



3rd WUWHS Reimbursement Meeting

13 January 2007

Hôpital Charles Foix, Paris

REPORT

One of the main aims of the meeting was to communicate the needs and objectives of both the WUWHS and those of the companies involved. The WUWHS has significant potential that should be maximised and industry can help with, and benefit from this.

Issues associated with reimbursement

The meeting began with a general discussion on issues relating to reimbursement. These are listed and described below:

Differentiate wound care materials from pharmaceutical medicines

- Reimbursement bodies tend to confuse wound care materials with pharmaceutical medicines because they do not understand the wound healing process and the intricacies of appropriate wound management. Therefore, there is the need for the promotion and education on the uniqueness of wounds.

Randomised controlled trials (RCTs)

- A possible consequence of the confusion surrounding wound care materials and pharmaceutical medicines is that many believe RCTs to be the only means by which reimbursement of a product should be granted. This is not possible for many products and there is the need for alternative collective evidence combining statistical data, methodologies from other types of studies and patient-based data.

Public support for chronic wound care

- The consensus is that patients with chronic wounds, unlike those with cancer or heart disease, are largely forgotten by the general public and there is a great need to raise awareness of this common condition and its associated problems. Raising public awareness of chronic wounds would emphasise their importance and this may help to gain reimbursement.

A common reimbursement process across Europe

- The availability of a single, common process to apply for reimbursement across all countries in Europe would greatly facilitate the procedure rather than having to apply for reimbursement in each separate country. This would mean that there is standardisation from country to country, which would preserve resources and save time, while at the same time maintain efficacy. However, it was believed that reimbursement could not be separated from the governmental activities of each country as it involves specific budgets associated with each particular country.

A guide to reimbursement

- A 'roadmap' to achieve reimbursement would facilitate the process and provide a guide on how to link clinical evidence and cost-effectiveness data to reimbursement.

What has the WUWHS achieved and what are its future plans?

- The first WUWHS document on pain at dressing change was produced in 2004 and since then, it has been used and adapted to the needs of local situations. Leading from this document, an implementation study in pain is due to start in 2007.
- A first draft of a WUWHS statement on reimbursement of wound dressings was produced in 2006 and it is thought of as a 'work in progress' that should be amended and developed so that relevant national organisations and associations would endorse it, which in turn would greatly facilitate the reimbursement process in each country.
- It is believed that the WUWHS should produce 'guiding principles' on specific aspects in the field of wound healing and these principles would bring together expertise and elements specific to the local setting, e.g. a document on wound exudate is due to be produced in 2007 and a document on vacuum-assisted closure (VAC) in wound care is planned for 2008.

Reimbursement: WUWHS statement

The first draft of the WUWHS document was written on the basis of two meetings during 2005 and 2006; it is available from the WUWHS website (www.wuwhs.org) and it has been published by the *International Wound Journal*. The delegates discussed ways of developing this document and general points are included below, whereas specific chapter contents are included in the appendix at the end of this document:

Efficacy criteria

- It is believed that different factors should be assessed when evaluating the efficacy of a particular wound healing product, rather than the traditional idea of considering the end of wound healing as being the only objective. This would reflect both the step-wise nature of the wound healing process itself and also the functionality of different products (often a consequence of the complicated manufacturing processes involved in creating these products). These materials have been designed to have specific absorbency, control the amount of exudate, limit infection and aid in the debriding process. As a consequence of these specific functionalities, no single product will be appropriate to all the steps involved in the wound healing process. In the USA for instance, there has been a campaign to communicate to all those involved in the care of wounds and to those involved in general healthcare (including government bodies) that the healing process is complicated and that it occurs in stages; thus, an evaluation of the efficacy of a product may be limited to only one aspect of healing. The belief is that a wider communication of this message would filter through to those responsible for reimbursement.

One suggestion was to use 'wound closure' as the primary objective, but there was some disagreement, since not all wounds follow a simple process that ends in permanent closure, e.g. when a skin graft is used, wound closure may be observed within a few days; however, the wound will then re-open after 2 or 3 weeks and it may not close again after this time. An alternative suggestion was to define a particular length of time over which a wound remained closed and did not re-open (e.g. 1 month). Another suggestion was to use the presence of an unruptured cover of keratinocytes as being representative of a healed wound.

Considering that not all wounds heal completely over a specified period of time, alternative outcomes or appropriate surrogate endpoints were deemed a reasonable option for measuring efficacy. Endpoints such as a 4-week reduction in wound size, reduction of pain, bacterial factors, the presence of persistent inflammation and moisture balance were all deemed parameters that were a measure of the efficacy of treatment. It was agreed that a broader perspective on wound healing is superior to just clinical endpoints; however, the greatest barrier will be to convince reimbursement authorities that these alternative outcomes are more appropriate in the field of wound healing. As mentioned previously, the most appealing way of achieving this is to separate the healing process into step-wise endpoints.

A cautionary note surrounding the adoption of alternative outcomes that reflect the step-wise nature of wound healing is that the healing stages can often be considered subjective. For instance, two physicians may view granulation very differently. The characteristics of the wound should be considered in tandem with those of the patient, so that wounds can be classified into 'severity bands', which would take into account both the wound and the patient. This would greatly facilitate the construction of clinical study methodologies and the interpretation of clinical data.

Products and services

- It was emphasised that the reimbursement statement should not only encompass dressings, but also other wound products and services, in addition to dressings for scars. Furthermore, the statement should recognise the importance of surgical procedures; unfortunately, reimbursement is more likely to be achieved when surgery is part of wound management. Thus, the WUWHS statement should incorporate all the products and services involved from injury, through wound healing and finally, scar modulation.

Alternatives to RCTs

- Data from RCTs should not be the only evidence available for achieving reimbursement of wound healing products and a lack of RCT data should not be a barrier to collecting information on the advantages/efficacy of materials. RCTs may not always reflect clinical practice and 'real-life' data from unselected patients may often be superior; this concept is only now starting to be accepted by those who decide on reimbursement. In the conclusion of the UK's National Institute for Clinical Excellence (NICE) assessment of surgical wound healing, which included dressings, RCTs were not considered the only, or indeed the most appropriate, method of evaluating products and interventions.

General comments on the WUWHS statement on reimbursement

- *Sequence of discussion*
It was agreed that wound dressings should form the first section of the reimbursement statement and that other products (e.g. devices, biological agents and surgery) should be discussed in subsequent sections.
- *Cost in relation to benefit*
The statement should incorporate a section on the current state of wound management and how today's innovations will shape the future of this setting. The aim is to instil an understanding of the functionality of wound products and not emphasise costs. For example in France, if the benefit to the patient is great, then the likelihood of gaining reimbursement is high.
- *Differentiating patients*
It should be emphasised that, even though wounds may appear similar, their management is dependent on the patient, i.e. the wound should not be considered in isolation to the patient. However, it was pointed out that patient characteristics should be taken into account when considering the cost of wound care, which in turn is associated with reimbursement of products.

- *Level of evidence*

The proposal was put forward of creating a position paper on the minimal level of evidence acceptable (globally) when considering the efficacy of dressings. This would facilitate construction of the WUWHS statement on reimbursement. There was much discussion on this subject, with the suggestion that evidence-informed (or evidence-based) medicine would be a useful combination of expert opinion, patient preference and scientific evidence. Level 1 evidence would likely come from patient case studies, while level 2 evidence would be obtained from case series. The interpretation of clinical data in wound care involves evidence of efficacy, efficiency and effectiveness. There is the need for an instrument that can measure the quality of evidence.

Future directions for the WUWHS

Collaboration with other societies and organisations

- Worldwide, there are some 30–32 wound healing societies and the question was raised whether achieving reimbursement would be facilitated by collaborating with some of these. For instance, reimbursement for wound healing products is not available in some countries and it was proposed that forming an alliance with societies in those countries would be beneficial.
- *World Health Organization (WHO)*
Formation of an alliance with the WHO has been attempted in the past, but it was not successful, partly due to political reasons.
- *International Confederation of Nurses (ICN)*
The WUWHS has already formed an alliance with the ICN and it has proven to be productive.
- *Eucomed*
With its mission statement, 'Improving patient and clinician access to modern, innovative and reliable medical technology', Eucomed appears a good option with which to form a collaboration. It represents 4500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Its members include national trade and pan-European product associations and internationally active manufacturers of all types of medical technology. It was proposed that the WUWHS share its thoughts with Eucomed on solving the problems associated with reimbursement of wound healing products.

Databases and publications

- *Position papers*
Position papers on some aspects of wound healing have already been published by some journals in certain countries, but it was proposed that the same approach be used for pressure-relieving systems/products and antiscarring agents.
- *Registry of reimbursed products*
An internet-based directory of reimbursed products in different countries was proposed as a powerful source of information for members of the WUWHS. The directory would include details of the rationale used for the successful application for reimbursement.

- *Database of studies of wound healing products*

One proposal was for physicians to input their own experiences of different wound healing products into a database. However, as mentioned previously, there is a great difficulty in standardising the stage of wound healing, which in turn would make it very difficult to both construct and analyse objectively such a database.

- *Database of health economic studies*

A further suggestion was to have a database of economic data on wound management from different countries; this may be useful to demonstrate the cost implications of wounds. This database would also include the 'burden of healing', incorporating the number of patients affected and epidemiological data on specific wounds, e.g. pressure ulcers and their impact on healthcare costs. Emphasising the impact of wounds on patients and on healthcare budgets may help in the ultimate goal of gaining reimbursement for products.

Such a database may be constructed on a local level in each country; for example, pharmacists and general physicians could be asked specific questions relating to the number of patients they have treated and the types of wounds they had.

The suggestion was to initially construct a database using published studies and only then, after appropriate education on wounds and their management, would individual healthcare workers be asked to put forward their data. There was awareness that such a database was already in existence, therefore it was proposed that an existing database should be updated in the first instance. To facilitate the process, all members of the WUWHS should be asked to submit data that they are aware of in their country. A single person should be dedicated to searching for and/or co-ordinating the collection of data.

A subsequent stage of such a database would be to incorporate comments on each study.