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DOI:

[10.1177/0268355518805658](https://doi.org/10.1177/0268355518805658)

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*Document Version*

Peer reviewed version

*Citation for published version (Harvard):*

Davies, H, Popplewell, M, Bate, G, Ryan, R, Marshall, T & Bradbury, A 2018, 'Publication of UK NICE Clinical Guidelines 168 has not significantly changed the management of leg ulcers in primary care: an analysis of The Health Improvement Network database ', *Phlebology*. <https://doi.org/10.1177/0268355518805658>

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Checked for eligibility: 17/12/2018

Huw OB Davies, Matthew Popplewell, Gareth Bate, Ronan P Ryan, Tom P Marshall, Andrew W Bradbury, Publication of UK NICE Clinical Guidelines 168 has not significantly changed the management of leg ulcers in primary care: An analysis of The Health Improvement Network database, *Phlebology*, © The Author(s) 2018. DOI: 10.1177/0268355518805658

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# **Publication of UK NICE Clinical Guidelines 168 has not significantly changed the management of leg ulcers in primary care: an analysis of The Health Improvement Network (THIN) database**

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## **Key Words**

Leg ulceration, ulcer, THIN, Primary Care, NICE, guidelines

## **Declaration of Conflicting Interests**

None declared.

## Abstract

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**BACKGROUND:** NICE Clinical Guidelines (CG)168, published in July 2013, recommend specialist vascular referral for all leg ulcers (LU), defined as a break in the skin below the knee that has not healed within 2 weeks.

**AIM:** To examine the impact of CG168 on the primary care management of LU using The Health Improvement Network (THIN) database.

**METHODS:** An eligible population of approximately 2 million adult patients was analysed over two 18-month periods before and after publication of CG168. Those with a new diagnosis of LU in each time period were analysed in terms of demographics, specialist referral, and superficial venous ablation (SVA).

**RESULTS:** We identified 7 532 and 7 462 new diagnoses of LU in the pre- and post-CG168 cohorts respectively. Patients with a new diagnosis of LU were elderly (median age 77 years both cohorts) and less likely to be male (47% both cohorts). There were 2 259 (30.0%) and 2 329 (31.2%) vascular service referrals in the pre- and post-CG168 cohorts respectively (hazard ratio, HR, 1.05, 95% CI 0.99, 1.11,  $p=0.096$ ). The median interval between GP diagnosis and referral was 1.5 days in both cohorts. Patients from both cohorts who were referred for a new diagnosis of LU were equally likely to receive SVA.

**CONCLUSIONS:** Disappointingly, we have been unable to demonstrate that publication of NICE CG168 has been associated with a meaningful change in LU management in primary care in line with guideline recommendations.

## Introduction

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In the United Kingdom (UK), the Scottish Intercollegiate Network (SIGN) <sup>1</sup>, the Royal College of Nursing (RCN) <sup>2</sup>, and National Institute for Health and Care Excellence (NICE), in the form of Clinical Knowledge Summary (CKS) <sup>3</sup> and Clinical Guidelines (CG) 168 <sup>4</sup>, have all published recommendations on the management of leg ulcers (LU). Unfortunately, there are important inconsistencies between these different UK guidelines, as well as between UK and international guidelines <sup>5 6</sup>. It is widely accepted by clinicians that the longer a LU has been present, the larger it is likely to be, the longer it is likely to take to heal, the more likely it is to recur, and so the greater the resulting burden on (and cost to) health and social services. As such, there is widespread agreement among vascular specialists that early LU referral, leading to diagnosis and appropriate, evidence-based treatment results in more clinically <sup>7, 8, 9</sup> and cost-effective care<sup>10</sup>. For these reasons NICE CG168, which was published in August 2013 and supersedes all other UK guidelines (outside Scotland) recommends that all people with a LU, defined as a 'skin break, below the knee, which has not healed within 2 weeks', be referred to a specialist vascular service <sup>4</sup>. The aim of the present study was to examine the impact of NICE CG168 on the primary care management and referral of LU using The Health Improvement Network (THIN) database.

## Methods

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This was a retrospective open cohort study using THIN which comprises a database of anonymised routine electronic medical records from over 500 UK general practices that use the Vision patient record system ([www.inps.co.uk/vision/health-improvement-network-thin](http://www.inps.co.uk/vision/health-improvement-network-thin)). THIN includes records from approximately 3 million current and 12 million former patients (about 4.5% of UK population) and is generalisable to the UK population<sup>11</sup>. Data captured in THIN includes demographics, coded symptoms and diagnoses, clinical measurements, prescriptions, and laboratory test results. THIN data collection was approved by the National Health Service (NHS) South-East Multicentre Research Ethics Committee in 2003, with prior approval for individual studies using anonymised data subject to review by an independent scientific review committee (<http://csdmruk.cegedim.com/our-data/ethics.html>) (approval for current study: 16THIN007).

NICE CG168 was published in July 2013. For this study, the pre-CG168 analysis period was 01/01/2012 – 30/06/2013 and the post-CG168 period was 01/01/2014 – 30/06/2015.

The six-month gap immediately after the publication of CG168 was introduced to allow for guideline dissemination to community practitioners (by means of NICE website, local electronic and postal mailing lists from regional healthcare commissioners).

Individual practices were included from the latest of: Vision installation date plus one year (to ensure that they were using the system to its full extent); practice acceptable mortality recording date (to ensure accurate recording of patient deaths and de-registrations)<sup>12</sup>; and the start of the period of interest.

Patients were included in the study if they had been registered with the practice for more than one year so allowing baseline data to be collected by practice and were aged  $\geq 18$  years.

The index date for a new episode of LU was defined as the date of a Read code in a patient record (<http://systems.digital.nhs.uk/data/uktc/readcodes>), if there was no record of LU in the previous year. A referral for an index LU episode was defined as a referral flag in the patient record on the same day as the index episode, or a Read coded entry indicating an outward referral within one day of the index episode. Referrals during follow-up were identified in a similar manner if the patient had a subsequent GP consultation for LU. LU surgery was identified using Read coded records for the procedures of interest. The most recent body mass index (BMI) recorded prior to each index episode was used for the analyses.

Baseline demographic and clinical characteristics of the source population and LU cases for the two periods of interest were described. Chi-square tests were used compare count data, and Wilcoxon rank-sum tests were used to compare non-normally distributed continuous data. Separate Cox proportional hazard models were used to compare the risk of referral and of surgery, both adjusted for patient demographic and clinical characteristics. Multiple imputation (10 imputations) was used to allow cases with missing BMI, Townsend quintile, and urban/rural residence data to be included in the analyses<sup>13</sup>. Model standard errors were adjusted for clustering by practice. Non-linear effects for age and BMI on each outcome were included using fractional polynomials<sup>14</sup>. All analyses were carried out using Stata 14.2.

## Results

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The two cohorts were well matched for age, sex, urban/rural residence, Townsend quintile and ethnicity. There were 7 532 and 7 462 new diagnoses of LU in the pre- and post-CG168 cohorts respectively (**Table 1**). LU incidence (new diagnoses per 1000 patient years) was 28.64 (95% CI 26.44, 31.07) pre-, and 27.85 (95% confidence interval (CI) 25.73, 30.20), post-G168 (adjusted incidence rate ratio IRR=0.97; 95% CI 0.94-1.00;  $p<0.001$ ). When compared to the THIN population as a whole, patients with a new diagnosis of LU were older (median [inter-quartile range, IQR] age 77 [65-86] vs 48 [34-63] years, pre-CG168; 77 [64-85] vs. 48 [34-63] years, post-CG 168), less likely to be male (46.6% vs. 49.0% pre-CG168; 46.9% vs. 48.9% post-CG168), more deprived (**Table 2**), and more likely to live in a rural community. There were 2 259 (30.0%) and 2 329 (31.2%) specialist referrals pre- and post-CG168 respectively (hazard ratio, HR, 1.05, 95% CI 0.99, 1.11,  $p=0.096$ ). There was a median delay between GP recorded diagnosis and specialist vascular service referral of 1.5 days (IQR 1.5-6.1) before and 1.5 (IQR 1.5-1.5) after CG 168 (**Figure 1**). However, the interval between diagnosis and superficial venous ablation (SVA) by means of surgery, endothermal ablation or ultrasound-guided foam sclerotherapy increased from a median of 4.48 months (IQR 3.07-7.47) pre-CG168 to 5.78 (IQR 3.87-10.74) post-CG168. The adjusted Cox model identified age, gender and Townsend scores as significant predictors of LU referral (**Table 3**). Patients in both cohorts were equally likely to receive superficial venous ablation (SVA) (surgery, endothermal ablation or ultrasound-guided foam sclerotherapy) (87 vs 80 procedures, IRR=0.94 95% CI 0.69-1.27;  $p=0.681$ ) as recorded locally in GP electronic records (not linked to hospital episode statistics, HES). The adjusted Cox model identified age and BMI as significant predictors of SVA (**Table 4**, **Figure 2**, **Figure 3**).

## Discussion

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Disappointingly, we have been unable to demonstrate that publication of NICE CG168 has been associated with a change in the primary care management of LU in line with guideline recommendations, with around 70% of people with a new LU still not being referred to a specialist vascular service. Although further research is required to understand why this is the case, reasons may include ignorance of CG168 or a preference for other guidelines (RCN, SIGN, and NICE CKS) which, in stark contrast to CG168, recommend referral only after 12 weeks of failed community management. It is also possible that variable local care

pathways that lack national direction from the UK Department of Health are responsible for varying referral rates, combined with recruitment difficulties in nursing (including district/community nursing) have led to modest and patchy uptake of CG168 through lack of specialist interest in wounds in the community setting. It is also noted that there was a more marked uptake of local guidelines in the authors' catchment area after local promotion of CG168 to community practitioners<sup>15</sup>. Interestingly, however, when people with LU are referred, the referral is made quite quickly from the initial recording of the presence of a LU by the GP in the patient's electronic record. It is likely however that ulcer has been present for some time prior to this and may even have been managed by community nurses before the patient had been reviewed by their own GP.

Our data on Townsend quintiles are in keeping with previous work which has shown an association between LU and increasing social deprivation<sup>16</sup>. Also, as previously observed by others, LU was diagnosed more often in the elderly and in women<sup>17</sup>, although whether this reflects a true gender difference in the incidence of LU is uncertain. The reasons for a higher incidence of LU in the rural population remains unclear, although rural dwelling has been previously identified as a barrier to accessing healthcare<sup>18, 19</sup>. Further work is required to understand if and why certain specific groups of people with LU are either not accessing primary healthcare, or not being referred appropriately to secondary care when they do.

Although the focus of CG168 is varicose veins, its referral recommendations for LU are very clear. Unfortunately, CG168 is not the only NICE guidance where it has been difficult to demonstrate a positive impact on patient care<sup>20</sup>. This may be due to guideline fatigue, especially among GP's. While NICE CG have no legal force, they are often used to benchmark standard of care in medicolegal cases and a failure to implement CG168 seems likely to increase the volume of litigation in this area of practice<sup>21, 22</sup>. Another important issue is that developing NICE CG's requires considerable resources with each guideline costing up to £500K (obtained from freedom of information request). Clinicians may be less willing to give of their time free of charge to sit on NICE advisory guideline committees if they feel that the product of their labours is unlikely to have demonstrable positive impact on patient care.

CG168 led to no increase in SVA for LU and, overall, the number of procedures recorded in the electronic GP record was extremely low. Further work linking THIN to HES would be required to determine if our analysis has underestimated the true intervention rate, especially in certain high-risk groups such as those with an elevated BMI<sup>23</sup>.

Importantly, the recent publication of the landmark study EVRA<sup>24</sup> has demonstrated that early endovenous SVA, with ultrasound-guided foam sclerotherapy being the most frequent modality used, significantly improved rates of ulcer healing, increased time free of ulceration out to 12 months and is highly cost-effective. The publication of this randomised controlled trial should, hopefully, further encourage colleagues in primary care to refer LU patients early to a specialist vascular service for diagnosis and, where appropriate, intervention in line with NICE guidelines<sup>25</sup>. Whilst adoption of CG168 LU guidance is likely to increase costs in the short-term, in the long-term, it is likely to be cost-neutral or better through reduced need for expensive, often prolonged and ineffective community nursing care (lacking specialist direction) and recurrent ulceration.

Unfortunately, our data demonstrates that the great majority LU patients are still not being referred in line with UK NICE national guidelines and so are being denied access to clinically and highly cost-effective healthcare. This requires a re-invigorated approach by the vascular community to advocate improved care for our LU patients. The publication of EVRA should be used by the vascular specialist community, to enhance community knowledge (both patient and healthcare practitioner) and understand the importance of specialist vascular referral and management of leg ulcer patients. CG168's clear guidance on LU should be advertised to healthcare workers involved in wound care as widely as possible to improve compliance and patient outcomes.

## **Conclusion**

In conclusion, LU is a relatively common condition that particularly affects the elderly, women and the socially deprived. The strength of the recommendations in CG168 reflects a convincing evidence base, which shows that prompt referral, diagnosis and treatment of LU not only improves healing and recurrence rates but is also highly cost-effective. It is disappointing that we have been unable to demonstrate that publication of NICE CG168 has been associated with an improvement in LU management in primary care. This is especially so given the results of the EVRA trial. While there may be specific reasons why CG168 LU recommendations have not been implemented, such as the existence of previous conflicting guidelines, the barriers to adoption are perhaps equally likely to be generic such that our data have broader implications for NICE guidelines.



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