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The health service costs of treating venous leg ulcers in the UK

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The health service costs of treating venous leg ulcers in the UK

Authors: Sean Urwin, Jo Dumville, Matt Sutton Nicky Cullum

Sean Urwin, PhD Student in Health Economics, Health organisation, Policy and Economics, Williamson Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK

Jo Dumville, Professor of Applied Health Research , Division of Nursing, Midwifery and Social Work, Manchester Academic Health Science Centre, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK

Matt Sutton, Professor of Health Economics, Health organisation, Policy and Economics, Williamson Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK

Nicky Cullum, Professor of Nursing, Division of Nursing, Midwifery and Social Work, Manchester Academic Health Science Centre, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK

Corresponding Author:

Sean Urwin sean.urwin@manchester.ac.uk

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Abstract

Objectives: To estimate and examine the direct healthcare costs of treating people with open venous leg ulcers in the UK.

Methods: We performed a cost-of-illness study using resource and prevalence data from a cross-sectional survey of nine NHS community locales over two week periods in 2015/2016. Examination of variation in these obtained costs was performed by ordinary least squares regression. We used additional resource use information from a randomised control trial and extrapolated costs to the UK for an annual period.

Results: The average two-week per person cost of treating a venous leg ulceration was estimated at £166.39 (95% CI: £157.78 to £175.00) with community staff time making up over half of this amount. Costs were higher where anti-microbial dressings were used and where wound care was delivered in the home. We derived a point prevalence of people with one or more venous leg ulcer of 2.9 per 10,000 population and estimated that the annual prevalence could be no greater than 76.8 per 10,000 population. Our estimated national cost of treating a venous leg ulcer was estimated at £95.11 million with a per person annual cost at £4842.48.

Conclusion: Our point prevalence figures are in line with the literature. However, our annual prevalence estimations and costs are far lower than those reported in recent literature which suggests that the costs of treating venous leg ulcers are lower than previously thought. Movement towards routinely collected and useable community care activity would help provide a transparent and deeper understanding of the scale and cost of wound care in the UK.

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7 **Strengths and limitations of this study**
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9 This work uses contemporary data collected from community health services at the point of wound care
10 delivery to estimate the direct healthcare costs of treating venous leg ulcers in the UK.
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13 We find that the direct healthcare costs associated with venous leg ulcer treatment are substantial but
14 significantly lower than has been previously estimated.
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17 We do not include the costs of ulcer prevention activity nor indirect costs such as productivity losses.
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1. Introduction

Venous leg ulcers are open wounds that are relatively common in older people. These wounds result from impaired blood flow in damaged or diseased leg veins, leading to complex physiological changes that result in skin breakdown and poor healing. Venous leg ulcers are typically long lasting, have a high risk of recurrence and a negative impact on health related quality of life [1,2]. In the UK, complex wounds, of which venous leg ulcers are the most common type, are mainly treated in the community by nursing teams [3,4].

Cost-of-illness studies of particular health conditions can provide useful support for service planning. Cost is an important metric as it can: quantify the scale of a condition or illness in monetary terms; justify interventions and policy focus; assist in the allocation of resources to the management of different conditions and provide the basis for an economic evaluation [5]. Analysis of the variation in a cost-of-illness by sub-groups is an informative feature of these studies of interest to public health decision makers [6].

One set of estimates of the cost to the NHS of managing people with venous leg ulcers have been widely used and have contributed to the development of a national wound care strategy. These estimates were based on routinely collected primary care data (The Health Improvement Network (THIN) database) [7]. The mean cost (of staff time and wound care) of a venous leg ulcer per annum was estimated as £7600 in the UK at 2015/16 prices with community nursing time accounting for 78% of this cost [7]. Also using primary care data the annual cost (of staff time and treatments) of venous leg ulcer care attributable to the NHS in the UK was reported as £941 million, with a further £836 million attributable to unspecified leg ulcers [8].

Whilst routinely collected primary care data may provide a useful insight into the cost of managing venous leg ulcers, there are potential limitations. Primary care data may not capture all community based activity (e.g., community nursing care) and it is challenging to separate wound-related care activity from activity related to co-morbidities. It is crucial to obtain costs we are confident are incurred due to the venous leg ulcer (the incremental cost); so that we can calculate the costs that could be reduced if a venous leg ulcer is prevented or healed.

Alternative data with which to explore the cost of venous leg ulcers to the health service are those from community nursing teams directly, supplemented by information about primary and secondary care resource use. Availability of these data is generally limited, with historically low use of electronic records and a lack of standardised data collection in community health care. Collection of 'real world data' from the community on resource use associated with venous leg ulcer care offers a desirable addition to the knowledge base on wound care costs.

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3 We have three aims in this paper. Firstly, to estimate the direct healthcare costs of treating people with
4 open venous leg ulcers, using survey data collected from NHS organisations in the North West of
5 England. We combine our survey data with healthcare data from a community-focused, pragmatic
6 randomised control trial involving people with venous leg ulcers [9] which included estimates of
7 healthcare use from hospital and primary care providers. Second, we examine whether, and to what
8 extent, patient and wound-related characteristics are associated with differences in the community costs
9 of venous leg ulcer treatment, as there is little evidence on this currently available. Third, we extrapolate
10 the direct care costs of venous leg ulcers to the whole of the UK.
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18 **2 Methods**

19 **2.1 Study Design and Data**

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21 We performed a cost-of-illness study of venous leg ulcer treatment from the healthcare provider (NHS)
22 perspective, including only direct healthcare costs. We used a ‘bottom up’ costing methodology and
23 took a prevalence-based approach. We followed the guidance on reporting for cost-of-illness studies
24 provided by Costa et al [10], Molinier et al [11], and Larg and Moss [12]. Further, we referred to
25 systematic reviews of cost-of-illness studies of wound care to ensure we reported the key components
26 relevant to the costing of wounds [13,14].
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31 We obtained resource use and prevalence data from cross-sectional surveys covering two-week periods
32 in June/August 2015 in four community NHS locales and in July 2016 in a further five NHS community
33 locales. The two-week data collection periods enabled community healthcare professionals to record
34 resource use once for each patient on their caseload. The strategy of data collection was based on a
35 previous study conducted in the city of Leeds, England [15].
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40 For this survey, one study form was completed for each person treated for a complex wound (including
41 those with venous leg ulcers) by NHS community services during each two-week survey. The form
42 captured data about each service user’s current wound and its care (see [3] for full details of survey
43 methods); focusing on treatments directly related to each person’s primary (most severe) wound at that
44 time (as judged by the healthcare professional completing the form). Our cost-of-illness estimate used
45 patient level data only from people whose most severe wound was a venous leg ulcer. The survey also
46 asked about the number of nurse visits per week for ulcer care and the duration of these visits. Each
47 survey questionnaire was completed by the NHS health professional who had the most contact with the
48 patient for ulcer-related care. The survey was anonymised and completed away from the ‘bedside’ with
49 no direct input from the patient.
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56 The survey only collected data on community activity, so we used primary and secondary care resource
57 use data from another important research source, VenUS IV [9]. This pragmatic trial compared two
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forms of compression treatment for people with one or more venous leg ulcer. The study performed a full economic analysis and as part of this, every three months for a maximum of 12 months, participants reported ulcer-related use of NHS services. We used the trial data to estimate typical resource use/costs of ulcer-related visits to the GP (surgery and home visits), practice nurse, hospital outpatient appointments (with a doctor or nurse) and hospital admissions (either day case or longer stays).

The combination of community activity from the survey and primary and secondary care costs from the trial ensured representation of all relevant resource use in the cost calculations for ulcer treatment.

2.2 Community Care Costs

We costed five elements of resource used from the survey data: all dressings, all bandages, hosiery, medication, and staff time. We assumed that: dressings and bandages were changed at every visit by a community nurse, with the number of visits based on the average number of community nurse visits (derived from the survey data). Where compression hosiery was recorded, we assumed use of a single hosiery kit for three months (or two in six months) and medication costs were for every two weeks. We applied a cost of zero if dressing, bandage, hosiery, medication or community healthcare use information was not recorded in the survey as we assumed the patient had not been treated with these.

Average costs for dressings, hosiery, bandage and medication were obtained using unit costs from the British National Formulary [16] (shown in appendix Table A1). We took the number and duration of community nurse visits directly from the survey and applied the hourly unit cost (from the mean of wage bands 5 to 7) from Personal Social Services Research Unit (PSSRU) unit costs at 2019 [17]. We included travel time associated with a nurse visit only if the patient received most of their hands-on wound care in a non-clinical setting (i.e. not in a community/clinic/health centre/GP practice). We did not have information on travel distances and therefore costed travel time on a per-visit basis.

We calculated the mean two-week community-associated health service cost of treating an individual's venous leg ulcer by summing dressing, hosiery, bandage, medication and staff costs at 2019 prices. The focus was over two weeks as this was the period of time over which the survey was conducted and where weekly values were reported (e.g., number of clinic visits per week), we multiplied them by two.

2.3 Variation in Community Care Costs

We explored whether, and to what degree, patient characteristics (age, sex, number of wounds, number of co-morbidities, ethnic group, patient mobility and location of most care delivery) and patient receipt of different resources (type of primary dressing, any secondary dressing use, bandage use and hosiery use) were associated with variations in the total two-week community care cost. Variation in the total cost by dressing type is of relevance as there is current uncertainty about the clinical effectiveness of antimicrobial dressings, which also have a higher unit cost than non-antimicrobial dressings. Further,

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3 current guidelines do not recommend the use of antimicrobial dressings [18] but there has been
4 increased annual expenditure on this dressing type [19]. We identify variation in the cost of a venous
5 leg ulcer derived from our survey data via ordinary least squares regression. We include patients with
6 complete information on patient characteristics and who also have a cost recorded for one out of the
7 four cost components.
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11 **2.4 Primary and Secondary Care Costs**

12 Primary and secondary care cost information was taken as a per participant cost directly from values
13 calculated in VenUS IV [9]. This was a cost of £998.31 per participant inflated to 2019 prices using the
14 NHS pay and prices cost inflation index from £907.60 [17] and divided to obtain a per two-week cost.
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20 **2.5 Extrapolation of prevalence to a national level**

21 To calculate a national point prevalence for people in the community being treated for venous leg
22 ulceration we first divided the number of those with a venous leg ulcer (as the most severe wound) in
23 the survey with the total population covered by the North West locales in 2015 (at 1,935,683) [3]. We
24 then applied this local point prevalence figure to the UK population of 66,796,800 for mid-2019 [20]
25 which assumes that the point prevalence in the North West is similar to the rest of the UK. We further
26 assume that our point prevalence is representative at every point of the year across the UK
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32 We were not able to calculate annual prevalence figures (in terms of people with one or more venous
33 leg ulcer episode in a year) with our data: we lacked detailed contemporary incidence and ulcer duration
34 data for individuals over this period. We could however, use our available data to estimate what the
35 maximum annual prevalence of people with venous leg ulcers receiving treatment in the community
36 may be by assuming a new set of patients being treated for a venous leg ulcer for every two-week period
37 of the year. We did this to give a suggested minimum (our point prevalence figure) and maximum figure
38 for the national annual prevalence of people treated in the community for venous leg ulceration. We
39 also estimated an annual period prevalence of venous leg ulcers using the incidence rate estimated by
40 Petherick et al [21] using THIN data. As sensitivity around our prevalence results, we further include
41 patients who have a venous leg ulcer that is not their most severe wound.
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49 **2.6 Extrapolation of cost to a national level**

50 To calculate the total annual cost of care for venous leg ulcers in UK we used our individual level cost
51 data combined with our point prevalence estimate. The snapshot of data is assumed to be representative
52 at the local level in terms of the costs and numbers of those with a venous leg ulcer of any two-week
53 point in the year. Therefore, we can scale the total cost obtained in our data to achieve the annual
54 national cost of community treated venous leg ulcers. As noted earlier, due to data limitations we can
55 only speculate what the corresponding annual prevalence associated with the annual cost we produce
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could be. The annual prevalence figures we derive from using a different source are used (in the denominator) with the estimated total national cost (in the numerator) to obtain an estimated per person annual cost.

3 Results

3.1 Community survey data: summary statistics

Of the 3057 patients recorded in the survey as being treated in the community for one or more complex wounds, 570 (18.7%) had a venous leg ulcer recorded as their primary (most severe) wound.

The average age of people with venous leg ulcers was 73.5 years old, with most patients being White British (92.6%) and living in owned/rented accommodation (88.9%) (Table 1). Amongst health-related variables: 54.2% of those with a venous leg ulcer could only walk with difficulty, on average patients had 1.95 wounds and 1.39 co-morbidities.

Table 1: Summary characteristics of 570 survey patients with venous leg ulcer as primary

	N	% or mean
Sex (n=531):		
Female	288	54.2%
Male	243	45.8%
Age (years)	562	73.52 (14.48)
Ethnicity (n=565):		
White British	523	92.6%
Black, Asian or Minority Ethnic Group	42	7.4%
Residency (n=566):		
Owned/rented	503	88.9%
Other	63	11.1%
Mobility (n=563):		
Walks freely	305	41.9%
Walks with difficulty	236	54.2%
Immobile	22	3.9%
Number of wounds	570	1.95 (1.87)
Number of co-morbidities	570	1.39 (1.13)
Received most wound care (n=569):		
Non-clinical setting	257	45.2%
Clinical setting	312	54.8%

Treatment and community staff ulcer-related resource use from the 570 patients whose primary wound was a venous leg ulcer is shown in Table 2. The most common primary dressing type used was non-antimicrobial (54.7%). Among antimicrobial dressings, silver-containing dressings were the most commonly used (14.6%). The majority of those with a venous leg ulcer were receiving some type of bandage (74.6%). 37.5% of patients were reported to be in receipt of venous leg ulcer medications, the

most commonly used was topic steroids (44.2% among those who had medication). Only one patient had no reported use of dressing, bandages, hosiery, medication nor community healthcare use. On average, patients received 1.9 visits per week from community nurses, lasting 34.9 minutes on average.

Table 2: Summary statistics of direct healthcare resource use amongst 570 survey patients with a venous leg ulcer as a primary wound

	N with this cost	% of total patients
Primary Dressing:		
Honey	51	8.9
Iodine	24	4.2
Silver	83	14.6
Other antimicrobial	36	6.3
Non-antimicrobial	312	54.7
No dressing reported	64	11.2
Secondary Dressing:		
Honey	1	0.2
Silver	5	0.9
Non-antimicrobial	250	43.9
No dressing	314	55.1
Any secondary dressing reported	260	45.6
Bandages:		
No bandage reported	145	25.4
4 layer compression	52	9.1
Short stretch	63	11.1
3 layer reduced compression	98	17.2
2 layer compression	82	14.4
Non compression	57	10.0
Dressing retention	24	4.2
Other	49	8.6
Hosiery:		
No hosiery reported	464	81.4
Class 1	40	7.0
Class 2	51	8.9
Class 3	14	2.5
Other	1	0.2
Ulcer-related medicines:		
Antibiotic	51	8.9
Topical steroids	88	15.4
Analgesics	60	10.5
No medicines reported	371	65.1

3.2 Community Care Costs

Table 3 summarises the wound-related healthcare costs of 570 people with one or more venous leg ulcer over a two-week period. The mean, per person, community-based ulcer treatment cost was £147.19 (95% CI: £138.58 to £155.80). Community staff time was the most costly element, representing 70.9% of the total community care cost. Among costs not related to staff time, dressing and bandage use accounted for the largest proportions of the total cost at 14.1% and 13.0%, respectively.

Table 3: Community healthcare costs £ (2019 prices) of individual venous leg ulcer treatment over two weeks

Cost component	Mean £ (% of total)	SD	95% CI: Lower	95% CI: Upper	25 th Percentile	Median	75 th Percentile
Dressing	20.76 (14.1)	13.52	19.64	21.87	12.82	14.36	25.64
Bandages	19.19 (13.0)	19.06	17.62	20.76	0	13.35	34.18
Hosiery	0.77 (0.5)	1.61	0.61	0.92	0	0	0
Medication	2.31 (1.6)	3.63	2.01	2.61	0	0	4.75
Community staff	104.35 (70.9)	97.65	96.32	112.38	46.20	81.5	127.70
All community	147.19	104.697	138.58	155.80	80.16	120.03	179.49

Note: We recoded one outlier of 62 nurse visits to the next highest value at 8 visits

3.3 Variation in Community Care Costs

We explored variation in the community care cost of treating a venous leg over a two-week period among 514 patients with complete information on covariates (Table 4). Treatment with a honey, silver or other antimicrobial primary dressing is associated with, on average, higher costs compared with use of a non-antimicrobial dressing. For example, use of a silver primary dressing is associated with a £65.27 (95% CI: £38.02 to £92.52) higher per-person cost on average than for people treated with a non-antimicrobial primary dressing. Patients who received most of their wound care in a clinic setting have £-44.91 (95% CI: -£64.68 to -£25.14) lower two-week community costs than people who received care in a non-clinic setting. For each extra reported wound, the patient has a higher average two weekly cost of £9.69 (95% CI: £4.06 to £15.33) associated with their venous leg ulcer. Those who walk with difficulty and those who are unable to walk have higher total costs of £37.75 (95% CI: £-8.50 to £84.01) and £20.25 (95% CI: £0.59 to £39.92), respectively, compared with those who can walk freely, although the latter difference is not statistically significant.

Table 4: Variation in total cost of venous leg ulcer treatment over a two-week period

	Difference in GBP	95% Confidence interval
Dressing: Honey (ref=non-antimicrobial)	18.59*	(-2.52 to 39.69)
Dressing: Iodine (ref=non-antimicrobial)	-11.78	(-42.54 to 18.98)
Dressing: Silver (ref=non-antimicrobial)	65.27***	(38.02 to 92.52)
Dressing: Other antimicrobial (ref=non antimicrobial)	29.43*	(-4.06 to 62.91)
Dressing: Not reported (ref=non antimicrobial)	8.98	(-27.21 to 45.17)
Any secondary dressing	9.38	(-5.93 to 24.69)
Any bandage use	48.63***	(27.24 to 70.02)
Any hosiery	-9.37	(-31.34 to 12.61)
Any medication	24.76***	(9.42 to 40.11)
Most wound related care in clinical setting (ref=non-clinical)	-44.91***	(-64.68 to -25.14)
Female	-25.56	(-64.53 to 13.40)
Age (50-69 years old)	-14.64	(-50.43 to 21.15)
Age (70-79 years old)	-22.74	(-57.19 to 11.71)
Age (80+ years old)	-39.33**	(-74.02 to -4.64)
Female*Age (50-69 years old)	32.93	(-19.61 to 85.48)
Female*Age (70-79 years old)	22.51	(-24.05 to 69.07)
Female*Age (80+ years old)	22.78	(-21.01 to 66.56)
White British (ref=other)	10.59	(-15.54 to 36.72)
Owned/ rented residence (ref=other)	-8.83	(-36.39 to 18.73)
Mobility: Walks with difficulty (ref=walks freely)	20.25**	(0.59 to 39.92)
Mobility: Immobile (ref=walks freely)	37.75	(-8.50 to 84.01)
Number of wounds	9.69***	(4.06 to 15.33)
Number of co-morbidities	0.50	(-6.12 to 7.11)
Constant	103.09***	(50.79 to 155.39)
N	514	

Note: Coefficients estimated using ordinary least squares regression. *p<0.1; **p<0.05; ***p<0.01

3.4 Primary and Secondary Care Costs

Primary and secondary care costs add £19.20 to the total community care cost for all patients (Table 5). This results in a total mean two weekly per person healthcare (including primary and secondary care use) cost of £166.39 (95% CI: £157.78 to £175.00).

Table 5: healthcare costs £ (2019 prices) for venous ulcer treatment

Cost component	Mean £ (% of total)	SD	CI: Lower	CI: Upper	25 th Percentile	Median	75 th Percentile
Primary & Secondary	19.20 (20.65)	-	-	-	-	-	-
Total healthcare	166.39	104.69	157.78	175.00	99.36	139.23	198.69

3.5 Extrapolation of Prevalence and Costs

The point prevalence of people with a venous leg ulcer in participating locales in the North West of England was 0.029% or 2.9 per 10 000 population (calculated as $(570/1935683)*10000$) shown in Table 6 which is identical to the figure in Hall et al [15]. Application of this point prevalence estimate nationally suggests 19670 people are treated in the community for a venous leg ulcer in the UK at any point in time. If we assume the point prevalence is constant throughout the year but with different patients at each time point we obtain a theoretical maximum annual period prevalence of 75.6 per 10,000 population. This is an extreme assumption suggesting a theoretical incidence rate of 72.7 per 10,000 population, which is very high compared with a previously estimated incidence rate from THIN data of 10 per 10,000 population [21]. We combined the incidence rate from Petherick et al [21] with our data to derive an annual period prevalence estimate of 12.90 per 10 000 persons which is 5.8 times smaller than our maximum annual prevalence estimate. Our point prevalence increases from 2.9 to 3.2 per 10 000 population once we include those with any venous leg ulcer.

From our data we estimate the annual community cost of treating venous leg ulcers to be £75,477,680 for the UK. Including primary and secondary care costs increases the figure to £95,114,080. As noted above the corresponding annual prevalence figure for our annual costs can be no higher than 76.8 per 10000 persons. Calculating a per person annual cost which includes primary and secondary care using the incidence rate from Petherick et al [21] provides a cost of £4787.61.

Table 6: Prevalence and total estimated costs of people treated in the community for venous leg ulceration with extrapolation to National levels

	National Level ^{^*}
Prevalence (most severe wound):	
Point	2.9 per 10000 persons
Annual (calculated with Petherick et al., [21] ^b incidence value)	12.9 per 10000 persons
Annual (calculated using theoretical maximum incidence based on survey data)	76.8 per 10000 persons
Prevalence (any wound):	
Point	3.2 per 10000
Annual (calculated with Petherick et al., [21] ^b incidence value)	13.2 per 10000 persons
Annual (calculated using theoretical maximum incidence based on survey data)	84.5 per 10000 persons
Annual Total Costs (most severe wound):	
Community based (based on assumed representativeness of survey data over 12 months)	£75,477,680
Per person (using annual prevalence calculated from Petherick et al [21] incidence)	£3799.21 ^a
Per person (using annual prevalence calculated with maximum incidence assumption)	£147.19 ^a
Community + primary +secondary care	£95,114,080
Per person (Petherick et al [21] incidence as above)	£4787.61 ^a
Per person (maximum prevalence)	£185.48 ^a

Note: [^]Assuming the point prevalence from the survey based on a population of 1 935 683 from nine North West community care trusts in England is representative of the rest of the UK. ^{*}Based on the 2019 mid-year population estimate of the UK at 66,796,800 [20]. ^aDerived using the total cost in the numerator and the estimated number with a venous leg ulcer annually in the denominator. ^bPetherick et al [21] incidence rate is 10 per 10 000 persons

4 Discussion

To date there has been limited use of community-collected information to inform service level cost estimates of treating venous leg ulcers. Our cost-of-illness analysis addresses this gap in the literature. We extend the coverage of our community-sourced resource use and cost data with inclusion of primary and secondary care resource use to obtain a more complete figure on direct healthcare costs.

The average two-week per person cost of treating a venous leg ulceration was estimated as £166.39 (95% CI: £157.78 to £175.00) with community staff time making up over half this total. Using community data only, estimated annual costs were higher where anti-microbial dressings were used and where wound care was delivered in the home. We can draw limited conclusions about the contribution of these factors to increased costs as people with more serious and slower to heal wounds may be more likely to receive care at home and/or anti-microbial dressings. However there is currently no clear

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3 evidence of benefit associated with the use of silver or any other antimicrobial dressings [18,19].
4 Likewise, treatment delivered in clinics where possible, rather than in patient homes, likely offers
5 savings in terms of staff time but it is also likely the least complex patients seen in clinic settings. Patient
6 characteristics such as age, mobility and the numbers of wounds were also associated with variation in
7 the total cost.
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11 Our point prevalence of 2.9 per 10,000 population triangulates well with other studies that also use
12 regional UK data. For example, the figure is identical to the 2.9 (95% CI: 2.5 to 3.3) per 10 000
13 population from Hall et al [15]. This study used a similar protocol but in different areas of the UK with
14 different staff and was undertaken some years earlier. Hall et al [15] also included those receiving care
15 in acute settings in their figures. An older study which used THIN data from 2001 to 2006 estimated
16 an annual prevalence of 8.28 per 10 000 (95% CI 8.17 to 8.39) person years and 14.07 (95% CI: 8.17
17 to 8.39) per 10 000 person years from the same time period using the General Practice Research
18 Database [21]. Our results are robust to the inclusion of those with a venous leg ulcer that is not their
19 most severe wound, increasing the point prevalence by 0.3 to 3.2 per 10,000 population.
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27 We were unable to estimate an annual period prevalence figure from our point prevalence estimate
28 because we lacked contemporaneous incidence and duration data. However we could use our data to
29 suggest that the annual prevalence of people with venous leg ulceration *can be no greater than* 75.6 per
30 10,000 population (using incidence rates reported in the literature). The annual prevalence of 59 per
31 10,000 population (assumed to mean 59 people not 59 ulcers) reported by Guest et al [7], is below our
32 maximum annual prevalence, but still very high given the extreme incidence of leg ulceration that would
33 be required to achieve these figures. Both estimates assume an incidence rate far in excess of those
34 found in the literature using THIN data at 14 per 10,000 population [21]. Guest et al. [7] also reported
35 an additional 85 per 10,000 population has having an unspecified leg ulcer. If we assume that at least
36 60% of Guest's unspecified leg ulcers are venous leg ulcers then the annual prevalence is increased to
37 110 per 10,000 annually: our data questions the validity of such high values.
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45 We estimate a national annual cost attributable to treating venous leg ulcers of £95.11 million; an
46 estimate that is only 15.9% of the £596.55 million reported by Guest et al [8] as the lower end of their
47 estimate (with an upper estimate of £921.94 million). Our estimated per-person annual cost of a venous
48 leg at £4787.61, which uses the incidence rate of Petherick et al [21], is 62.6% of the equivalent cost
49 obtained by Guest et al [7] at £7615.03. Key differences are that Guest et al [7,8] used information from
50 a GP based dataset that included a study population of 505 selected from a random sample of 6000
51 patients in the THIN database. By contrast, we used a bottom-up approach to costing, using information
52 from audits of all patients treated by participating NHS organisations. The costing method of Guest et
53 al [7] compared the costs of 505 venous leg ulcer patients to those without a venous leg ulcer to obtain
54 the incremental cost. Importantly our cost components were similar to those of Guest et al [7], and we
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3 agree that community staff time is the largest component of the total cost. Guest et al [7] also considered
4 the cost of care delivered once people's ulcers had healed. This may explain some of the differences in
5 cost although ulcer-related care in the absence of an actual wound is likely to be limited. A cost for the
6 direct management of venous leg ulcers has also been obtained using GP data obtained from Wales over
7 an 11 year period (2007 to 2017) this estimated a cost of £7706 per patient per annum [23]. The work
8 notes that as nursing data were not available this was estimated for the study, and then reported as the
9 main cost drive in the results. The value of the work presented here is that empirical community nursing
10 data informed the estimates. It is not clear from this study what prevalence estimates were used to
11 extrapolate to UK costs that are presented.
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18 Our study has some limitations, in that we only considered the costs associated with bandages and
19 dressings for the primary wound and we assumed all recorded visits were with a nurse. Recording of
20 ulcer-related staff time may be overestimated if the healthcare profession did not distinguish between
21 visits that were for care of the primary wound and no other wounds or co-morbidities. Even so, if the
22 healthcare professionals in our questionnaire could not separate venous leg ulcer specific care time and
23 treatment from other patient co-morbidities then our cost is likely to be over-estimated and move further
24 closer to estimates in the literature. There is little information on travel time by nurses and current
25 reimbursement based on distance; therefore, we used old rates of reimbursement per visit. A further
26 limitation is that we only had direct healthcare resource use to use for costing. Other direct costs such
27 as surgery and indirect costs such as productivity loss were not available. However, there is little
28 representative information about wound care in a community setting in general and we note these as
29 future areas to obtain cost information.
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38 Leg ulcer care is costly to the NHS but we suggest it may not be as costly as has been claimed in
39 previous highly cited and influential work [7,8,22]. There are difficulties in comparing the available
40 data from different sources, in part due to a lack of information on methods used and further
41 transparency may allow differences in figures to be better understood. Fundamentally, our ability to
42 estimate costs, scrutinise the quality of care and observe links between care and outcomes in wound
43 care is hampered by a lack of routinely collection and useable information in community services. The
44 absence of a clinical database for community wound care also hinders clinical communication and
45 monitoring of patient progress. An accurate picture of the cost and prevalence of venous leg ulcers,
46 which we have aimed to provide in this study, can be used to further understand the cost and scale of
47 wound care and a basis from which to more realistically estimate the scale of potential savings.
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37 **Contributors:** NC and JD conceived the idea for the overall project; all authors contributed to the study
38 design; SU was responsible for data analysis, all authors contributed to data analysis. SU created the
39 original draft of the manuscript. All authors contributed to the interpretation of study findings, critical
40 revision of the manuscript for important intellectual content and approval of the final manuscript.
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45 **Competing interests** None declared
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47 **Disclaimer: To add**
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49 **Ethics approval: Not required**
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51 **Data sharing statement** No additional data are available
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Appendix

Table A1: Assigned unit costs

Resource use item	Cost (2019 prices)	Source
Dressings:		
Honey	£5.89	Joint Formulary Committee [16]
Iodine	£0.41	Joint Formulary Committee [16]
Silver	£9.38	Joint Formulary Committee [16]
Other anti-microbial	£5.80	Joint Formulary Committee [16]
Non anti-microbial	£3.41	Joint Formulary Committee [16]
Hosiery:		
Class 1	£23.92	Joint Formulary Committee [16]
Class 2	£23.99	Joint Formulary Committee [16]
Class 3	£29.04	Joint Formulary Committee [16]
Other	£29.75	Joint Formulary Committee [16]
Bandages:		
4 layer compression	£9.29	Joint Formulary Committee [16]
Short stretch	£3.55	Joint Formulary Committee [16]
3 layer reduced compression	£5.08	Joint Formulary Committee [16]
2 layer compression	£9.09	Joint Formulary Committee [16]
Non compression	£1.79	Joint Formulary Committee [16]
Dressing retention	£0.35	Joint Formulary Committee [16]
Other	£17.32	Joint Formulary Committee [16]
Medication:		
Analgesics	£7.76	Joint Formulary Committee [16]
Topical Steroids	£4.75	Joint Formulary Committee [16]
Pentoxifylline	£13.68	Joint Formulary Committee [16]
Antibiotics	£4.94	Joint Formulary Committee [16]
Healthcare use:		
Nurse visit use (home based)	£46 per hour	PSSRU Unit Costs 2019 [17]
	£1.50 travel cost per visit	PSSRU Unit Costs 2010 [24]
Nurse, GP, Outpatient and	£998.31 (applied to all patients)	VenUs IV trial [9]

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5 & 6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5 & 6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5 & 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5 & 6
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 & 6 & 7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5 & 6 & 7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	6
		(d) If applicable, describe analytical methods taking account of sampling strategy	-
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7 & 9
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8 & 9
		(b) Indicate number of participants with missing data for each variable of interest	-
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	-
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12 & 13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The health service costs of treating venous leg ulcers in the UK: evidence from a cross-sectional survey based in the north west of England

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3 **The health service costs of treating venous leg ulcers in the UK: evidence from a cross-**
4 **sectional survey based in the north west of England**
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9 Authors: Sean Urwin, Jo Dumville, Matt Sutton, Nicky Cullum

10 Sean Urwin, PhD Student in Health Economics, Health organisation, Policy and Economics,
11 Williamson Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK
12
13

14
15 Jo Dumville, Professor of Applied Health Research, Division of Nursing, Midwifery and Social
16 Work, Manchester Academic Health Science Centre, Jean McFarlane Building, University of
17 Manchester, Oxford Road, Manchester, M13 9PL, UK
18
19

20
21
22 Matt Sutton, Professor of Health Economics, Health organisation, Policy and Economics, Williamson
23 Building, University of Manchester, Oxford Road, Manchester, M13 9PL, UK
24
25

26
27 Nicky Cullum, Professor of Nursing, Division of Nursing, Midwifery and Social Work, Manchester
28 Academic Health Science Centre, Jean McFarlane Building, University of Manchester, Oxford Road,
29 Manchester, M13 9PL, UK
30
31

32 Corresponding Author:

33
34 Sean Urwin sean.urwin@manchester.ac.uk
35
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Abstract

Objectives: To estimate and examine the direct healthcare costs of treating people with open venous leg ulcers in the UK.

Design: Cost-of-illness study

Setting: A cross-sectional survey of nine NHS community locales over two-week periods in 2015/2016

Methods: We examined the resource use and prevalence of venous leg ulcer treatment in the community. Examination of variation in these obtained costs was performed by ordinary least squares regression. We used additional resource use information from a randomised control trial and extrapolated costs to the UK for an annual period.

Results: The average two-week per person cost of treating patients where a venous leg ulceration was the primary (most severe) wound was estimated at £166.39 (95% CI: £157.78 to £175.00) with community staff time making up over half of this amount. Costs were higher where anti-microbial dressings were used and where wound care was delivered in the home. Among all those with any recorded venous leg ulcer (primary and non-primary), we derived a point prevalence of 3.2 per 10,000 population and estimated that the annual prevalence could be no greater than 84.5 per 10,000 population. We estimated that the national cost of treating a venous leg ulcer was £102 million with a per person annual cost at £4787.70.

Conclusion: Our point prevalence figures are in line with the literature. However, our annual prevalence estimations and costs are far lower than those reported in recent literature which suggests that the costs of treating venous leg ulcers are lower than previously thought. Movement towards routinely collected and useable community care activity would help provide a transparent and deeper understanding of the scale and cost of wound care in the UK.

Strengths and limitations of this study

We use contemporary data collected from NHS community services where most venous leg ulcer wound care is delivered in the UK.

We have applied rigorous and transparent cost of illness methodology

We have isolated the direct healthcare cost associated with the treatment of venous leg ulcers in this multimorbid patient population.

We assume the nine surveyed locales are representative of the rest of the UK in terms of venous leg ulcer prevalence and community-related treatment cost.

1. Introduction

Venous leg ulcers are open wounds that are relatively common in older people. These wounds result from impaired blood flow in damaged or diseased leg veins, leading to complex physiological changes that result in skin breakdown and poor healing. Venous leg ulcers are typically long lasting, have a high risk of recurrence and a negative impact on health related quality of life [1,2]. In the UK, complex wounds, of which venous leg ulcers are the most common type, are mainly treated in the community by nursing teams [3,4].

Cost-of-illness studies of particular health conditions can provide useful support for service planning. Cost is an important metric as it can: quantify the scale of a condition or illness in monetary terms; justify interventions and policy focus; assist in the allocation of resources to the management of different conditions and provide the basis for an economic evaluation [5]. Analysis of the variation in a cost-of-illness by sub-groups is an informative feature of these studies of interest to public health decision makers [6].

One set of estimates of the cost to the NHS of managing people with venous leg ulcers have been widely used and have contributed to the development of a national wound care strategy. These estimates were based on routinely collected primary care data (The Health Improvement Network (THIN) database) [7]. The mean cost (of staff time and wound care) of a venous leg ulcer per annum was estimated as £7600 in the UK at 2015/16 prices with community nursing time accounting for 78% of this cost [7]. Also using primary care data the annual cost (of staff time and treatments) of venous leg ulcer care attributable to the NHS in the UK was reported as £941 million, with a further £836 million attributable to unspecified leg ulcers [8].

Whilst routinely collected primary care data may provide a useful insight into the cost of managing venous leg ulcers, there are potential limitations. Primary care data may not capture all community-based activity (e.g., community nursing care) and it is challenging to separate wound-related care activity from activity related to co-morbidities. It is crucial to obtain costs we are confident are incurred due to the venous leg ulcer (the incremental cost); so that we can calculate the costs that could be reduced if a venous leg ulcer is prevented or healed.

Alternative data with which to explore the cost of venous leg ulcers to the health service are those from community nursing teams directly, supplemented by information about primary and secondary care resource use. Availability of these data is generally limited, with historically low use of electronic records and a lack of standardised data collection in community health care. Collection of 'real world data' from the community on resource use associated with venous leg ulcer care offers a desirable addition to the knowledge base on wound care costs.

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3 We have three aims in this paper. Firstly, to estimate the direct healthcare costs of treating people with
4 open venous leg ulcers, using survey data collected from NHS organisations in the North West of
5 England. We combine our survey data with healthcare data from a community-focused, pragmatic
6 randomised control trial involving people with venous leg ulcers [9] which included estimates of
7 healthcare use from hospital and primary care providers. Second, we examine whether, and to what
8 extent, patient and wound-related characteristics are associated with differences in the community costs
9 of venous leg ulcer treatment, as there is little evidence on this currently available. Third, we extrapolate
10 the direct care costs of venous leg ulcers to the whole of the UK.
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18 **2 Methods**

19 **2.1 Study Design and Data**

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21 We performed a cost-of-illness study of venous leg ulcer treatment from the healthcare provider (NHS)
22 perspective, including only direct healthcare costs. We used a ‘bottom up’ costing methodology and
23 took a prevalence-based approach. We followed the guidance on reporting for cost-of-illness studies
24 provided by Costa et al [10], Molinier et al [11], and Larg and Moss [12]. Further, we referred to
25 systematic reviews of cost-of-illness studies of wound care to ensure we reported the key components
26 relevant to the costing of wounds [13,14].
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32 We obtained resource use and prevalence data from cross-sectional surveys covering two-week periods
33 in June/August 2015 in four community NHS locales and in July 2016 in a further five NHS community
34 locales. The two-week data collection periods enabled community healthcare professionals to record
35 resource use once for each patient on their caseload. The strategy of data collection was based on a
36 previous study conducted in the city of Leeds, England [15].
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41 For this survey, one study form was completed for each person treated for a complex wound (including
42 those with venous leg ulcers) by NHS community services during each two-week survey. The form
43 captured data about each service user’s current wound and its care (see [3] for full details of survey
44 methods); focusing on treatments directly related to each person’s primary (most severe) wound at that
45 time (as judged by the healthcare professional completing the form). Our cost-of-illness estimate used
46 patient level data only from people whose primary (most severe) wound was a venous leg ulcer. The
47 survey also asked about the number of nurse visits per week for ulcer care and the duration of these
48 visits. Each survey questionnaire was completed by the NHS health professional who had the most
49 contact with the patient for ulcer-related care. The survey was anonymised and completed away from
50 the ‘bedside’ with no direct input from the patient.
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57 The survey only collected data on community activity, so we used primary and secondary care resource
58 use data from another important research source, VenUS IV [9]. This pragmatic trial compared two
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3 forms of compression treatment for people with one or more venous leg ulcer. The study performed a
4 full economic analysis and as part of this, every three months for a maximum of 12 months, participants
5 reported ulcer-related use of NHS services. We used the trial data to estimate typical resource use/costs
6 of ulcer-related visits to the GP (surgery and home visits), practice nurse, hospital outpatient
7 appointments (with a doctor or nurse) and hospital admissions (either day case or longer stays).
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12 The combination of community activity from the survey and primary and secondary care costs from the
13 trial ensured representation of all relevant resource use in the cost calculations for ulcer treatment.
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16 **2.2 Community Care Costs**

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18 We costed five elements of resource used from the survey data: all dressings, all bandages, hosiery,
19 medication, and staff time. We assumed that: dressings and bandages were changed at every visit by a
20 community nurse, with the number of visits based on the average number of community nurse visits
21 (derived from the survey data). Where compression hosiery was recorded, we assumed use of a single
22 hosiery kit for three months (or two in six months) and medication costs were for every two weeks. We
23 applied a cost of zero if dressing, bandage, hosiery, medication or community healthcare use
24 information was not recorded in the survey as we assumed the patient had not been treated with these.
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30 Average costs for dressings, hosiery, bandage and medication were obtained using unit costs from the
31 British National Formulary [16] (shown in appendix Table A1). We took the number and duration of
32 community nurse visits directly from the survey and applied the hourly unit cost (from the mean of
33 wage bands 5 to 7) from Personal Social Services Research Unit (PSSRU) unit costs at 2019 [17]. We
34 included travel time associated with a nurse visit only if the patient received most of their hands-on
35 wound care in a non-clinical setting (i.e. not in a community/clinic/health centre/GP practice) using
36 information from the 2010 Personal Social Services Research Unit (PSSRU) unit costs [18]. We did not
37 have information on travel distances and therefore costed travel time on a per-visit basis.
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43 We calculated the mean two-week community-associated health service cost of treating an individual's
44 venous leg ulcer by summing dressing, hosiery, bandage, medication and staff costs at 2019 prices. The
45 focus was over two weeks as this was the period of time over which the survey was conducted and
46 where weekly values were reported (e.g., number of clinic visits per week), we multiplied them by two.
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51 **2.3 Variation in Community Care Costs**

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53 We explored whether, and to what degree, patient characteristics (age, sex, number of wounds, number
54 of co-morbidities, ethnic group, patient mobility and location of most care delivery) and patient receipt
55 of different resources (type of primary dressing, any secondary dressing use, bandage use and hosiery
56 use) were associated with variations in the total two-week community care cost. Variation in the total
57 cost by dressing type is of relevance as there is current uncertainty about the clinical effectiveness of
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3 antimicrobial dressings, which also have a higher unit cost than non-antimicrobial dressings. Further,
4 current guidelines do not recommend the use of antimicrobial dressings [19] but there has been
5 increased annual expenditure on this dressing type [20]. We identify variation in the cost of a venous
6 leg ulcer derived from our survey data via ordinary least squares regression. We include patients with
7 complete information on patient characteristics and who also have a cost recorded for one out of the
8 four cost components.
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13 **2.4 Primary and Secondary Care Costs**

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15 Primary and secondary care cost information was taken as a per participant cost directly from values
16 calculated in VenUS IV [9]. This was a cost of £998.31 per participant inflated to 2019 prices using the
17 NHS pay and prices cost inflation index from £907.60 [17] and divided to obtain a per two-week cost.
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21 **2.5 Extrapolation of prevalence to a national level**

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23 To calculate a national point prevalence for people in the community being treated for venous leg
24 ulceration we first divided the number of those with a venous leg ulcer (including all venous leg ulcers
25 whether they were the primary (most severe) wound or not) in the survey with the total population
26 covered by the North West locales in 2015 (at 1,935,683) [3]. We then applied this local point
27 prevalence figure to the UK population of 66,796,800 for mid-2019 [21] which assumes that the point
28 prevalence in the North West is similar to the rest of the UK. We further assume that our point
29 prevalence is representative at every point of the year across the UK.
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35 For extrapolation to a national level we make two assumptions: (i) the Greater Manchester population
36 is not dissimilar from the rest of the UK in terms of prevalence of people with venous leg ulcers and
37 (ii) the two-week period from which the data came is similar to the rest of the year (i.e., there is no
38 evidence of seasonal variation in venous leg ulcer prevalence). We compare our point prevalence with
39 a similar study [15] to add face validity to these assumptions.
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44 We were not able to calculate annual prevalence figures (in terms of people with one or more venous
45 leg ulcer episode in a year) with our data: we lacked detailed contemporary incidence and ulcer duration
46 data for individuals over this period. We could however, use our available data to estimate what the
47 maximum annual prevalence of people with venous leg ulcers receiving treatment in the community
48 may be by assuming a new set of patients being treated for a venous leg ulcer for every two-week period
49 of the year. We did this to give a suggested minimum (our point prevalence figure) and maximum figure
50 for the national annual prevalence of people treated in the community for venous leg ulceration. We
51 also estimated an annual period prevalence of venous leg ulcers using the incidence rate estimated by
52 Petherick et al [22] using THIN data. As sensitivity around our prevalence results, we further remove
53 patients who have a venous leg ulcer that is not their primary (most severe) wound.
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2.6 Extrapolation of cost to a national level

To calculate the total annual cost of care for venous leg ulcers in the UK we used our individual level cost data combined with our point prevalence estimates. The snapshot of data is assumed to be representative at the local level in terms of the costs and numbers of those with a venous leg ulcer of any two-week point in the year. Therefore, we can scale the total cost obtained in our data to achieve the annual national cost of community treated venous leg ulcers. As noted earlier, due to data limitations we can only speculate what the corresponding annual prevalence associated with the annual cost we produce could be. The annual prevalence figures we derive from using a different source are used (in the denominator) with the estimated total national cost (in the numerator) to obtain an estimated per person annual cost. We did not have a total cost for patients where the venous leg ulcer was not their primary (most severe) wound. We therefore applied the average cost from the primary venous leg ulcer group to the non-primary group when calculating the estimated total national cost and per person annual cost.

2.7 Patient and public involvement

There was no patient or public involvement in this study.

3 Results

3.1 Community survey data: summary statistics

Of the 3057 patients recorded in the survey as being treated in the community for one or more complex wounds, 570 (18.7%) had a venous leg ulcer recorded as their primary (most severe) wound.

The average age of people with venous leg ulcers was 73.5 years old, with most patients being White British (92.6%) and living in owned/rented accommodation (88.9%) (Table 1). Amongst health-related variables: 54.2% of those with a venous leg ulcer could only walk with difficulty, on average patients had 1.95 wounds and 1.35 co-morbidities.

Table 1: Summary characteristics of 570 survey patients with a venous leg ulcer as their primary (most severe) wound

	N	% or mean
Sex (n=531):		
Female	288	54.2%
Male	243	45.8%
Age (years)		
	562	73.52 (14.48)
Ethnicity (n=565):		
White British	523	92.6%
Black, Asian or Minority Ethnic Group	42	7.4%
Residency (n=566):		
Owned/rented	503	88.9%
Other	63	11.1%
Mobility (n=563):		
Walks freely	305	41.9%
Walks with difficulty	236	54.2%
Immobile	22	3.9%
Number of wounds		
	570	1.95 (1.87)
Number of co-morbidities		
	570	1.39 (1.13)
Received most wound care (n=569):		
Non-clinical setting	257	45.2%
Clinical setting	312	54.8%

Treatment and community staff ulcer-related resource use from the 570 patients whose primary wound was a venous leg ulcer is shown in Table 2. The most common primary dressing type used was non-antimicrobial (54.7%). Among antimicrobial dressings, silver-containing dressings were the most commonly used (14.6%). The majority of those with a venous leg ulcer were receiving some type of bandage (74.6%). 37.5% of patients were reported to be in receipt of venous leg ulcer medications, the most commonly used was topic steroids (44.2% among those who had medication). Only one patient had no reported use of dressing, bandages, hosiery, medication nor community healthcare use. On average, patients received 1.9 visits per week from community nurses, lasting 34.9 minutes on average.

Table 2: Summary statistics of direct healthcare resource use amongst 570 survey patients with a venous leg ulcer as their primary (most severe) wound

	N with this cost	% of total patients
Primary Dressing:		
Honey	51	8.9
Iodine	24	4.2
Silver	83	14.6
Other antimicrobial	36	6.3
Non-antimicrobial	312	54.7
No dressing reported	64	11.2
Secondary Dressing:		
Honey	1	0.2
Silver	5	0.9
Non-antimicrobial	250	43.9
No dressing	314	55.1
Any secondary dressing reported	260	45.6
Bandages:		
No bandage reported	145	25.4
4 layer compression	52	9.1
Short stretch	63	11.1
3 layer reduced compression	98	17.2
2 layer compression	82	14.4
Non compression	57	10.0
Dressing retention	24	4.2
Other	49	8.6
Hosiery:		
No hosiery reported	464	81.4
Class 1	40	7.0
Class 2	51	8.9
Class 3	14	2.5
Other	1	0.2
Ulcer-related medicines:		
Antibiotic	51	8.9
Topical steroids	88	15.4
Analgesics	60	10.5
No medicines reported	371	65.1

3.2 Community Care Costs

Table 3 summarises the wound-related healthcare costs of 570 people with their primary (most severe) wound recorded as a venous leg ulcer over a two-week period. The mean, per person, community-based ulcer treatment cost was £147.19 (95% CI: £138.58 to £155.80). Community staff time was the costliest element, representing 70.9% of the total community care cost. Among costs not related to staff time, dressing and bandage use accounted for the largest proportions of the total cost at 14.1% and 13.0%, respectively.

Table 3: Community healthcare costs £ (2019 prices) of individual venous leg ulcer treatment over two weeks

Cost component	Mean £ (% of total)	SD	95% CI:		25 th Percentile	Median	75 th Percentile
			Lower	Upper			
Dressing	20.76 (14.1)	13.52	19.64	21.87	12.82	14.36	25.64
Bandages	19.19 (13.0)	19.06	17.62	20.76	0	13.35	34.18
Hosiery	0.77 (0.5)	1.61	0.61	0.92	0	0	0
Medication	2.31 (1.6)	3.63	2.01	2.61	0	0	4.75
Community staff	104.35 (70.9)	97.65	96.32	112.38	46.20	81.5	127.70
All community	147.19	104.697	138.58	155.80	80.16	120.03	179.49

Note: We recoded one outlier of 62 nurse visits to the next highest value at 8 visits

3.3 Variation in Community Care Costs

We explored variation in the community care cost of treating a venous leg ulcer over a two-week period among 514 patients with complete information on covariates (Table 4). Treatment with a honey, silver or other antimicrobial primary dressing is associated with, on average, higher costs compared with use of a non-antimicrobial dressing. For example, use of a silver primary dressing is associated with a £65.27 (95% CI: £38.02 to £92.52) higher per-person cost on average than for people treated with a non-antimicrobial primary dressing. Patients who received most of their wound care in a clinic setting have £-44.91 (95% CI: -£64.68 to -£25.14) lower two-week community costs than people who received care in a non-clinic setting. For each extra reported wound, the patient has a higher average two weekly cost of £9.69 (95% CI: £4.06 to £15.33) associated with their venous leg ulcer. Those who walk with difficulty and those who are unable to walk have higher total costs of £37.75 (95% CI: £-8.50 to £84.01) and £20.25 (95% CI: £0.59 to £39.92), respectively, compared with those who can walk freely, although the latter difference is not statistically significant.

Table 4: Variation in the total cost of venous leg ulcer treatment over a two-week period

	Difference in GBP	95% Confidence interval
Dressing: Honey (ref=non-antimicrobial)	18.59*	(-2.52 to 39.69)
Dressing: Iodine (ref=non-antimicrobial)	-11.78	(-42.54 to 18.98)
Dressing: Silver (ref=non-antimicrobial)	65.27***	(38.02 to 92.52)
Dressing: Other antimicrobial (ref=non-antimicrobial)	29.43*	(-4.06 to 62.91)
Dressing: Not reported (ref=non-antimicrobial)	8.98	(-27.21 to 45.17)
Any secondary dressing	9.38	(-5.93 to 24.69)
Any bandage use	48.63***	(27.24 to 70.02)
Any hosiery	-9.37	(-31.34 to 12.61)
Any medication	24.76***	(9.42 to 40.11)
Most wound related care in clinical setting (ref=non-clinical)	-44.91***	(-64.68 to -25.14)
Female	-25.56	(-64.53 to 13.40)
Age (50-69 years old)	-14.64	(-50.43 to 21.15)
Age (70-79 years old)	-22.74	(-57.19 to 11.71)
Age (80+ years old)	-39.33**	(-74.02 to -4.64)
Female*Age (50-69 years old)	32.93	(-19.61 to 85.48)
Female*Age (70-79 years old)	22.51	(-24.05 to 69.07)
Female*Age (80+ years old)	22.78	(-21.01 to 66.56)
White British (ref=other)	10.59	(-15.54 to 36.72)
Owned/ rented residence (ref=other)	-8.83	(-36.39 to 18.73)
Mobility: Walks with difficulty (ref=walks freely)	20.25**	(0.59 to 39.92)
Mobility: Immobile (ref=walks freely)	37.75	(-8.50 to 84.01)
Number of wounds	9.69***	(4.06 to 15.33)
Number of co-morbidities	0.50	(-6.12 to 7.11)
Constant	103.09***	(50.79 to 155.39)
N	514	

Note: Coefficients estimated using ordinary least squares regression. *p<0.1; **p<0.05; ***p<0.01

3.4 Primary and Secondary Care Costs

Primary and secondary care costs add £19.20 to the total community care cost for all patients (Table 5). This results in a total mean two weekly per person healthcare (including primary and secondary care use) cost of £166.39 (95% CI: £157.78 to £175.00).

Table 5: healthcare costs £ (2019 prices) for venous ulcer treatment

Cost component	Mean £ (% of total)	SD	CI: Lower	CI: Upper	25 th Percentile	Median	75 th Percentile
Primary & Secondary	19.20 (20.65)	-	-	-	-	-	-
Total healthcare	166.39	104.69	157.78	175.00	99.36	139.23	198.69

3.5 Extrapolation of Prevalence and Costs

The point prevalence of people with a venous leg ulcer in participating locales in the North West of England was 0.032% or 3.2 per 10 000 population (calculated as $(612/1935683)*10000$; shown in Table 6); a figure only 0.3 per 10 000 population larger than a previous UK estimate [15]. This figure includes those with a venous leg ulcer as their primary (most severe) wound and those a venous leg ulcer as their non-primary wound. Application of this point prevalence estimate nationally suggests 21,119 people are treated in the community for a venous leg ulcer in the UK at any point in time. If we assume the point prevalence is constant throughout the year but with different patients at each time point we obtain a theoretical maximum annual period prevalence of 84.5 per 10,000 population. This is an extreme assumption suggesting a theoretical incidence rate of 81.3 per 10,000 population, which is very high compared with a previously estimated incidence rate from THIN data of 10 per 10,000 population [22]. We combined the incidence rate from Petherick et al [22] with our data to derive an annual period prevalence estimate of 13.2 per 10 000 persons which is 6.4 times smaller than our maximum annual prevalence estimate. Our point prevalence decreases from 3.2 to 2.9 per 10 000 population once we exclude those for whom their venous leg ulcer is not the primary (most severe) wound.

From our data we estimate the annual community cost of treating venous leg ulcers to be £81,039,192 for the UK for those where the venous leg ulcer was the primary or non-primary wound. Including primary and secondary care costs increases the figure to £102,122,480. As noted above the corresponding annual prevalence figure for our annual costs can be no higher than 84.5 per 10000 persons. Calculating a per person annual cost which includes primary and secondary care using the incidence rate from Petherick et al [22] provides a cost of £4787.70.

Table 6: Prevalence and total estimated costs of people treated in the community for venous leg ulceration with extrapolation to National levels

	National Level ^{^*}
Prevalence (primary and non-primary wound):	
Point	3.2 per 10000 persons
Annual (calculated with Petherick et al., [22] ^b incidence value)	13.2 per 10000 persons
Annual (calculated using theoretical maximum incidence based on survey data)	84.5 per 10000 persons
Annual Total Costs (primary and non-primary wound):	
Community based (based on assumed representativeness of survey data over 12 months)	£81,039,192
Per person (using annual prevalence calculated from Petherick et al [22] incidence)	£3799.27 ^a
Per person (using annual prevalence calculated with maximum incidence assumption)	£147.19 ^a
Community + primary +secondary care	£102,122,480
Per person (Petherick et al [22] incidence as above)	£4787.70 ^a
Per person (maximum prevalence)	£185.48 ^a
Prevalence (primary wound only):	
Point	2.9 per 10000 persons
Annual (calculated with Petherick et al., [22] ^b incidence value)	12.9 per 10000 persons
Annual (calculated using theoretical maximum incidence based on survey data)	76.8 per 10000 persons
Annual Total Costs (primary wound only):	
Community based (based on assumed representativeness of survey data over 12 months)	£75,477,680
Per person (using annual prevalence calculated from Petherick et al [22] incidence)	£3799.21 ^a
Per person (using annual prevalence calculated with maximum incidence assumption)	£147.19 ^a
Community + primary +secondary care	£95,114,080
Per person (Petherick et al [22] incidence as above)	£4787.61 ^a
Per person (maximum prevalence)	£185.48 ^a

Note: [^]Assuming the point prevalence from the survey based on a population of 1 935 683 from nine North West community care trusts in England is representative of the rest of the UK. ^{*}Based on the 2019 mid-year population estimate of the UK at 66,796,800 [21]. ^aDerived using the total cost in the numerator and the estimated number with a venous leg ulcer annually in the denominator. ^bPetherick et al [22] incidence rate is 10 per 10 000 persons

4 Discussion

To date there has been limited use of community-collected information to inform service level cost estimates of treating venous leg ulcers. Our cost-of-illness analysis addresses this gap in the literature. We extend the coverage of our community-sourced resource use and cost data with inclusion of primary and secondary care resource use to obtain a more complete figure on direct healthcare costs.

The average two-week per person cost of treating a venous leg ulceration was estimated as £166.39 (95% CI: £157.78 to £175.00) with community staff time making up over half this total. Using

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3 community data only, estimated annual costs were higher where anti-microbial dressings were used and
4 where wound care was delivered in the home. We can draw limited conclusions about the contribution
5 of these factors to increased costs as people with more serious and slower to heal wounds may be more
6 likely to receive care at home and/or anti-microbial dressings. However there is currently no clear
7 evidence of benefit associated with the use of silver or any other antimicrobial dressings [19,20].
8 Likewise, treatment delivered in clinics where possible, rather than in patient homes, likely offers
9 savings in terms of staff time but it is also likely the least complex patients seen in clinic settings. Patient
10 characteristics such as age, mobility and the numbers of wounds were also associated with variation in
11 the total cost.
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18 Our point prevalence of 3.2 per 10,000 population triangulates well with other studies that also use
19 regional UK data and reinforces the face validity of our extrapolation of cost and prevalence to a
20 national level. For example, the figure is only 0.3 higher to the 2.9 (95% CI: 2.5 to 3.3) per 10 000
21 population from Hall et al [15] which used a similar protocol but in different areas of the UK with
22 different staff and was undertaken some years earlier. Hall et al [15] also included those receiving care
23 in acute settings in their figures. An older study which used THIN data from 2001 to 2006 estimated an
24 annual prevalence of 8.28 per 10 000 (95% CI 8.17 to 8.39) person years and 14.07 (95% CI: 8.17 to
25 8.39) per 10 000 person years from the same time period using the General Practice Research Database
26 [22]. Our results are robust to the exclusion of those with a venous leg ulcer that is not their non-primary
27 wound, decreasing the point prevalence by 0.3 to 2.9 per 10,000 population.
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35 We were unable to estimate an annual period prevalence figure from our point prevalence estimate
36 because we lacked contemporaneous incidence and duration data. However, we could use our data to
37 suggest that the annual prevalence of people with venous leg ulceration *can be no greater than* 84.5 per
38 10,000 population (using incidence rates reported in the literature). The annual prevalence of 59 per
39 10,000 population (assumed to mean 59 people not 59 ulcers) reported by Guest et al [7], is below our
40 maximum annual prevalence, but still very high given the extreme incidence of leg ulceration that would
41 be required to achieve these figures. Both estimates assume an incidence rate far in excess of those
42 found in the literature using THIN data at 14 per 10,000 population [22]. Guest et al. [7] also reported
43 an additional 85 per 10,000 population as having an unspecified leg ulcer. If we assume that at least
44 60% of Guest's unspecified leg ulcers are venous leg ulcers then the annual prevalence is increased to
45 110 per 10,000 annually: our data questions the validity of such high values.
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53 We estimate a national annual cost attributable to treating those with a venous leg ulcer as the primary
54 (most severe) wound at £95.11 million; an estimate that is only 15.9% of the £596.55 million reported
55 by Guest et al [8] as the lower end of their estimate (with an upper estimate of £921.94 million). Our
56 estimated per-person annual cost of a venous leg at £4787.70, which uses the incidence rate of Petherick
57 et al [22], is 62.6% of the equivalent cost obtained by Guest et al [7] at £7615.03. Key differences are
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3 that Guest et al [7,8] used information from a GP based dataset that included a study population of 505
4 selected from a random sample of 6000 patients in the THIN database. By contrast, we used a bottom-
5 up approach to costing, using information from audits of all patients treated by participating NHS
6 organisations. The costing method of Guest et al [7] compared the costs of 505 venous leg ulcer patients
7 to those without a venous leg ulcer to obtain the incremental cost. Importantly our cost components
8 were similar to those of Guest et al [7], and we agree that community staff time is the largest component
9 of the total cost. Guest et al [7] also considered the cost of care delivered once people's ulcers had
10 healed. This may explain some of the differences in cost although ulcer-related care in the absence of
11 an actual wound is likely to be limited.
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18 Data used for this study offers advantages over primary care collected data as it directly captured
19 community nurse activity for costing. Our study also has limitations: our extrapolation of costs and
20 prevalence relies upon assumptions that the nine locales are similar to the rest of the UK and at different
21 points within the year. More specifically, if the populations included in the nine locales are older and
22 are more deprived than the a 'typical' local, then our cost and prevalence can be considered an
23 overestimate. We searched the literature for further evidence of seasonal variation in leg ulcer incidence
24 and found none, nor any biological basis for thinking that one might exist. Extrapolation aside, our
25 study represents the venous leg ulcer point prevalence and treatment based on an area of roughly 2
26 million people.
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33 We also note that we only considered the costs associated with bandages and dressings for the primary
34 wound and we assumed all recorded visits were with a nurse. Recording of ulcer-related staff time may
35 be overestimated if the healthcare profession did not distinguish between visits that were for care of the
36 primary wound and no other wounds or co-morbidities. We were not able to calculate community costs
37 for those whom the venous leg ulcer was not the primary (most severe) wound. Thus, in extrapolating
38 costs using a point prevalence of primary (most severe) and non-primary venous leg ulcers, we have
39 assumed no difference in community costs incurred for those with venous leg ulcers as their primary
40 (most severe) or non-primary wound. However, the vast majority of people surveyed had a venous leg
41 ulcer as their primary wound, with an increase of only 0.3 per 10,000 population once those a non-
42 primary venous leg ulcer were included.
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50 There is little information on travel time by nurses and current reimbursement based on distance;
51 therefore, we used old rates of reimbursement per visit. A further limitation is that we only had direct
52 healthcare resource use to use for costing. Other direct costs such as surgery and indirect costs such as
53 productivity loss were not available which we note as future areas to obtain cost information.
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57 Whilst our regression analysis of total costs highlights factors associated with this cost, it cannot be
58 used to draw causal inference. For example, there may be unobserved factors relating to patient health
59 that are not accounted for in the regression that may explain variation in the total cost.
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3 Leg ulcer care is costly to the NHS but we suggest it may not be as costly as has been claimed in
4 previous highly cited and influential work [7,8,23]. There are difficulties in comparing the available
5 data from different sources, in part due to a lack of information on methods used and further
6 transparency may allow differences in figures to be better understood. Fundamentally, our ability to
7 estimate costs, scrutinise the quality of care and observe links between care and outcomes in wound
8 care is hampered by a lack of routinely collection and useable information in community services. The
9 absence of a clinical database for community wound care also hinders clinical communication and
10 monitoring of patient progress. An accurate picture of the cost and prevalence of venous leg ulcers,
11 which we have aimed to provide in this study, can be used to further understand the cost and scale of
12 wound care and a basis from which to more realistically estimate the scale of potential savings.
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20 **Contributors:** NC and JD conceived the idea for the overall project. SU, JD, NC and MS contributed
21 to the study design. SU was responsible for data analysis. SU created the original draft of the
22 manuscript. SU, JD, NC and MS contributed to the interpretation of study findings, critical revision of
23 the manuscript for important intellectual content and approval of the final manuscript.
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28 **Competing interests** None declared
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30 **Disclaimer: To add**
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32 **Ethics approval: Not required**
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34 **Data availability statement:** No additional data are available
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For peer review only

Appendix

Table A1: Assigned unit costs

Resource use item	Cost (2019 prices)	Source
Dressings:		
Honey	£5.89	Joint Formulary Committee [16]
Iodine	£0.41	Joint Formulary Committee [16]
Silver	£9.38	Joint Formulary Committee [16]
Other anti-microbial	£5.80	Joint Formulary Committee [16]
Non anti-microbial	£3.41	Joint Formulary Committee [16]
Hosiery:		
Class 1	£23.92	Joint Formulary Committee [16]
Class 2	£23.99	Joint Formulary Committee [16]
Class 3	£29.04	Joint Formulary Committee [16]
Other	£29.75	Joint Formulary Committee [16]
Bandages:		
4 layer compression	£9.29	Joint Formulary Committee [16]
Short stretch	£3.55	Joint Formulary Committee [16]
3 layer reduced compression	£5.08	Joint Formulary Committee [16]
2 layer compression	£9.09	Joint Formulary Committee [16]
Non compression	£1.79	Joint Formulary Committee [16]
Dressing retention	£0.35	Joint Formulary Committee [16]
Other	£17.32	Joint Formulary Committee [16]
Medication:		
Analgesics	£7.76	Joint Formulary Committee [16]
Topical Steroids	£4.75	Joint Formulary Committee [16]
Pentoxifylline	£13.68	Joint Formulary Committee [16]
Antibiotics	£4.94	Joint Formulary Committee [16]
Healthcare use:		
Nurse visit use (home based)	£46 per hour	PSSRU Unit Costs 2019 [17]
	£1.50 travel cost per visit	PSSRU Unit Costs 2010 [18]
Nurse, GP, Outpatient and	£998.31 (applied to all patients)	VenUs IV trial [9]

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5 & 6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5 & 6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5 & 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5 & 6
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 & 6 & 7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5 & 6 & 7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	6
		(d) If applicable, describe analytical methods taking account of sampling strategy	-
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7 & 9
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8 & 9
		(b) Indicate number of participants with missing data for each variable of interest	-
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	-
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12 & 13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.