

Institution: The University of Manchester		
Unit of Assessment: 3 (Allied Health Professions, Dentistry, Nursing and Pharmacy)		
Title of case study: Optimising outcomes for people with venous leg ulcers		
Period when the underpinning research was undertaken: January 2012 - February 2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name:	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Dame Nicky Cullum	Professor of Nursing	2011 - present
Jo Dumville	Professor of Applied Health Research Senior Lecturer in Applied Health Research	2019 - present 2013 - 2019
Paul Wilson	Senior Lecturer in Implementation Sciences Research Fellow	2019 - present 2014 - 2019
Period when the claimed impact occurred: August 2013 - July 2020		
Is this case study continued from a case study submitted in 2014? N		
1. Summary of the impact		
<p>Venous leg ulcers are painful, recurring wounds affecting a minimum of 20,000, mainly older people, in the UK at any one time. These ulcers result in large wound-specific NHS care costs annually. Findings from our University of Manchester research have improved outcomes for people with venous leg ulcers and increased efficiency in the NHS. We demonstrated that multi-component compression bandages with an elastic layer are more effective at healing venous leg ulcers than other bandage options. We subsequently showed that, for people eligible to receive them, 2-layer compression stockings are similarly effective for treating venous leg ulcers but reduce ulcer recurrence and are more cost-effective. In 2018 alone, increased prescribing of 2-layer stockings saved the NHS approximately GBP7,000,000.</p>		
2. Underpinning research		
<u>Overall summary of underpinning research</u>		
<p>Our Cochrane systematic review [1] showed that multi-component bandages for people with venous leg ulcers lead to increased healing at lower cost than no compression or single-layer systems. Furthermore, multi-component systems with an elastic layer are more effective than inelastic systems. Our subsequent randomised controlled trial (457 participants), funded by NIHR to fill the evidence gap identified by our systematic review, showed that 2-layer compression stockings are more cost-effective than the 4-layer (elastic containing) multi-component bandages and also reduce ulcer recurrence rates [3,4]. Survey data highlighted the need for translation of this research into practice to increase the use of 2-layer compression stockings.</p>		
<u>Details of underpinning research</u>		
<p>Our qualitative research with leg ulcer patients showed for the first time that complete ulcer healing is the outcome that is most important to them [2]. Our Cochrane systematic review [1] drew together 48 randomised trials (4,321 participants), including the first meta-analysis</p>		

of individual patient data in the wounds field, to explore the effect of compression on ulcer healing.

- **Our review showed that compression increases ulcer healing compared with no compression. Multi-component compression systems are more effective in healing venous leg ulcers than single layer systems. Multi-component bandage systems with an elastic layer are more effective than inelastic bandage systems [1].**

Whilst multi-component bandages are effective, they are bulky to wear and their safe application requires training and skill. 2-layer, below-knee, compression stockings are much less bulky and do not require skilled application, they deliver predictable and consistent levels of pressure and may be more comfortable.

- **Our systematic review showed little in the way of robust evaluation by randomised controlled trial of 2-layer compression stockings for treating open venous leg ulcers [1].**

In response, we conducted a randomised controlled trial (VenUS IV, involving 457 people) [3,4]. This large, rigorous pragmatic trial compared the 4-layer bandage with 2-layer compression stockings in those people suitable for stocking use. We found that:

- **Ulcers treated with 4-layer bandages or with 2-layer compression stockings take a similar amount of time to heal [3,4].**
- **On average, people receiving stockings were less likely to experience ulcer recurrence and stockings were more cost-effective (annual costs on average GBP302 less per person) [3,4].**

We conducted a cross-sectional survey in Greater Manchester and East Lancashire to determine the extent of use of 2-layer stockings: the total population covered by the study was 1,935,683. The survey found that:

- **Whilst there was use of multi-component compression bandages, there was almost no use of 2-layer compression stockings across these areas, highlighting the need for translation of research into practice to encourage impact [5].**

3. References to the research

1. O'Meara S, **Cullum N**, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database Systematic Reviews* 2012, Issue 11. Art.No.:CD000265 doi: [10.1002/14651858.CD000265.pub3](https://doi.org/10.1002/14651858.CD000265.pub3). Grant: *Compression for venous leg ulcers: National Institute of Health Research-funded Cochrane systematic review (via infrastructure funding). (Cullum was Senior Review author; conceptualised and designed the review. Dumville made major contributions to the review.)*
2. **Cullum N**, Buckley H, **Dumville J**, Hall J, Lamb K, Madden M, Morley R, O'Meara S, Goncalves PS, Soares M, Stubbs N. Wounds research for patient benefit: a 5-year programme of research. *Programme Grants Appl. Res.* 2016; 4(13) doi: [10.3310/pgfar04130](https://doi.org/10.3310/pgfar04130). Grant: *Wound Research for Patient Benefit: National Institute of Health Research-funded Programme Grant for Applied Research (GBP1,749,280). (Cullum was Chief Investigator of research programme. Dumville made major contributions to the work.)*
3. Ashby R, Gabe R, Ali S, Adderley U, Bland JB, **Cullum N**, **Dumville J**, Iglesias CP, Kang'ombe AR, Soares MO, Stubbs NC, Torgerson DJ. Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (Venous leg Ulcer Study IV, VenUS IV): a randomised controlled trial. *Lancet* 2014; 383:871-9 doi: [10.1016/S0140-6736\(13\)62368-5](https://doi.org/10.1016/S0140-6736(13)62368-5)
4. Ashby R, Gabe R, Ali S, Saramago P, Chuang L-H, Adderley U, Bland JM, **Cullum NA**, **Dumville JC**, Iglesias CP, Kang'ombe AR, Soares MO, Stubbs NC, Torgerson

DJ. Compression hosiery versus compression bandaging in the treatment of venous leg ulcers: a randomised controlled trial, mixed treatment comparison and decision analytic model. *Health Technol Assess.* 2014;18:1-293, v-vi. doi: [10.3310/hta18570](https://doi.org/10.3310/hta18570). Grant: VenUS IV: National Institute of Health Research-funded randomised controlled trial (GBP1,012,623). (Dumville was Chief Investigator of this study. Cullum was Co-Investigator and covered maternity leave as Chief Investigator.)

5. Gray TA, Rhodes S, Atkinson RA, Rothwell K, **Wilson P, Dumville JC, Cullum NA.** Opportunities for better value wound care: a multiservice, cross-sectional survey of complex wounds and their care in a UK community population. *BMJ Open* 2018 22;8(3): e019440. doi: [10.1136/bmjopen-2017-019440](https://doi.org/10.1136/bmjopen-2017-019440). Grant: National Institute of Health Research-funded Collaboration for Leadership in Applied Health Research and Care – Greater Manchester (GBP10,000,000). (Cullum was Co-Investigator and Lead for the Wound Healing theme. Wilson and Dumville made major contributions to the work.)

4. Details of the impact

Context

Venous leg ulcers are the most common type of complex wound: they are painful and unpleasant for those affected and incur high costs for the NHS. Venous ulcers can be treated with compression applied to the leg by bandages or stockings, but there are many compression options since these medical devices come to market rapidly, generally without evidence of clinical and cost-effectiveness. Within this context our research has provided high certainty evidence to support decision-making by all stakeholders.

Pathways to impact

1. Our work has been cited in international guidelines and recommended evidence practice documents including:

Systematic review of compression [1] — (i) *Management of Chronic Venous Disease Clinical: Practice Guidelines of the European Society for Vascular Surgery (2015)*. (ii) *Management of patients with venous leg ulcers. Wounds Australia and the European Wound Care Association (2016)*. (iii) *Public Health England. Venous leg ulcers: Infection diagnosis and microbiological investigation. Quick reference guide for primary care: For consultation and local adaptation (2016)* and (iv) *National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summaries (2019)**.

VenUS IV [3,4] — (i) *NICE Clinical Knowledge Summary (2019)* Wounds UK. Best Practice Statement: Holistic Management of Venous Leg Ulceration. London (2016)* and (ii) *NHS England Rightcare Scenario: Betty's story (2017)*.

**The main UK Guideline for venous leg ulcers has not been updated since 2010: discussions are underway with NICE. In the interim and in recognition of key evidence that required recognition this Clinical Knowledge Summary was rapidly updated in 2019.*

2. We have undertaken extensive local knowledge mobilisation and implementation work via the NIHR CLAHRC-GM Leg Ulcer Quality Improvement (ILUMIN) Programme, considered a pathway to impact here. This was an evidence-based improvement strategy to enhance delivery of evidence-based quality standards for leg ulcer management which included: use of the highest level of compression therapy possible where clinically appropriate and use of high compression 2-layer stocking kits, where clinically appropriate.

Reach and significance of the impact

Influencing and sustaining the use of effective modes of compression for venous leg ulceration. There are many compression options for leg ulcer treatment. Our systematic review, which is the main evidence internationally for compression, has been pivotal in promoting compression therapy as the only venous leg ulcer-focused medical device proven to reduce time to ulcer healing. By evidencing the need for compression and by identifying multilayer compression with an elastic layer as the most effective bandage option, our

research increased and contributed to promoting and sustaining high levels of optimal compression prescribing in the UK and internationally.

We demonstrate our impact in England using routine NHS community prescribing data (England). In 1998, about 200,000 packs of multi-component elastic-containing bandages were used to treat venous leg ulcers; this increased to approximately 800,000 packs in 2014 [A].

Further support of our positive impact on compression use comes from the Regional Chief Nurse North (NHS England & NHS Improvement) who has formally acknowledged the importance of the research cited in this case study in '*promoting and sustaining high levels of optimal compression prescribing in the UK*' [B]. This point is also acknowledged by the Director of the National Wound Care Strategy Programme: our Cochrane review [1] informs the National Wound Care Strategy Programme's approach for venous leg ulcers and impacted on the decision to include a compression-related indicator in the planned 2020/21 NHS Commissioning for Quality and Innovation (CQUIN) on assessment, diagnosis and treatment of lower leg wounds and forms the evidence base for that indicator [C].

The compression review [1] has also had impact internationally. For example, the review has been "*...pivotal in sustaining the promotion of compression therapy to patients and staff in the 4VLU Collaboration in New Zealand, a combined academic and clinical research group. The six clinical centres in the 4VLU Collaboration are located in the major cities across the country (Auckland, South Auckland, Hamilton, [covering the Waikato region], Wellington, Christchurch, Dunedin [covering Otago and Southland regions) and together provide services to 55% of the New Zealand population*" [D].

Whilst our work led to the promotion of compression bandages internationally, it also highlighted where there was further potential to evaluate non-bandage compression products which had the potential to be valuable (less reliant on operator skill, less bulky).

Increasing use of 2-layer compression stockings. In 2013, before publication of VenUS IV findings, there were 25,237 complete 2-layer stocking kits prescribed in England in the community: that figure had been stable for 8 years (Figure 1). Following publication of VenUS IV there was a year-on-year increase in prescribing of 2-layer stockings. In 2018, 46,521 full kits were prescribed: an increase of 21,284 kits from 2013 (an 84% increase; Figure 1).

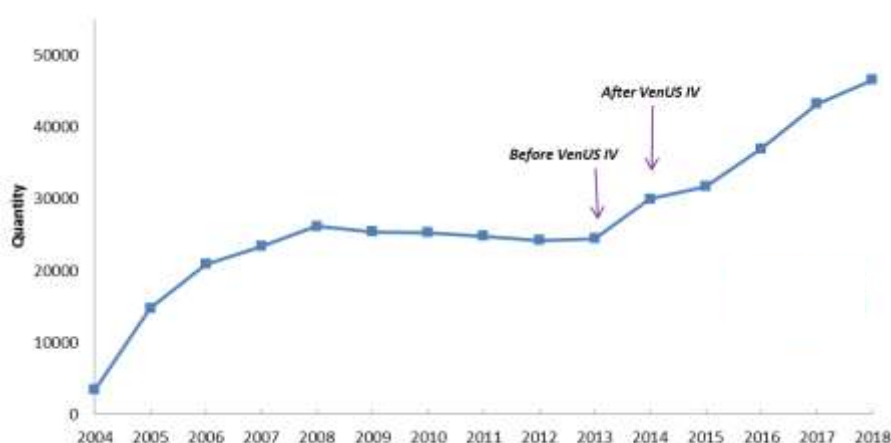


Figure 1: Quantity of 2-layer compression stocking kits (stocking and liners together) prescribed annually in England Community NHS Services [A].

As each person receives an average of two kits annually, we can estimate that approximately 23,260 people received 2-layer compression stockings in 2018. With a mean annual cost-saving of hosiery (estimated from VenUS IV) of GBP302 per person compared with standard compression this equates to a mean saving for the NHS of approximately GBP7,000,000 in 2018. We are confident in attributing this increase to VenUS IV and subsequent knowledge mobilisation: there was no other significant research or quality improvement activity in the area at the time in the UK or internationally.

Increased use of 2-layer compression stockings is further evidenced by the results of a recent survey of 139 registered nurses in the UK who regularly treat people with venous leg ulcers. Data showed that 2-layer compression stockings are the third most frequently used type of compression, used by most respondents [E]. Whilst similar pre-2014 data are not available we know from working with over 30 trial sites during VenUS IV that 2-layer compression stockings were used infrequently (in total 6.8% of participants were receiving this at baseline) and in many NHS Trusts were not listed in their wound treatment formulary.

Measurement of increased use of 2-layer compression stockings in local areas. From our local NIHR-CLAHRC-GM ILUMIN implementation work, we have local data demonstrating further impact in terms of increased use of 2-layer compression stockings for venous ulcer treatment. At the start of ILUMIN in East Lancashire in November 2017, 2-layer compression stockings were worn by 8% of people with a venous leg ulcer, compared with 25% on completion of this work in October 2018 [F].

Local data from NHS Wakefield Clinical Commissioning Group show 100 2-layer compression stocking kits used in year 2013/14, increasing to more than 450 stocking kits in 2018/19 (only 8 months of data available for this last year). Activity by local clinical teams that supported this increase was driven by the findings of VenUS IV [G, H].

5. Sources to corroborate the impact

- A. Prescribing cost data: accessed from <https://digital.nhs.uk/data-and-information/publications/statistical/prescription-cost-analysis/> These data contain annual prescription usage and cost from community settings in England for each individual product listed in the British National Formerly. Data from the Wound Management section has been used to explore use of different compression systems over time.
- B. Testimonial from the Regional Chief Nurse North, NHS England, dated 4 February 2019, highlighting the importance of the research and its impact in promoting and sustaining effective care.
- C. Testimonial from the Director of the National Wound Care Strategy Programme, dated January 2020, highlighting the importance of the research and how this has been used to underpin activities that are the focus of national efforts to improve care for those with venous leg ulcers.
- D. Testimonial from a Professor of Nursing, The University of Auckland, New Zealand, dated 22 June 2020, confirming the impact of directing and sustaining compression use across much of New Zealand.
- E. Oates A, Udderley U. Survey of registered nurses' selection of compression systems for the treatment of venous leg ulcers in the UK. *Journal of Tissue Viability*. Volume 28: 115-9. doi: [10.1016/j.jtv.2019.02.004](https://doi.org/10.1016/j.jtv.2019.02.004) . Presents data on the types of compression nurses are using to treat venous leg ulcers in the UK.
- F. Data from the ILUMIN project in Manchester and East Lancashire showing baseline hosiery use and subsequent increased use over time.
 - i. East Lancs Hospitals NHS Trust data
 - ii. Manchester NHS Foundation Trust data
- G. Wakefield Clinical Commissioning Group prescribing data showing increased use of 2- layer hosiery, provided by a Vascular Nurse Consultant, Mid Yorks NHS Trust in 2019.
- H. Testimonial from a Vascular Nurse Consultant, Mid Yorks NHS Trust, dated 7 February 2020, confirming local increase in use of 2-layer compression stockings in relation to VenUS IV findings.