Modelling the economic benefits of gold standard care for chronic wounds in a community setting

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ABSTRACT

Chronic leg ulcers are costly to manage for health service providers. Although evidence-based care leads to improved healing rates and reduced costs, a significant evidence-practice gap is known to exist. Lack of access to specialist skills in wound care is one reason suggested for this gap.

The aim of this study was to model the change to total costs and health outcomes under two versions of health services for patients with leg ulcers: routine health services for community-living patients; and care provided by specialist wound clinics. Mean weekly treatment and health services costs were estimated from participants' data (n=70) for the 12 months prior to their entry to a study specialist wound clinic, and prospectively for 24 weeks after entry.

For the retrospective phase, mean weekly costs of care were A$130.30 (SD $12.64) and these fell to A$53.32 (SD $6.47) for the prospective phase. Analysis at a population level suggests if 10,000 individuals receive 12 weeks of specialist evidence-based care, the cost savings are likely to be A$9,238,800. Significant savings could be made by the adoption of evidence-based care such as that provided by the community and outpatient specialist wound clinics in this study.

Keywords: economic analysis, costs, chronic leg ulcers, evidence-based care.

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INTRODUCTION

Chronic leg ulcers are costly to manage for health services and lead to large quality of life burdens for patients. Data on costs for treatment of leg ulcers is somewhat limited in availability and amongst available analyses methodologies vary, rendering comparisons difficult. Most literature comes from Europe and the United Kingdom (UK), with a limited number of studies from North America and Australia or New Zealand. Estimates from the UK suggest that the total cost of wound treatment equates to 2–3% of the NHS budget[1-5]. Chuang *et al.*[6] stated the annual costs of treating venous leg ulcers in the UK ranged from £1,500 to £1,800 (A$2,687–A$3,224) per patient. A study comparing treatment costs for leg ulcers between Sweden and the UK[7] reported that the average cost per patient in Sweden ranged from €1,332 to €2,585 (A$1,973–A$3,829), whereas in the UK the costs per patient ranged from €814 to €1,994 (A$1,206–A$2,954). It was suggested the difference in costs was predominately attributable to increased frequency of dressing changes in Sweden, with time to heal an important factor contributing to costs in both countries.

Time to heal, health professional time and dressing changes are widely acknowledged to be significant drivers of cost in the care of leg ulcers, with complications such as infection being a further factor to consider[1,2,4,7-11]. Indeed Kerstein *et al.*[10] noted that the use of less expensive dressings at the outset actually *increased* costs in the long term due to the requirement for more dressing changes and increased risk of complications. In their analysis of several studies reporting on leg ulcer protocols, Kerstein and colleagues[10] reported the costs per patient for each ulcer healed (in the year 2000) ranged

from US$1,873 to US$15,053 (A$2,019–A$16,226). However, these studies were limited to 12-week protocols, thus excluding slower to heal ulcers, which would add to both the total costs and the variability. An analysis of health care costs for the treatment of venous leg ulcers in the Canadian province of Ontario found the annual cost per client in standard community care settings to be CA$5,554 (A$5,435) per patient[12]. In Australia, a study in 2006 compared the cost-effectiveness of traditional individual home nursing with a community group care model for a sample of 56 patients with leg ulcers. The total combined annual cost to the service provider, client/carers and community for patients receiving home nursing was substantial at A$41,216. In comparison, the total expense was significantly lower for the group Leg Club® model of care at A$33,698. This difference was attributed largely to in-kind support provided by the community and shorter time to healing in the group care model[13].

In terms of total costs to the health care system, Chuang *et al.*[6] suggested costs to the NHS for treatment of venous leg ulcers in 2006 totalled £300m–£600m (A$540m–A$1.1billion); Yarwood-Ross and Haigh[14] suggested the 2004 cost to the NHS totalled £400m (A$720m), while the total annual costs reported by Posnett and Franks for 2005–06 were slightly more conservative at £168m–£198m (A$301m–A$355m). In France, the total cost for leg ulcer care in 2002 was estimated to fall between €126m and €882m (A$187m–A$1.3billion)[3], while in Germany the costs for treating leg ulcers in both community and hospital totalled €1.63billion (A$2.42billion). Posnett and Franks[2] noted that nurse time contributed to 33%–41% of total costs. Given the major cost drivers are consistently noted to be dressing changes, time to heal and complications (particularly if hospital admission is required), this is perhaps not surprising.

A recent Australian Wound Management Association report[15] outlining the cost-effectiveness of compression therapy for venous leg ulcers details significant cost reductions when evidence-based practice is adhered to. This report estimated the average cost of treatment per patient for the period 2012–2013 was A$3,883 when compression therapy was used, compared to A$10,743 for patients who did not receive treatment with compression therapy. This equates to an expected saving per patient of A$6,328[15]. In their analysis of the health care costs of venous leg ulcers in different stages of severity, Harding, Posnett and Vowden[9] found that ulcers classified as "deteriorating" or "severe" cost two–six times more per patient per week than those classified as "progressing toward healing". Specifically, the average weekly costs of treating venous leg ulcers ranged from £88 to £637 (A$158–A$1,142) per patient, while maintaining a healed ulcer costs £6 per patient per week. Shannon[12] suggested that if best practice care was followed, the costs reduced significantly, reporting an annual saving of CA$4,000 (A$3,916) per client when best practice care was used instead of standard community care.

Thus it appears that health care costs for venous leg ulcers are strongly related to the standard of care provided. Evidence-based care, including less frequent dressing changes leading to reduced complications, is likely to cost the health care system much less than standard or *ad hoc* care. A recent study by Edwards *et al.*[16] found individuals who presented to health services with a leg or foot ulcer below the knee showed evidence of improvements in healing and decreased use of health care services when changes were made to their model of care. However, while there is evidence that improving services for chronic leg ulcers will reduce resources used and increase health benefits, this has not been well quantified. Further, in quantifying the benefits, the extra costs of improving services need to be included and valued. Good estimates of the change to total costs and health benefits show decision makers the value of better coordinated care for patients.

The aim of this paper was to describe the analysis of data collected by Edwards *et al.*[16] to model the change to total costs and health outcomes under two versions of health services for patients with leg or foot ulcers below the knee. The outcomes under the relatively uncoordinated set of services used by patients prior to being enrolled in the above study will be compared to the situation where they received evidence-based or 'gold standard' care.

METHODS

Data

Data collection procedures are reported in detail by Edwards *et al.*[16], with a summary of the method provided here. Participants were recruited from a community wound clinic and from an outpatient wound clinic in a metropolitan hospital in Brisbane, Australia. The single inclusion criterion was that they presented with a leg or foot ulcer below the knee, and the three exclusion criteria were: (a) unable to speak or understand English; (b) presence of cognitive impairment; and (c) ulcers involving malignancy. Both study sites provided multidisciplinary health professionals and participants were offered free compression therapy (predominantly a four-layer high-compression bandage system) for the duration of the study. Data were collected using a design with a retrospective and prospective phase. The retrospective phase used a survey and chart audit to measure health service use during the 12 months prior to enrolment in the study. Prospective observational data collection occurred over six months after enrolment, during which participants attended one of two specialist wound care services.

On admission to the study, information was collected on demographics, medical history and variables known to influence healing rates. The *retrospective* data collection covered the 12 months prior to admission and included all health services used, investigations, dressings/bandages and loss of functional ability. The *prospective* phase involved weekly data collection and measurement for 24 weeks post-admission, with data of concern including health services use, investigations, dressings/bandages used for wound management, and wound healing outcomes. In addition, data on quality of life, pain and functional ability were collected on admission and then at 12 and 24 weeks. The quality of life measure relevant for this study was the SF-12[17]. Participants were 54% male, ranging in age from 27 to 95

with a mean of 70 years; 21% used a walking aid; and 72% received government support via pension or unemployment benefits. Further details of the sample can be found in the companion article[16].

This study received ethical approval from the Human Research Ethics Committees at each of the participating organisations and complied with the Declaration of Helsinki ethical rules. Written informed consent was obtained from all participants.

DATA ANALYSIS AND MODELLING

Wound healing outcomes

A state-based model[18] was developed to show cases of leg and foot ulcers among a cohort of 1000 hypothetical individuals (Figure 1). The model was based on information provided by the sample recruited (n=70) during the retrospective and prospective phases of data collection. The model is used to summarise how the cohort transition between two living states of '*healed*' and '*ulcer*' and enter an absorbing state of '*dead*'.

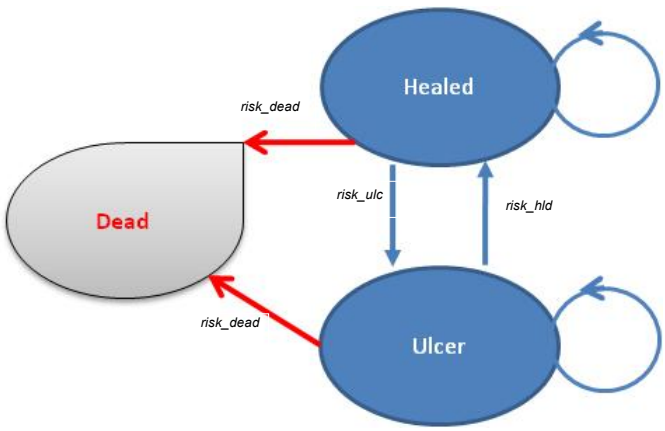

Figure 1: State-based model of leg and foot ulcers among a cohort of hypothetical individuals

Phase One: Retrospective data collection

The model began on 23 July 1996 when the first patient included in the retrospective phase reported the occurrence of the leg or foot ulcer for which they presented for treatment in this study. It is assumed that all participants were in a '*healed*' state prior to this date. As time passes, the model shows more patients reporting the first occurrence of the study leg or foot ulcer. The daily risk of transitioning into the '*ulcer*' state is shown by the parameter '*risk_ulcer*' in Figure 2. During the retrospective phase this is estimated by the number of individuals who reported a first occurrence on any day by the total number of occurrences reported for the time period.

The risk of entering the '*dead*' state from either '*healed*' or '*ulcer*' is shown by the parameter '*risk_dead*', which depends on the individual's age and gender, and daily values are estimated from the Australian Bureau of Statistics life tables[19].

Phase Two: Prospective data collection

On 16 April 2009 the first patient was recruited into the prospective cohort and they began to receive evidence-based care in a specialist wound clinic. From this point forward, risk of becoming healed for the surviving members of cohort (*risk_hld*) increase and the level of implementation of evidence-based care increases. The daily risks of being healed are estimated by the number of individuals who are reported as healed by the staff of the wound clinics by the total number of individuals in the study. The first patient was reported healed on 2 June 2009, 47 days after the prospective phase began. Two patients developed a new leg ulcer after healing during the prospective phase, one six weeks after healing and one three weeks after healing. These two recurrent ulcers both healed within six weeks. The model finished on 29 February 2011.

Cost outcomes

Mean weekly treatment and health services costs were estimated from the data gathered for the last 12-month period prior to patients entering the specialist wound care clinics, and for the 24 weeks after patients entered the specialist wound clinics. The health services cost items included were all consultations with a GP, community-based nurse, occupational therapist, physiotherapist, podiatrist and medical specialist. The cost of Meals on Wheels and home help services were included. The cost of these bandage and compression therapy products used by patients were included: elasticised tubular retention bandages; crepe bandages; long-stretch compression bandages; short-stretch compression bandages; compression hosiery (including custom-made where needed); and multilayer compression bandage systems. Also included were the costs of the following products and dressings: zinc paste bandages; paraffin gauze; hydrocolloid dressings; low-adherent dressings; silicones; alginates; Hydrofibre®; hydrogels; silver dressings; foams; iodine products; barrier wipes and creams; prescribed topical medications; topical negative pressure therapies; fixatives; undercast padding; wound cleansing solutions; medicated honey products; hypertonic saline; semi-permeable films; and, deodorising dressings. Health services were valued in line with Australian federal Government reimbursements via the Medical Benefits Schedule (*Medicare*) and a review of market prices for all relevant products was used to value all consumable items (which is available in spreadsheet form from the authors on request). The additional costs of delivering the gold standard care were based on specialist wound clinicians' salaries.

Quality of life outcomes

SF-12 health survey outcomes were collected at baseline when the retrospective phase ended, and then at 12 and 24 weeks. These data were mapped onto EQ-5D utility values using an algorithm developed by Gray *et al.*[20]. This estimates a utility score between zero and one to describe the value of the health state of patients. Baseline utility scores were used to describe the health outcomes of cohort members during the retrospective phase, and the 12- and 24-week scores were used to estimate quality adjusted life years (QALYs) for

the period of prospective data collection when gold standard care had begun.

Parameter uncertainty

Mean weekly costs were summarised for the sample and the variance estimated. These were fitted to a prior gamma distribution using the method of moments[21] to reflect the skew typically found in costs data. Mean weekly QALYs were summarised and variances estimated and were fitted to beta distributions, as were all transition probabilities. One-thousand random re-samples were taken from all distributions. This gave rise to 1000 estimates of the change to total cost (ΔC), change to total QALYs (ΔE) and net-monetary-benefit.

RESULTS

The outcomes of the epidemiological model are shown in Figure 2 with the first patients reporting onset of a chronic wound on 23 July 1996. The number of dead increases smoothly over time, showing advancing age and consequent mortality risk. The number of individuals with a chronic wound increases in a less smooth manner due to the small size of the data set that informs the model. All of the individuals still alive at the start of the prospective data collection on 16 April 2009 had a chronic ulcer (n=905); this is to be expected as it was a criterion for entry into the study. There was rapid reduction in the numbers of individuals with a chronic wound as healing outcomes accrued during the prospective data collection phase that began on 16 April 2009. By the time the prospective data collection was completed, 613 out of the 887 patients still alive in the modelled cohort were healed.

The mean weekly cost and health benefit outcomes per patient are shown in *Table 1*.

Table 1: Per patient weekly cost and QALY outcomes

	Weekly costs (A$) mean(SD)	Weekly QALYs mean(SD)
Retrospective phase	$130.30 ($12.64)	0.0104 (0.0006)
Prospective phase	$53.31 ($6.47)	0.01 (0.0004)
Difference between phases	–$76.99 ($14.27)	0.000321 (0.000735)

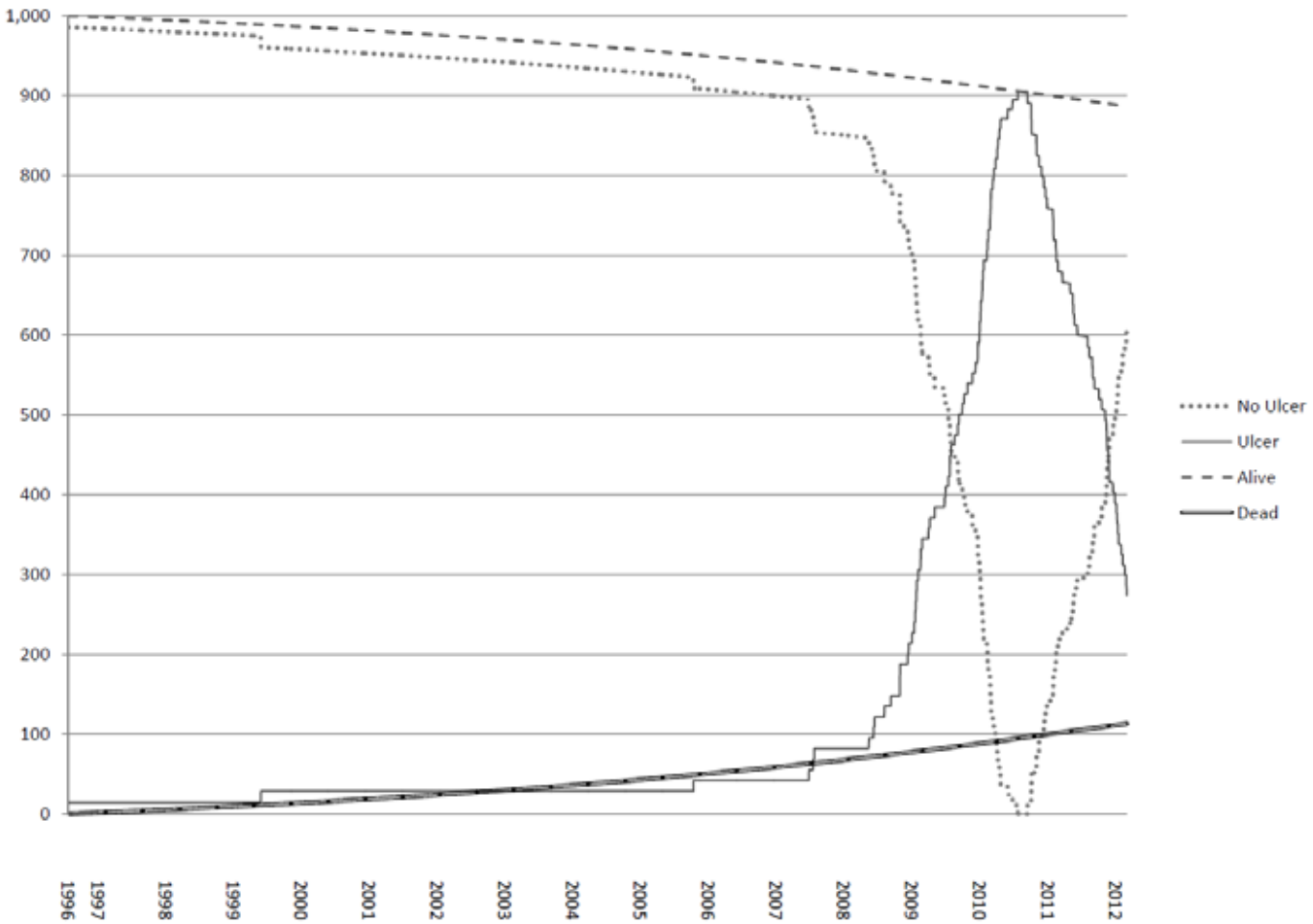

Figure 2: Epidemiological model of patients with chronic leg and foot ulcers

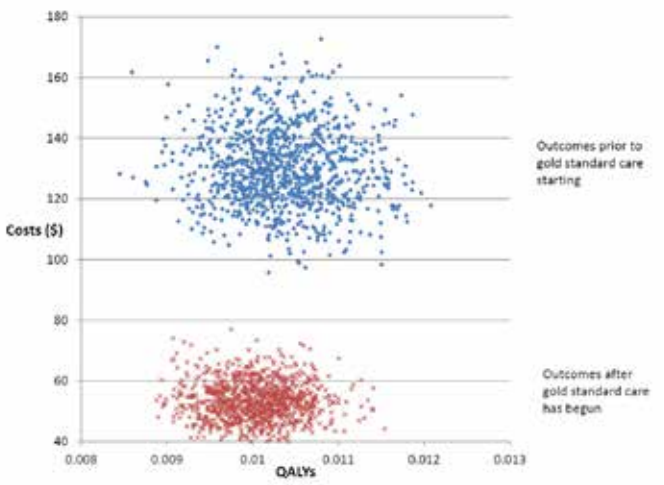

Figure 3: Uncertainties in parameters and comparison of costs and QALY outcomes

For the retrospective phase mean weekly costs of care were $A130.30 (SD $12.64) and these fell to $A53.32 (SD $6.47) for the prospective phase. The mean incremental cost saving was $A76.99 (SD $14.27) per patient week. The mean number of QALYs per patient per week were almost identical at 0.0104 (SD 0.0006) for the retrospective phase and 0.01 (SD 0.0004) for the prospective phase. All uncertainties arising from the model parameters are shown in Figure 3. This reveals that quality of life outcomes measured by QALYs gained are very similar for the two phases of the model, but costs are clearly reduced after gold standard care has begun.

These results can be interpreted at a population level by multiplying the difference in costs and the difference in QALYs by the number of individuals who could benefit from specialist gold standard care and the number of weeks for which they would enjoy that benefit. For example, if 10,000 individuals would enter this program for an average of 12 weeks each then the cost savings from having the program are likely to be A$9,238,800 (€6,073,377) for the duration of 12 weeks. Because the quality of life outcomes are so close, despite improved clinical outcomes, it would be prudent to assume there is no clinical or meaningful change among a population based on this study data.

DISCUSSION

The above analysis indicates that significant savings could be made for health services by the adoption of specialist gold standard care such as that provided by the community specialist wound clinic and the outpatient specialist wound clinic in this study.

There are, however, a number of limitations to this analysis. Firstly, the quality of the retrospective data is not known, and hence the retrospective analysis might not be accurate in its conclusions. Further, prospective data were observational and not experimental; ideally a randomised controlled trial (RCT) would provide a more precise means of comparing the costs of health services.

Despite research which shows that leg ulcers impact on quality of life, particularly when not healing, very little change in QALYs was found. This might have been due to the SF12 not having sufficient sensitivity to detect changes in this group. There are condition-specific quality of life tools available which may have improved sensitivity; however, the initial choice of the SF12 was based on previous evidence of sensitivity in leg ulcer populations[22] and the ease with which the results can easily be used to calculate QALYs. Certainly, it would be worth investigating this dilemma further. Finally, without further data, longer term outcomes are not known. For a condition with well-documented chronicity, such information is vital to the assessment of treatment effectiveness.

The outcomes of these analyses suggest that a decision to adopt gold standard, evidence-based care for the healing of patients with a leg or foot ulcer below the knee will reduce service use and save costs for health services; the main driver of such savings being that ulcers are healed earlier and so the rate at which services are accessed reduces. The ideal study design to confirm these preliminary data would be a prospective RCT where participants are randomised to 'existing care' or 'specialist wound clinics' and then followed up for one to two years after enrolment. All costs and quality of life outcomes could be collected prospectively and compared in a cost-effectiveness model.

With significant increases in people over the age of 65 projected to occur over the next several decades, prevalence of venous leg ulcers will also increase substantially. Thus it is imperative that a systems-wide response to the treatment of leg ulcers be developed that will have the best outcomes for patients and sustainability within the health care system. This preliminary analysis suggests that provision of coordinated gold standard care could go a long way towards addressing this need. However, further investigations are required for confirmation of these findings.

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