmacists may apply their own cost margins to the cost of a device; therefore the total cost for the outpatient can vary from one region to another.

Within the hospital, medical devices can be included in the cost per day or per diagnostic category (disease-specific reimbursement). Dressings in Europe, the USA, Canada, Australia and in African and Asian countries are included in the hospital expenses. The cost can be decreased enormously depending on negotiations between hospitals or groups of hospitals and the relevant companies. The choice of product available to physicians working in a particular hospital is defined by a committee, often including clinical specialists and decision makers. The role of the committee is also to ensure good clinical practice and to facilitate the appropriate use of devices by healthcare professionals. For the more costly devices, such as negative pressure therapy, skin substitutes, hydro jets and growth factors, signed prescriptions are often required and monitored by predefined specialists. There is a great variability in the availability of products and relative costs between countries.

Protocols for good clinical practice and guidelines on how to use dressings to maximise their effect are best developed by a working party consisting of inter-professional wound specialists and other interested parties. These working parties also help decision makers to manage, distribute and maintain other medical devices, such as pressure relieving systems. In instances where hospital working parties work with professional carers in the home, a patient education programme should be available, including information leaflets on available services.

Some recent studies have confirmed the improved efficacy of inter-professional teams and a supportive clinical environment. The optimal organisation should include well-trained professionals who are involved at every stage of care, from the time that the patient presents

with a wound until it is completely healed. This educational need has to be reinforced to all health care professionals and decision makers.

Medical devices are optimally utilised by a team that includes bedside nurses specialising in wound care (able to evaluate and debride wounds) in collaboration with other health care professionals. The lack of education to caregivers, such as general nurses, is one of the weak-points in wound care practice. As many as 20% to 35% of nurses in developed countries do not receive education in moist wound healing, with this rate approaching 90% in emerging countries. In many countries, there is little or no teaching of wound management for medical students. Nurse, physician and other health care professional training schools should be encouraged to offer a minimum of 25 hours' teaching on preventative and therapeutic aspects of common clinical wound management situations. In addition, nurses who are already professionally qualified should receive significant continuing education or professional development opportunities in wound management. In some instances, however, the impact of traditional local practices led by surgeons and dermatologists is so great that a major system paradigm change is required in order to introduce evidence-based best clinical practices with modern moist wound healing. To this effect, the WUWHS is proposing a robust educational programme (see table below) incorporating different models for nurses and general physicians.

An example of a graduated educational programme is outlined below:

Level of training in wound care	Number of hours	Recognition	Financial consequences for nurses
Level 1	25	Certificate of attendance on prevention	None; recognition within a working group
Level 2	25	Certificate of attendance on wound management	None; recognition within a working group
Level 3	100 (including theory and practice)	University diploma or equivalent	Can be a source of income in practices involved in wound prevention and treatment
CME system	Dependent on the specific requirements of a country	Yes	Can reach a level of official recognition

Organisation of care and reimbursement in certain countries worldwide

Examples given below are taken from a range of countries and describe the coverage available and limitations of reimbursement systems, along with how the care of chronic wounds is organised in these regions:

In Spain, care of wounds (regardless of aetiology) occurs both in an outpatient and a hospital setting. Once a patient is hospitalised, a surgeon will evaluate the wounds on a regular basis, while nursing staff will attend to the dressings, adhering to protocols established at a regional level (for instance, the 'Comunidad Autonoma de Aragon' has produced a protocol for the prevention of pressure ulcers). When a patient leaves hospital, the protocol for wound care specific to that patient is followed at a local level by care centres distributed throughout a region. Care is provided either at these centres or at home in cases where patients cannot travel. Dressings and devices are selected by a group of decision makers at the regional level, and are chosen from a restricted list of products offered by a group of companies. The dressings and devices are free of charge for the patients.

In the UK, dressings and devices available to patients who are cared for at home are defined by the 'Drug Tariff' – a monthly publication of products that can be prescribed and paid for by the National Health Service.

The Drug Tariff is not an arbitrarily defined list, but contains only devices that have been tested and evaluated. The exact criteria for selection of a product are not published, but inexpensive devices are more likely to be listed than expensive ones, although cheaper items may not always be the most cost-effective. For instance, new (more expensive) devices may reduce the nurse time required and provide relief from pain for the patient. However, recently, the Drug Tariff was modified to take into account new medical devices. Within a hospital, this list is not applicable, but rather, a specialised hospital committee can define its own list of products. The transition from within to outside a hospital can, however, be difficult. The Drug Tariff cannot be considered a guide to good practice, but more a guide to products reimbursed in the UK.

In Northern European countries, the public health system is well developed and is available to all citizens. Most of the dressings are covered and reimbursed in the public and private systems, which coexist in Finland. In Norway, Sweden and Denmark, the public system makes up the majority of the reimbursement.

In Australia, veterans have their dressings and devices provided by the government, while all other patients must purchase their own products.

Reimbursement from the commercial perspective

For companies, an open market is the most profitable situation and reimbursement of devices is certainly assurance of being integrated into the general therapeutic armamentarium of public and private hospitals. Companies are very interested in developing products that could be reimbursed. However, the optimal market for a company to promote their product is the homecare setting. The box below gives an overview of the recommended processes for reimbursement.

- **Health economics**

There is a need to design methodologies to suitably measure the clinical value and cost effectiveness of wound care products and services. These data must be convincing to purchasers and other decision makers in the process of purchasing and procurement of products and services. These data must also take into account the concept of silo budgeting.

- **Commoditisation**

Wound dressings are grouped according to material type. There is little regard for the unique properties of a product (particularly in advanced wound dressings), which give rise to specialised clinical outcomes. This results in such product types being treated as commodities in a competitive bidding situation. The resultant reduction in price reduces revenue for further innovation. It is important to classify wound products by their functionality.

- **Market access**

There is a need for easier and quicker access to new wound treatment technologies, in addition to a defined reimbursement process for durable medical equipment in wound care.

- **Homecare**

Reimbursement is required for products and services in the homecare setting.

One of the main concerns is the methodology used for clinical trials. In general, companies are reluctant to develop randomised controlled trials that are considered expensive and risky. As an alternative, companies are more likely to develop studies with a lower level of evidence or emphasise a direct marketing approach to facilitate clinician experience. Observational studies are also used by companies, as these correspond well with a consensus between wound healing specialists. There is a need for a more open access regulatory policy and consensus building as part of a fair access to the market. Many companies are willing to engage in an open discussion with health authorities and are flexible with regard to developing new methods to analyse the efficacy of innovative devices.

Regulatory requirements for reimbursement

Level of evidence	Randomised controlled trials	Controlled trials	Observational studies	Database	Delphi panel
Cost	High	Medium	Low	To be defined	Low
Main criteria	End of healing	End of healing Pain Complete debridement Formation of uniform granulation tissue Quality of life	Pain Complete debridement Formation of uniform granulation tissue Quality of life	Pain Complete debridement Formation of uniform granulation tissue Quality of life	Multiple choice questionnaire
Value for decision makers	+++	+	?	?	?

Regulatory requirements for reimbursement

Most authorities will adopt a common attitude in which reimbursement is based on product classification and evidence. The level of evidence is an important issue, alongside a discussion with experts and companies. However, the evidence level alone is inadequate, particularly since only the end of healing is considered the main outcome criterion. Most experts recognise the difficulty in obtaining homogenous populations to include in studies and they are aware of the problems associated with designing or adapting existing protocols, obtaining financial support for such trials, and finally, obtaining reimbursement when efficacy, efficiency and effectiveness have been established.

At the present time, reimbursement of devices is more likely to be granted based on expert opinion rather than on randomised trials, since most of the devices have not achieved a level of evidence expected by authorities. In this situation and with the available knowledge, the choice of a minimal set of devices should be proposed as a uniform basis for each country. Furthermore, development of a clear reimbursement methodology for new devices should be discussed between the key stakeholders (the expert, the company and the decision maker). In some countries, the authorities have the option of paying experts to carry out independent, multicentre studies. Within the European Community, it is possible to obtain institutional funding to develop protocols for this kind of study.

The Cochrane group has developed evidence-based recommendations for wound healing products. At present, hydrocolloids are the only class of moist wound healing product that has achieved a good level of evidence. Systematic reviews include a summary of the scientific evidence, but they often lack the expert opinion component of a systematic collection and patient preference is not fully evaluated. Other products or methods of treatment, such as negative pressure therapy, have achieved an accepted expert opinion consensus, leading to reimbursement by some health care authorities and by the FDA for a probationary period of time. The company that marketed the product has developed randomised trials to provide additional evidence for the product to become reimbursed on a permanent basis.

In some countries, such as France, a few medical devices are reimbursed – hydrocolloids being the major class of products. New products have been developed specifically for this market with different components, but to obtain reimbursement, they all include a low percentage of hydrocolloids. This combination of products has enabled components such as silver to be reimbursed – not as a silver product *per se*, but as a predefined mixed ratio of silver and hydrocolloid.

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New products under development should achieve a certain level of efficacy, founded on evidence-based medicine rather than purely meeting the reimbursement requirements in a particular country. The challenge is to develop new randomised controlled trials so that they are viable options for the companies, i.e. not overly complicated, relatively inexpensive and with relatively clearly-defined surrogate outcomes. The crucial factor remains that complete wound healing is currently the only criterion considered by the FDA and other regulatory bodies. Experts at the international level, however, believe that this should be redefined.

The use of complete wound healing was a useful criterion when knowledge on wound healing was limited. However, the different stages of wound healing (debridement, granulation tissue formation and re-epithelialisation) have now been defined as recognised stages and acceptable outcome points in the wound healing process. The WUWHS therefore proposes the definition of precise clinical criteria for each stage and to validate these based on a Delphi panel approach.

An international consensus could provide a cornerstone for developing clinical trial protocols. For instance, a device may be designed for a specific, limited part of the wound healing process rather than complete wound healing. This would explain why some devices specifically designed for only one stage of wound healing (e.g. promotion of granulation tissue formation) have failed to obtain reimbursement approval.

It is also evident that there has been some difficulty with regard to a uniform classification of devices with some authorities making different rulings and classifying the same products as drugs or biological agents. A uniform and international classification policy by regulatory authorities would save on development costs. Agencies need to appreciate that obtaining results from randomised controlled trials in chronic wounds remains difficult due to the vast array of aetiologies of these wounds, the advanced age of the population and the high risk of drop-out from studies owing to the high incidence of adverse events. Randomised controlled trials with a shorter duration and surrogate outcomes need to be combined with an organised approach to expert and patient preference. New products can then be effectively developed to improve patient outcomes, health care provider efficiency and cost effectiveness.

The World Union of Wound Healing Societies advocates that all patients globally should have access to modern and appropriate methods of treatment. This will include a range of modern dressing materials, devices, drugs and surgical options as appropriate for each individual country. There is an urgent need for further detailed evaluation of novel interventions in wound healing. This should include studies that demonstrate benefits in healing but, equally, advantages in terms of cost effectiveness and improved patient quality of life and/or control of specific symptoms associated with wounds that are difficult to heal.

Politicians, healthcare professionals and patients all have a responsibility to try and ensure that patients with wounds and wound healing difficulties have access to innovations that have taken place over the past 30 years or so. Lack of education or awareness of the problems of wound healing can no longer be seen as adequate justifications for denying patients access to appropriate and modern standards of healthcare.