A cost-effectiveness analysis of two community models of care for patients with venous leg ulcers

• **Aim:** To conduct a cost-effectiveness analysis based on data from a randomised controlled trial comparing traditional community home nursing with a community Leg Club model for chronic venous leg ulcer management in the south-east metropolitan area of Queensland, Australia.
• **Method:** Participants were randomised to the Leg Club (n=28) or home visits (n=28). Data were obtained on resources/related costs incurred by the service provider, clients and carers, and the community.
• **Results:** From the collective perspective (service provider, clients and carers, and the community), at six months the incremental cost per healed ulcer was $AU515 (€318) and the incremental cost per reduced pain score was $AU322 (€199). For the service provider, Leg Club intervention resulted in cost savings and better health effects when compared with home nursing.
• **Conclusion:** On both clinical and economic grounds, the Leg Club model appears to be more cost-effective than traditional home nursing for the treatment of chronic venous leg ulcers. However, clients and the local community contribute substantial financial and in-kind support to the operation of both services.

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venous leg ulcers; community management; cost analysis; Leg Club; home nursing

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Community leg ulcer clinics have emerged as a new approach to leg ulcer management. Studies have found that they improved healing rates[1-3] when compared with individual nursing care. Such clinics provide easier access to wound care specialist nurses, increased social interaction and improved information exchange between health-care team members.[4] The Lindsay Leg Club model has extended this concept (Box 1).[4]

Economic studies of leg ulcer management strategies have mainly concentrated on management products rather than modes of delivery or systems of care.[5] However, four studies have investigated the cost-effectiveness of different models of delivery,[6-9] three of which compared new leg ulcer clinic interventions with traditional home nursing.[6,7,9]

Clinic costs were either lower[7,9] or similar,[6] while healing rates were 10–68% better than traditional home nursing.[6,7,9] However, Bosanquet et al.'s[6] use of historical controls for the 'usual care group' may have exaggerated the difference in effects, while in Ellison et al.'s study[7] it is unclear whether healing improvements in the clinic sample were attributable to the clinic model or the different bandaging techniques used: the clinics used specialised high compression techniques whereas 'traditional care' involved alternative products.

Kerstein et al.[8] studied home nursing and physician care services using identical protocols, and found increased costs with home nursing, although both yielded similar levels of effectiveness.

Aim

This study aimed to evaluate the cost-effectiveness of a new model of community nursing care for clients with chronic leg ulcers, compared with traditional home community nursing care. It was undertaken as part of a randomised controlled trial (RCT) comparing effectiveness, in terms of healing, pain and quality-of-life outcomes,[10,11] of the Leg Club model with traditional community nursing.

This paper reports on the cost-effectiveness analysis to assess which model is most economically efficient. Unlike the three UK cost-effectiveness studies,[6,7,9] the analysis includes not only the perspective

Box 1. The Lindsay Leg Club model

The Lindsay Leg Club model is based on the provision of ulcer management and preventive care within an informal, relaxed 'drop-in' centre, promoting social interaction, community involvement and ownership.[4] Collective treatment is provided in an informal environment to de-stigmatise the condition and encourage information exchange and educational opportunities for both clients and staff

of the service provider, but also those of clients and the community. These results thus provide economic information on venous leg ulcer services for various provider groups and their consumers.

Ethical approval was received from St Luke's Nursing Service and Queensland University of Technology human research ethics committee.

Method

Sample

The sample consisted of 56 clients — 28 in the intervention (Leg Club) group and 28 in the control (home nursing) group — referred to St Luke's Nursing Service in the south-east metropolitan region of Queensland, Australia.

To be included patients had to have a venous leg ulceration and an ankle brachial pressure index (ABPI) between >0.8 and <1.3 on admission.

Patients with diabetes, ulcers of non-venous aetiology or who were too immobile to be transported to the Leg Club via volunteer transport were excluded.

Participants provided written informed consent and were randomised via a computerised program to receive treatment either at individual home visits from community nurses (the control group) or from the community nurses during a weekly visit to a Leg Club (the intervention group).

Procedure

Study protocols were developed for all participants based on evidence-based assessment and treatment guidelines[12] (primarily short-stretch compression) to promote consistency. Ten community registered nurses were updated and educated on the assessment and treatment guidelines, and research project protocols before starting the trial.

All participants (in both groups) received comprehensive health assessment and treatment including:

- ABPI assessment
- Referral for further circulatory assessment if needed
- Venous ulcer treatment based on above guidelines
- Advice and support about venous leg ulcers
- Follow-up management and preventive care.

Leg Club participants had access to peer support, social interaction and goal-setting to assist in the management of functional and social activities.

Health outcomes

- **Number of healed ulcers** This was a concrete and clear clinical endpoint that took into account the total number of participants receiving each service and the proportion whose ulcers had fully healed. Wound assessments were undertaken on admission and at 12 and 24 weeks.
- **Reduced pain score** Pain improvement rates are the proportion of clients with a clinically important reduction in self-reported pain score. Pain levels were measured using the Rand Medical Outcomes Study Pain Measures.[13] Pain severity ranged from 1 (no pain) to 6 (extreme pain). A score reduction of three or more was considered clinically significant and had implications for conducting normal daily activities such as shopping and doing housework independently.

Further details on the instruments and measures used for other indicators of pain, functional ability and quality of life in the larger study (but not included in this analysis) are available elsewhere.[10,11]

Costs

Types of resources used for both groups included:

- Those borne directly by the service provider, such as health-care personnel, equipment, travel, consumables and operating expenses
- Those borne by clients, such as travel expenses, dressings and bandages
- In-kind resources provided by the community, such as volunteers and equipment.

The timescale for the collection of cost data was three and six months, aligning with the health-outcomes data assessments.

Data on resource quantities were recorded by the project staff. Personnel costs were calculated using award rates of pay,[14] and included estimates of employer on-costs. Operating costs included vehicle leasing, medical consumables, production of resource and educational materials, printing, office administration support, telephone and other incidental items. The cost of medical and office assets used to establish the services, such as Doppler devices and foot stools, was annuitised over the useful life of each asset to obtain its equivalent annual cost.[15,16]

Out-of-pocket expenses incurred by participants as consumers of the services were estimated — these included travelling expenses, dressings, bandages and other expenses. Information on specific brands and quantities of dressings and bandages for each participant was recorded. Out-of-pocket expenses were estimated up to the time taken for ulcers to heal (or not), and so were lower for faster healers. Travelling costs for those who drove to the Leg Club were estimated using each client's residential suburb and mode of transport. Cost per kilometre travelled was obtained from reports on average five-year running costs for cars.[17] Fares for public transport, and other out-of-pocket expenses, such as Leg Club donations, recorded by project staff were included.

Volunteers helped run the Leg Club, and the value of their time was estimated using the market replacement cost method.[18] This is the cost incurred if the volunteer was hired in the marketplace. The value of unpaid work was estimated using national reports from the Australian Bureau of Statistics, which provided hourly costs for volunteer and carer work.[18]

Ulcer-healing and pain data were managed and analysed using a sequential analysis technique;[19] further

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details are available in previous reports.[10,11] Monetary values were rounded up to the nearest dollar and reported in Australian dollars and Euros (2005 exchange rate: $AU1 = €0.6175). Goods and services taxes were included in market estimates as these represent a cost to clients and the health provider. Discounting future costs and benefits was not undertaken due to the short study duration. No assumptions were made on the future benefits or costs of the service.

Analysis

The analyses combined both cost and health outcomes data simultaneously to produce separate cost-effectiveness ratios (cost per healed ulcer and cost per reduced pain score) for both groups. Lower cost-effectiveness ratios indicate greater economic efficiency. However, incremental cost-effectiveness ratios (ICERs) are the key outcomes of interest. With new interventions there is often an efficiency trade-off between increased costs and increased health benefits. The incremental costs and incremental health effects of Leg Clubs over the home nursing service quantify this potential trade-off to produce ICERs, and are expressed algebraically:

$$\text{ICER} = \frac{C_{LC} - C_{HN}}{E_{LC} - E_{HN}}$$

where C is total costs, E is units of effectiveness (healed ulcers and pain improvement scores), LC is Leg Club (intervention) group, and HN is the home nursing (control) group.

All cost-effectiveness ratios were reported from two perspectives: the service provider only and the collective perspective of the service provider, clients and the broader community.

Sensitivity analysis plays an important role in economic evaluations for quantifying the extent of uncertainty often present in data measurement and/or valuation. Using a one-way sensitivity analysis, the results were recalculated over a range of plausible high and low values around the best estimates of cost and health outcome data in the base analysis. Variables where some uncertainty existed included personnel costs, client bandaging and dressings, travelling costs and volunteer inputs. In addition, healing rates were altered to check their influence on the stability of the results. These variables were altered separately using a univariate approach holding all others constant.

Results

Sample profile

Forty-six per cent of participants were female and 54% male, while 68% were aged 71 years or over. Fifty-eight per cent lived alone; 82% received either the aged or military service pension, 14% received disability support pensions and 4% were self-funded.

Costs of Leg Club compared with home nursing

Table 1 summarises the resource unit quantities and costs incurred for each management option. Costs were categorised into those accruing to the service provider, clients and community. Community costs include those estimated from in-kind support.

- **Total costs to the service provider** The Leg Club incurred lower costs than home nursing by $1727 (€1066) over three months through lower personnel and vehicle leasing costs than normally generated by nurses travelling to clients' homes.
- **Total costs to the service provider, community and clients** Compared with resources from the service provider, the financial and in-kind contributions from clients and the community were substantial. Total costs to the community for Leg Club were slightly higher than home nursing over three months: $13,245 (€8179) versus $10,997 (€6790).

Bandages and dressings were bought by clients in both groups and represent the largest cost item overall. Over three months, mean bandage and dressing expenses were $159 (€98) for Leg Club participants and $222 (€137) for those receiving home nursing.

Costs for each model of care over six months show parallel results, with absolute costs approximately doubling from three to six months, with the exception of bandages/dressings and travel costs. These latter expenses incorporated time to healing (the actual need for bandages/dressings and travel, which depended on healing performance). Leg Club participants had shorter healing times, so their out-of-pocket costs over time were lower than those for patients receiving home nursing.

- **Cost per healed ulcer to service provider** The Leg Club cost less and more of its clients' ulcers healed at both time periods. Cost savings were $1727 (€1066) and $3464 (€2139) for 0–3 months and 0–6 months respectively (Table 1). The cost per healed ulcer for home nursing was three times that for Leg Club at 0–3 months and twice that at 0–6 months. These savings are reflected by the negative incremental cost per healed ulcer (-$693 [-€428] at 0–6 months).
- **Cost per healed ulcer to service provider, community and clients** From the collective perspective, the Leg Club cost more than home nursing but produced higher healing rates and had lower costs per healed ulcer at 0–3 months — $1019 (€629) versus $1571 (€970) respectively — and at 0–6 months — $1546 (€955) versus $2061 (€1273). The incremental cost per healed ulcer at 0–6 months was $515 (€318), which represents the extra cost to the collective community to produce more healed ulcers at 0–6 months.
- **Cost per reduced pain score to service provider** More clients attending Leg Clubs experienced clinically meaningful reductions in pain

Table 1. Summary of total costs by each model of care for 0–3 and 0–6 months

	0–3 months				0–6 months			
	Leg Club		Home nursing		Leg Club		Home nursing	
	$AUS	€	$AUS	€	$AUS	€	$AUS	€
Service provider								
Operating expenses:								
• personnel*	2207	1363	3038	1876	4405	2720	6075	3752
• admin. support (follow-up calls, paperwork)	224	138	224	138	448	277	448	277
• consumables (medical, gloves etc)	441	272	441	272	882	545	882	545
• vehicle leasing†	291	180	932	576	582	359	1865	1152
• mobile phones	124	76	247	152	247	152	493	305
Equipment (portable, medical)‡	—	—	132	82	—	—	265	161
Subtotal	3287	2029	5014	3096	6564	4053	10,028	6192
Client/carers								
Travel (self only n=10)§	1860	1148	—	—	2863	1768	—	—
Bandages and other medical supplies§	4610	2846	5983	3694	6785	4190	10,580	6534
Other out-of-pocket expenses/donations	267	166	—	—	535	330	—	—
Catering and club activities	51	32	—	—	103	63	—	—
Subtotal	6788	4192	5983	3694	10,285	6351	10,580	6534
Community (in-kind support)								
Leg Club volunteers	2229	1376	—	—	4458	2753	—	—
Rental and electricity	185	114	—	—	370	229	—	—
Maintenance/cleaning	254	157	—	—	504	311	—	—
Insurance (building)	216	133	—	—	432	267	—	—
Equipment (portable, medical, office, furniture)‖	286	177	—	—	573	354	—	—
Subtotal	3170	1958		—	6337	3913		—
Total	**13,245**	**8179**	**10,997**	**6790**	**23,186**	**14,317**	**20,608**	**12,726**

* Leg Club: based on one experienced registered nurse plus one personal care assistant for three out of every four weeks and two registered nurses plus one personal care assistant for one week out of every four weeks @four hours each per week; home nursing: based on two registered nurses each week @10.3 hours per week. Includes 20% employer on-costs
† Leasing a small four-cylinder vehicle @ 40,000km/year: Leg Club : one vehicle five hours/week; home nursing : two vehicles eight hours/week
‡ Two Dopplers for home nursing; annual equivalent cost pro-rata
§ Travel and bandages/dressings: frequency/quantity account for time to healing for all participants. Many participants lived over 15km from the Leg Club
‖ Purchased with community grant monies

scores at both time periods. From the service provider perspective, costs per reduced pain score ratios were lower for Leg Club than for home nursing at 0–3 months — $299 (€184) versus $2507 (€1548) — and at 0–6 months — $505 (€312) versus $2006 (€1238).

• **Cost per reduced pain score to service provider, clients and community** Similarly, from the collective perspective, the costs per reduced pain score ratios were lower for Leg Club than for home nursing at 0–3 months — $1204 (€743) versus

Table 2. Results of one-way sensitivity analysis on incremental cost per healed ulcer*

	0–3 months				0–6 months			
	Leg Club		Home nursing		Leg Club		Home nursing	
	$AUS	€	$AUS	€	$AUS	€	$AUS	€
Base analysis	375	232	375	232	515	318	515	318
Personnel costs (AU$/hr)								
RN level 1 grade 1	346	214	432	267	449	277	652	402
RN level 1 grade 8	409	253	302	187	600	371	341	211
Bandages (AU$)								
0.8	221	136	575	355	244	150	939	580
1.2	528	326	176	109	786	486	93	57
Travel costs (AU$/km)								
Large car	481	297			646	399		
Volunteer costs (AU$/hr)								
0	157	97			324	200		
17	612	378			1415	873		
Healing rates								
x 0.8	749	463	281	173	1289	796	368	227
x 1.2	281	173	449	277	322	199	859	531

* From the collective perspective of the nursing service provider, clients and community

$5499 (€3395) — and at 0–6 months — $1784 (€1101) versus $4121 (€2545). These noticeably lower cost ratios can be attributed to the substantially higher number of clients who experienced clinically meaningful reductions in pain scores, compared with the home-nursing clients. The incremental cost per pain reduction score ratio was $322 (€199) for 0–6 months.

Sensitivity analyses

Results of one-way sensitivity analyses on ICERs, using numbers of healed ulcers and the collective perspective outcome, are provided in Table 2.

The most substantial cost items were tested over a range of low and high estimates around the best estimate used in the base analysis. The base analyses ICERs were $375 (€232) and $515 (€318) over 0–3 and 0–6 months respectively. Personnel costs were tested over the low and high salary grade increments within the level 1 domiciliary nursing state award.[14] Bandages and dressings were tested over 20% variance in actual costs estimated. Variations in annual kilometres estimated for leased vehicles changed leasing costs minimally and were excluded from the sensitivity analysis. Client travel costs were varied according to car size rather than the small car base estimate, and volunteer costs were tested over $0–17 per hour.

For Leg Club, the ICER was smaller than in the base analysis when personnel and bandage costs were at low estimates and if no volunteer expenses were included. Changes in salary increments within the grade 1 staffing level resulted in relatively moderate variations (-$71–169) in the ICER. Smaller changes occurred when client travel expenses varied.

However, if client expenditure on bandages and dressing varied by 20%, a large impact was felt on the ICER for both services, especially home nursing, at 0–6 months. A small change in bandage and dressing costs exerted large price variation for clients as a group. Volunteer in-kind support at the higher estimates substantially increased the ICER to $1415 (€873) at six months.

Small changes in healing rates (±20%) produced large variations in ICERs from $322 (€199) to $1289 (€796) for Leg Club. For example, if Leg Club had 20% fewer healed ulcers (equivalent to 3/28 clients with non-healing ulcers) the ICER increased 2.5- fold from $515 (€318) to $1289 (€796) at six months.

Discussion and limitations

This is the first economic evaluation to compare Leg Clubs with traditional home nursing models of care. Over both time periods, the former produced superior health outcomes to the latter.

Clients and the local community contribute substantial financial and in-kind support integral to the operation of both services; without this, neither model could operate. As a group attending and supporting Leg Clubs, their willingness to pay an additional $515 (€318) over six months for a 20% increase in healing rates needs to be acceptable, affordable and sustainable. Without this mutual cost-sharing of treatment resources (particularly medical equipment, bandages and dressings), expected health gains could not occur.

If a successful partnership is formed between the service provider, potential clients and the community, then the Leg Club represents an excellent public health investment.

From the service provider's perspective, Leg Club is clearly more economically efficient than traditional or usual home nursing practice due to the superior health outcomes and lower costs achieved — the latter largely due to community support.

Other health and social benefits of Leg Club are important for providers to acknowledge.

For clients, improved quality of life, better functional ability, the reduced need for external home-help services, greater socialisation and respite care relief are some of the potential advantages over home nursing that have been omitted from the cost-effectiveness analysis.

As with all economic evaluations, the key goal is economic efficiency, although other decision-making criteria, such as service quality, equity, acceptability and accessibility, are also necessary for comprehensive health service management.

In this study cost and effectiveness data were largely available, credible at the individual level (rather than extrapolated from the research literature) and derived from a RCT.

Nevertheless, sensitivity analyses were undertaken for several variables to check the stability of the base values and associated ICERs and to measure the effect different values may have on the results. They showed that the results are sensitive to changes of ±20% in healing rates achieved by the two services, volunteer costs and, at six months, client bandage and dressing expenses. Therefore, healing rates achieved by Leg Club need to be at least 20% higher than for home nursing to maintain or decrease the incremental cost per healed ulcer of $515 (€318) at six months. Other cost changes have a reasonably stable effect on incremental cost-effectiveness ratios.

This analysis used two important clinical outcomes:

- Completely healed ulcers
- Reduction in pain scores.

While an ulcer with a dramatically reduced area (by at least 50%) is likely to be of value to clients and an indication of successful treatment to service providers, from an economic viewpoint these clients still require full treatment and resources. Thus, for analysis purposes, they were treated the same as clients with non-healing ulcers.

Other measures that may have added value to the analysis, but were unavailable, are wound-free days and ulcer recurrences.

This study has a number of caveats. The sample size is small, limiting the estimation of costs. However, the clinical benefits of Leg Club over home nursing achieved statistically significant differences.[11] Follow-up time was short and data on ulcer recurrences were excluded. This could have underestimated the total costs and overestimated healing outcomes achieved by Leg Club. Indirect community costs that were omitted may include greater health and social service utilisation through opportunistic screening and referrals of clients for further health and social care.

The results are consistent with UK studies comparing the efficiency of leg ulcer clinics with traditional home nursing.[6,7,9]

This project was a RCT using personnel from the same organisation and locality, and delivered a standardised treatment protocol.

However, the Australian health system for the care of older people differs from the UK system: health costs are shifted from the health system towards patients and the community.

Further health services research would be valuable on other components of service delivery, such as client compliance, satisfaction and sustainability. Similarly, a more natural 'real-world' setting than a clinical trial is required, where it is possible that the natural behaviours and motivations of health professionals and patients may have been altered to ensure a successful trial.

Increased partnerships, with mutual benefits, between product companies and health professionals, for affordable and equitable patient outcomes, would improve service delivery of similar Leg Clubs in the future.

This project has shown both clinical and economic evidence in favour of a Leg Club model of care, which should thus be considered a method of treating chronic venous leg ulcers in the community, especially from a service provider viewpoint.

Extensive client and community resources and expenses are required for both models to operate. Measures that promote the affordability, equity and accessibility of these services should therefore be paramount to ensure quality health care reaches those in greatest need. ■

Contributorship statements

Louisa Gordon: developing concepts and design, analysis and interpretation of data, drafting the article, and final approval

Helen Edwards: concept and design of clinical trial, critical review of drafts for intellectual content, interpretation of data, and final approval

Mary Courtney: concept and design of clinical trial, critical review of drafts for intellectual content, and final approval

Kathleen Finlayson: drafting the article, critical review of drafts for intellectual content, interpretation of data, and final approval

Patricia Shuter: drafting the article, and final approval

Ellie Lindsay: critical review of drafts for intellectual content, and final approval

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