The effectiveness of digital imaging and remote expert wound consultation on healing rates in chronic lower leg ulcers in the Kimberley region of Western Australia

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined remote expert wound consultation using the Alfred/Medseed Wound Imaging System (AMWIS) for patients with chronic leg and foot ulcers. The wounds were photographed and measured at each patient's clinic attendance. The data were then electronically transferred every 2 weeks for remote review by a wound care consultant who returned wound management advice to the treating clinician.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with chronic wounds of the lower extremity (i.e. leg ulcers).

Setting
The setting was secondary care. The economic study was carried out in Kimberley, Australia.

Dates to which data relate
The effectiveness evidence was collected from October 2002 to October 2003. The resource use and costing data were drawn from studies published in 2000 and 2003. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Not all of the retrospective costing was carried out on the same sample of patients as that used in the effectiveness analysis. Some cost items were estimated for a hypothetical cohort of 43 patients, based on international data (Schonfeld et al. 2000 and Haughton et al. 2003, see 'Other Publications of Related Interest' below for bibliographic details).

Study sample
The authors calculated that two groups of at least 42 patients each would be required to detect a clinically significant difference of 12% in the wound healing rate, with a power of 0.8 and significance level of 0.05. Patients were eligible for inclusion if they had a documented diagnosis of chronic ulcer of the lower extremity, were treated as a wound care
outpatient at one of the trial site hospitals, and gave informed consent. Those aged younger than 18 years, or with disorientation, mental impairment or unstable medical co-morbidity, were excluded. The patients predominantly had venous, arterial, mixed or diabetic neuropathic ulcers of the lower extremity and were being treated as outpatients at the respective hospitals. The authors did not report how the final study sample was selected from among those eligible patients. There were 50 patients (24 male, 26 females) in the intervention group and 43 patients (27 male, 16 female) in the control group. The mean age was 63.5 years in the intervention group and 49.5 years in the control group.

**Study design**
The study was a randomised controlled trial (RCT) that was conducted in four centres, the unit of randomisation being the clinical site. The length of follow-up appears to have been the time horizon of the trial (i.e. 1 year). No losses to follow-up were reported in the paper.

**Analysis of effectiveness**
It was not stated whether the analysis of the clinical study was conducted on an intention to treat basis or for treatment completers. The effectiveness outcomes reported were the mean healing rate differences between the study groups, and the number of amputations and number of deaths occurring in each group. The healing rates were calculated by determining the percentage decrease in surface area (calculated in mm²) between the first visit and discharge visit, divided by the total number of weeks treated. T-tests for independent samples were used to compare differences in healing rates. The healing rates were adjusted for age and gender using linear regression. The patients in the control group had fewer leg wounds, were younger and more likely to be men than patients in the intervention group. The intervention group presented a high incidence of diabetic ulcers.

**Effectiveness results**
The mean healing rate difference between the groups was 11.7%, (p=0.012). The healing rate was 6.8% per week in the intervention group and -4.9% per week in the control group.

There were 6 amputations in the control group and 1 in the intervention group.

There were 2 deaths in the control group, but none in the intervention group, during the study period.

The authors found that age and gender did not significantly contribute to the variation in healing rates between the groups.

**Clinical conclusions**
Healing rates were significantly more favourable for patients in the intervention group, independently of the age and gender of the patients. Although amputation rates and mortality were higher for the control group, the differences found could not easily be compared.

**Measure of benefits used in the economic analysis**
There was no summary measure of benefits in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
The costs considered were those of the health care provider. Healing treatment costs, consultant costs for intervention patients, transport costs for patients undergoing amputation, and hospitalisation costs of amputation were measured. The analysis did not include the costs of ongoing management and support for amputees. The quantities and the costs were estimated from a mixture of actual data (consultant, transport and amputation costs), published literature and authors' assumptions. Some quantity data were mainly drawn from actual numbers of consultations and amputations during the study period (October 2002 to October 2003), while cost data, including healing rate data, were drawn from
published evidence and authors’ assumptions. Overall, the costs and the resource quantities were not analysed separately. The actual costs for individual patients were not available from the trial sites, so the authors estimated the total group costs for 43 patients per group. Discounting was not carried out, but it would not have been relevant given the 1-year time period.

### Statistical analysis of costs
The costs were treated deterministically.

### Indirect Costs
The indirect costs were not included.

### Currency
Australian dollars (Aus$).

### Sensitivity analysis
No sensitivity analysis was performed.

### Estimated benefits used in the economic analysis
Not relevant since a cost-consequences analysis was performed.

### Cost results
The total costs were Aus$670,226 in the intervention group and Aus$862,161 in the control group.

The total cost-savings in the intervention group amounted to Aus$191,935, based on 43 patients in each group.

The authors also noted that the exclusion of surgical and transport costs (representing the majority of cost-differences) still produced a saving of Aus$83,774, owing to the reduced length of treatment in the intervention group.

### Synthesis of costs and benefits
The costs and benefits were not combined as this was, in effect, a cost-consequences analysis.

### Authors’ conclusions
Compared with the control group, the healing rates were significantly more favourable and the costs were reduced for patients in the intervention group. The authors stated that their findings highlighted the value of the contribution made by the clinical nurse consultant to the effectiveness of wound care.

### CRD COMMENTARY - Selection of comparators
The comparator represented standard practice in the authors’ setting and you should decide whether this is true in your own setting. Unfortunately, the description of standard care in the study was somewhat incomplete.

### Validity of estimate of measure of effectiveness
The analysis was based on an RCT, which was appropriate for the study question. However, the quality of the RCT, particularly in terms of the unit of randomisation and blinding of the outcome measurement, might not have been optimal. It was unclear whether the study sample was representative of the study population, as no comparison was drawn and critical haemoglobin A1c measurements for the diabetic sub-group were not collected. The patient groups
were not comparable at baseline in some relevant clinical characteristics and reasons for this were not given. The authors found that age and gender did not significantly affect the results, but did not control for differences in ulcer aetiology. They presented some results for the diabetic sub-group but these were neither complete nor reflected in the data tables. The authors noted that the positive healing rate in the intervention group was independent of age and gender. However, they recommended caution in interpreting the results in the diabetic sub-group, owing to the lack of laboratory results for haemoglobin A1c levels in these patients. In addition, the amputation rates and mortality differences could not easily be compared because of unknown and potentially higher disease or co-morbidity severity levels in control group patients. The statistical analysis of effectiveness was otherwise handled credibly. The authors reported further limitations to their effectiveness study. For example, the lack of data on compliance with dressings by patients in both groups, and the high rate of staff turnover at the trial sites during the study.

Validity of estimate of measure of benefit
The authors did not derive a measure of benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
Although the costs were estimated from a health care perspective, the long-term costs of amputation were not included despite being relevant to the analysis. This was acknowledged by the authors, but was unlikely to affect the conclusions given the far higher rate of amputation in the control group. Overall, the costs and the quantities were not reported separately, which would hinder reflation exercises to other settings. A single annual cost of healing an ulcer was drawn from published studies, with no indication of the likely appropriateness of this figure or the resource use contributing to it. The authors reported that this cost was inflated from 2000 prices, but did not state the price year used in the analysis. No statistical analysis of the costs or quantities was performed. It was unclear whether costs or charges were used in the estimation of consultation, transport and amputation costs.

Other issues
The authors did not make comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed, and the authors appear to have generalised their results to any "remote" wound care setting without qualification. The authors also appear to have neglected to present results for the diabetic sub-group in full.

Implications of the study
The authors suggested that future studies would benefit from several areas of research. In particular, the estimation of the ongoing cost of care of amputees; the possibility of reducing the 2-weekly frequency and duration of wound consultation used in the study; the effect on staff retention of using the AMWIS system together with a remote consultant; and the determination of the degree to which wound management practices improve as a consequence of remote consultation. They also highlighted issues for successful implementation of the AMWIS; information technology support proved critical across all study sites in the areas of data management and storage, and clinical leadership and support was of vital importance to the project.

Source of funding
None stated.

Bibliographic details

Other publications of related interest
Schonfeld WH, Villa KF, Fastenau JM, et al. An economic assessment of Apilgraf (Graftskin) for the treatment of hard-


**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
Amputation; Chronic Disease; Clinical Trials as Topic; Cost Savings; Costs and Cost Analysis; Foot Ulcer; Health Care Costs; Image Processing, Computer-Assisted; Leg Ulcer /economics /therapy; Linear Models; Radiographic Image Enhancement; Random Allocation; Rural Health; Telemedicine; Western Australia; Wound Healing; Wounds and Injuries /economics /etiology /therapy

**AccessionNumber**
22005007517

**Date bibliographic record published**
31/03/2006

**Date abstract record published**
31/03/2006