National Wound Care Strategy Programme

Excellence. Every Patient. Every Time.

Preventing and Improving Care of Chronic Lower Limb Wounds

Implementation Case

Executive summary

Background

The burden of chronic lower limb wound care is large and growing with significant and unwarranted variation in the use of evidence-based care. There are at least as many people with foot ulcers but without diabetes, as there are people with diabetic foot ulcers, and more than half of all major lower limb amputations are in people that do not have diabetes. The health care needs for both groups are very similar but without diabetes, it is difficult to access the necessary care to prevent amputation and reduce the risk of death.

In 2019, there were an estimated 739,000 leg ulcers in England with estimated healthcare costs of £3.1 billion per annum. The quality of care varies widely and many people with leg ulcers do not receive effective evidence-based care that increases healing and reduces recurrence. Unless action is taken to improve care, the prevalence is predicted to grow by 4% per annum.

This situation presents a valuable opportunity for quality improvement to deliver better patient outcomes and secure better value from existing resources in line with the requirements of the recent NHS Long Term Plan (2019) to prevent harm, increase productivity of staff, and produce financial savings.

This report, prepared by the National Wound Care Strategy Programme ('NWCSP'), assesses the impact of introducing service change to implement the NWCSP recommendations to prevent chronic lower limb wounds and improve care for people with these wounds. It details:

- Projected prevalence of chronic lower limb wounds and associated NHS costs.
- The degree to which care can be improved through service change along with the potential clinical and patient benefits.
- The potential economic and financial benefits from such improvement.
- Potential costs of implementation; and
- Possible timescales to realise the stated benefits.

Key proposals to improve care

1. Change the model of care provision to allow more people with chronic lower limb wounds to receive equitable care in dedicated chronic lower limb services staffed by clinicians with appropriate time, knowledge, and skills and with established referral routes to escalate care.
    - Increase early diagnosis and treatment
    - Deliver care in a clinic setting, where possible
    - Encourage supported self-care, where possible

2. Increase the delivery of evidence-based care for chronic lower limb wounds
    - For arterial leg and foot ulcers
        - Offloading /casting for pressure relief
        - Rapid access to specialist vascular services for vascular reconstruction

        - Optimisation of co-morbidities including disease management

    - For venous leg ulceration:
        - Strong multi-layer compression therapy
        - Endovenous ablation surgery
        - Post-healing compression therapy

3. Improve data and information to support clinical decision making and enable quality improvement to be monitored.
    - Implementation of point of care, NHS compliant digital technology

The impact of implementing the NWCSP recommendations

Changing the model of care provision to enable full implementation of the NWCSP recommendations has the potential to deliver more evidence based and equitable care along with financial benefits to the NHS equivalent to a net present value of £14.6bn and a benefit-cost ratio of 9.8 over 30 years. These benefits are primarily achieved through a c.30% reduction in leg ulcer prevalence from improved leg ulcer healing and recurrence, which in turn will significantly reduce the future cost burden of leg ulcer care to the NHS.

In the first few years following implementation, most of the benefits are expected to be non-cash releasing due to an initial increase in the amount of clinical time and equipment used from increasing the delivery of evidence-based care. However, after several years the reduction in leg ulcer prevalence will lead to a reduction in the consumption of clinical time and equipment, which is expected to generate £9.7bn of cash releasing benefits. When the cost of implementation is included, there will be an estimated £7.8bn of net cash releasing savings, equivalent to a 9% cash saving on the NHE cost of leg ulcer care in England. There is also expected to be £6.8bn of non-cash releasing savings (efficiencies) from an estimated 23% reduction in clinical time spent on lower limb ulcer care which will increase staff capacity. However, it is likely that this saving of clinical time could result in some financial savings. This suggests the cash-releasing savings estimate is likely to be understated.

In addition, it is expected that implementing the NWCSP recommendations could lead to an immediate in-year 11% reduction in the cost of dressings and wound care products. A further 23% in-year saving could be achieved if rapid improvements are made in the delivery of evidence-based care which improves healing and recurrence outcomes.

It is estimated that the implementation of the NWCSP recommendations could cost £225m during a three-year implementation period, with further running costs required thereafter. Full payback can be achieved within six years, although this is based on highly conservative assumptions on when the benefits will be realised. It is also recognised earlier payback could be achieved through different implementation models available.

In addition to the NPV and financial benefits, implementation of the NWCSP recommendations is likely to significantly improve the quality of life for people with chronic lower limb wounds by improving healing, reducing recurrence, and reducing amputation rates. Time spent attending clinical appointments becomes available for work or leisure activities and some people may be able to re-commence paid employment or take up leisure activities that were not possible with an open wound.

There are also financial benefits for patients as healing means that that it is no longer necessary to fund travel costs for clinic appointments or undertake additional laundry for soiled clothing or bed linen. Physical and psychological health will improve as healed

wounds do not smell and are less likely to be painful, reduce mobility and impede sleep. Anxiety about malodour and leakage can lead to social isolation so healing is also associated with psychosocial benefits such as reduction in anxiety and greater willingness to socialise.

Conclusion

Addressing the variation in lower limb care presents a crucial opportunity to tackle the growing burden of wound care, improve the quality of life for people with chronic lower limb wounds and secure better value from existing health care resources.

Contents

Glossary

Term	Description
Amputation	The removal of a part of the lower limb due to failure to heal a wound Minor amputation: below the ankle Major amputation: above the ankle (above or below knee)
Arterial leg ulcer	A wound, of any aetiology, on the leg below the knee and on or above the ankle that fails to progress towards healing as normal due to problems with arterial supply.
Arterial / venous leg ulcer	A wound on the leg below the knee and on or above the ankle that fails to progress towards healing as normal due to problems with both the arterial supply and venous return. This type of ulcer is often referred to as a 'mixed' ulcer.
Benefit cost ratio	The ratio benefits to costs from an intervention – the amount of benefits generated for every £1 of investment.
Compression therapy	See Multi-layer graduated compression therapy
Chronic lower limb wound	Any wound on the leg below the knee that fails to progress towards healing as normal. This includes wounds (ulcers) on the foot or leg.
Critical limb threatening ischaemia	An advanced stage of peripheral artery disease (PAD) usually characterised by continuous foot pain and/or ulcers.
Diabetic foot ulcer	A wound, of any aetiology, on the foot of a person with suspected or proven diabetes mellitus that fails to progress towards healing as normal due to complications with diabetes.
Endovenous ablation surgery	Day-case surgical procedure performed within the vein through a 'keyhole' approach that uses heat or an alternative methodology to close off varicose veins.
Evidence-based care	This represents a form of care underpinned by good quality research, in which patients are treated with compression bandages
Foot ulcer	A wound, of any aetiology, on the foot that fails to progress towards healing as normal.
Interventional radiological **revascularisation**	a medical sub-specialty of radiology that uses minimally invasive image-guided procedures to diagnose and treat venous disease. Endovenous ablation surgery (see above) is an example.
Leg ulcer	A wound, of any aetiology, on the leg below the knee and on or above the ankle that fails to progress towards healing as normal.
Leg Club®	A social model of care where members (patients) are encouraged to be partners in the care they receive and respected as experts in their own condition[1].
MDT	Multi-disciplinary team – a clinical team made up from different clinical professions (e.g. podiatry, nursing, medicine)
'Mixed' leg ulcer	See arterial/venous leg ulcer.
Multi-layer graduated compression therapy	Any combination of bandaging or hosiery layers that apply therapeutic compression ('squeeze') where the greatest pressure is at the ankle and becomes progressively less at the calf.

[1] Further information can be found on https://www.legclub.org/what-is-a-leg-club

	• ‘Strong’ compression therapy is compression therapy that aims to deliver 40mmHg at the ankle which is the recommended compression level for venous leg ulceration • ‘Reduced’ compression therapy is graduated compression therapy that aims to deliver less than 40mmHg at the ankle and which may be appropriate for people with arterial/venous (‘mixed’) leg ulceration.
Net present value	This is the difference between the present value of benefits and present value of costs from a project. This provides a consistent method for measuring the impact of a project where cashflows occur over time.
Normal healing	Cascade of biological events which usually result in restoration of skin integrity over a four to six-week period.
Optimism Bias	This is the natural bias people have in underestimating likelihood and impact of adverse consequences and overestimating the likelihood and impact of desirable outcomes. In practice, optimism bias is captured in numerical estimations by applying a standard reduction to estimated benefits and a standard increase to estimated costs.
Other care	Care that is not underpinned by evidence and best practice. These patients are unlikely to achieve the better healing rates of those receiving evidence-based care
Peripheral arterial disease (PAD)	A condition caused by a build-up of fatty deposits (atheroma) inside the arteries, meaning less blood can get through.
Podiatrist	Clinical specialist in foot wound care
Present value	The value in the present of a sum of money, in contrast to some future value it will have when it has been invested at compound interest.
Pressure ulcer	A wound primarily caused by unrelieved pressure to the skin.
Reduced compression therapy	See ‘Multi-layer graduated compression therapy’
Revascularisation surgery	See ‘Surgical Revascularisation’
Social care model	Clinical care provided within a social environment, an example of which is the Lindsay Leg Club®.
Sensitivity analysis	This is the process of understanding how potential uncertainty and variation in underlying assumptions can affect the results of an analysis conducted. It is used to provide confidence in the robustness of these results.
Strong compression therapy	See ‘Multi-layer graduated compression therapy’
Surgical Revascularisation	A surgical procedure to improve blood flow to a body part or organ that has suffered reduced blood flow. This can be endovascular i.e. using balloons or stents or surgical requiring an operation often in the form of a bypass.
Vascular disease	When venous circulation is compromised by failures within the vein systems that enable venous return from the feet and legs to the heart.
Venous disease	See vascular disease
Venous leg ulcer	A wound on the leg below the knee and on or above the ankle that fails to progress towards healing as normal due to vascular / venous disease.

Wound	A break in the skin which may arise from relatively minor trauma such as knocking a leg or ill-fitting shoes. A wound is referred to as an ‘ulcer’ when it fails to progress towards healing as normal (usually because of an underlying medical or surgical condition e.g. vascular disease)

1 Introduction

1.1 The state of care for people with chronic lower limb wounds in England

The burden of England chronic lower limb wound care[2] is both large and growing and is coupled with significant and unwarranted variation in the use of evidence-based care[3]. This presents a valuable opportunity for quality improvement to deliver better patient outcomes and secure better value from existing resources by preventing harm, increasing productivity of staff, and producing financial savings in line with the requirements of the recent NHS Long Term Plan[4].

The National Wound Care Strategy Programme (NWCSP) has been commissioned by NHS England to develop a wound care national strategy for England. The national strategy is being designed by working with key partners to:

- establish the underlying clinical and economic case for change,
- identify the desirable improvements in patient care and health outcomes, and
- describe the necessary changes and interventions required to deliver these improvements.

Improving all chronic lower limb wound care is one of the programme priorities.

The NWCSP has published clinical recommendations for chronic lower limb wounds[5]. These recommendations build on clinical guidelines which have existed for over 20 years, but which have never been systematically implemented. It is proposed that changing the model of service delivery to enable these recommendations to be implemented in full will achieve better patient outcomes and more effective use of health care resources.

This report supports other ongoing quality improvement initiatives (including a CQUIN for community nursing services[6] and a care element for enhanced care in care homes [7]).

1.2 Purpose of this report

This report, prepared by the National Wound Care Strategy Programme ('NWCSP'), provides a robust and compelling business case for local integrated care systems to adopt a model of care delivery capable of preventing chronic lower limb wounds and improving care for people with these wounds (such as leg ulcers and non-diabetic foot ulcers). It presents findings on the significant financial, economic and health benefits of improving chronic lower limb wound care through changes across the integrated care system to enable the delivery of the NWCSP evidence-based recommendations for chronic lower limb wounds

[2] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that wounds impose on the National Health Service in the UK BMJ Open 2015;5: e009283. doi: 10.1136/bmjopen-2015-009283.
[3] Gray TA, Rhodes S, Atkinson RA, et al 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*;8: e019440. doi: 10.1136/bmjopen-2017-019440
[4] NHS Long Term Plan (2019) https://www.longtermplan.nhs.uk/

[5] NWCSP Draft Recommendations for Lower Limb Care (2020) https://www.ahsnnetwork.com/wp-content/uploads/2020/05/@NWCSP-DRAFT-Lower-Limb-Recommendations-20.03.20.pdf
[6] NHS England (2020) Commissioning for Quality and Innovation (CQUIN) guidance for 2020-2021 (CCG11) https://www.england.nhs.uk/publication/commissioning-for-quality-and-innovation-cquin-guidance-for-2020-2021/
[7] NHS England (2020) The Framework for Enhanced Health in Care Homes (V2) https://www.england.nhs.uk/wp-content/uploads/2020/03/the-framework-for-enhanced-health-in-care-homes-v2-0.pdf

This report does not address care for people with diabetic foot ulcers as that issue falls within the remit of the NHS England National Diabetes Treatment and Care Programme and is thus out of scope for the NWCSP. Similarly, although chronic oedema (lymphoedema) can contribute to foot and leg ulceration, the management of chronic oedema is outside the scope of the NWCSP so not addressed in detail in this report. However, the NWCS acknowledges a unified approach can yield systemic improvements as there is significant overlap in pathology and treatment as well as the teams that manage all these patients.

The report provides an assessment of the impact of implementing the NWCSP recommendations by detailing:

- The projected prevalence of chronic lower limb wounds and the associated costs to the NHS, without any additional improvements in the delivery of care.
- The degree to which care can be improved through changing the structural environment for the delivery of lower limb care to enable the implementation of the NWCSP recommendations, along with the potential clinical benefits resulting from improved leg ulcer healing and recurrence.
- The impact of improved care in reducing both chronic lower limb wound prevalence and the cost burden on the NHS.
- The potential costs required to implement the recommendations of the NWCSP to realise the stated benefits, both in terms of one-off and ongoing costs.
- The possible timescales by which the net benefits can be realised.

This report presents a national picture on the likely impact of the NWCSP recommendations, but the state of wound care can vary significantly across health geographies. Therefore, the model used to underpin the results outlined in this report is made available to enable individual health organisations to customise the model to their local chronic lower limb wound population to inform development of a local case for change.

1.3 The structure of this report

The remainder of this report is structured as follows:

Section 2 describes the case for change in the delivery of chronic lower limb wound care in England. It provides context on the current state of lower limb wound care, the scope for improvement and how implementing the recommendations of the NWCSP can realise these improvements.

Section 3 summarises the approach taken to understand the impact of the NWCSP recommendations, including a summary of the modelling approach and the process by which assumptions and methodology have been verified.

Section 4 presents the results on the impact of the NWCSP recommendations, including the potential cost of implementation and the associated clinical, economic and financial benefits. Section 4 also details the results of sensitivity analysis to test the robustness of the findings and potential limitations of the analysis.

Section 5 concludes the main findings of this report

Section 6,7,8 and 9 are the appendices, detailing the assumptions and methodology used in the analysis, a summary of the estimated annual costs and benefits. Section 9 provides a brief guide for users of the model accompanying this report.

Section 10 acknowledges individuals who have supported the development of this report

2 Improving chronic lower limb wound care

2.1 Introduction to chronic lower limb wound care in England

What are chronic lower limb wounds?

Most wounds heal within a few weeks, but some are much slower to heal (or fail to heal) due to underlying chronic conditions that require appropriate treatment. A chronic lower limb wound is a wound below the knee that fails to heal as normal. Such wounds can be on the leg below the knee, on or above the ankle (leg ulcer) or on the foot (foot ulcer).

Leg ulcers most commonly occur because of problems with blood return through the venous system (venous leg ulceration) but some are due to insufficient blood reaching the lower leg due to peripheral arterial disease (arterial ulceration). Some leg ulcers are due to a combination of both arterial and venous problems ('arterial/venous' or 'mixed' leg ulceration).

Foot ulcers in people without diabetes, usually occur due to peripheral arterial disease, or less frequently due to other causes such as rheumatoid arthritis and connective tissue disorders such as scleroderma.

The impact of chronic lower limb wounds

Chronic lower limb wounds account for at least 42% of all wounds in the UK[1]. Leg ulcers affect many people in the UK and are the most common type of wound accounting for 34% of the total wound population (compared to 7% pressure ulcers and 8% diabetic foot ulcers)[8].

Leg ulceration is more common in older people and among women more than men, although this may be related to the longer life expectancy of women. Living with lower limb ulceration can be miserable due to pain, malodour and leakage, impaired mobility, anxiety, sleep disturbance and social isolation[9].

The implementation of the NICE Guideline for diabetic foot problems[10] which recommends the establishment of multidisciplinary diabetes foot care teams in hospitals and foot protection teams in community has improved care for people with diabetic foot ulceration. However, over half of all major lower limb amputations are now in people that do not have diabetes and minor amputations are rising with the increase driven by non-diabetic men[11].

Chronic lower limb wounds are slow healing so account for a large proportion of the total wound care spend. In 2015, the Burden of Wounds study provided a spotlight on acute and chronic wound care. It estimated that in 2012-13 there were 2.2 million patients with wounds in the UK, with the annual NHS cost of managing these wounds was £4.5- £5.1 billion after adjusting for comorbidities[12]. Since then, the cost of wound care for an average CCG is estimated to have increased from £26.7 million to £50 million pa [13]. A large proportion of this

[8] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that wounds impose on the National Health Service in the UK *BMJ Open* 2015;5: e009283. doi: 10.1136/bmjopen-2015-009283.
[9] Briggs M, Flemming K. Living with leg ulceration: a synthesis of qualitative research. *Journal of Advanced Nursing*. 2007:319-28.
[10] NICE. (2016). Clinical Guideline - Diabetic foot problems: prevention and management. [NG19]
[11] Ahmad, N., Thomas, G. N., Gill, P. & Torella, F. 2016. The prevalence of major lower limb amputation in the diabetic and non-diabetic population of England 2003-2013. Diab Vasc Dis Res, 13, 348-53. 9
[12] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that wounds impose on the National Health Service in the UK *BMJ Open* 2015;5: e009283. doi: 10.1136/bmjopen-2015-009283.
[13] Guest JF, Vowden K and Vowden P, The health economic burden that acute and chronic wounds impose on an average clinical commissioning group / health board in the UK. *Journal of Wound Care* 26 (6) June 2017 292-303.

will be for leg ulcer care but inadequately managed non-diabetic foot ulceration is also likely to incur significant healthcare costs.

Evidence-based therapy for chronic lower limb wounds

Care for chronic lower limb wounds varies according to the underlying cause and is outlined in detail in the NWCSP Recommendations for Lower Limb Wounds[14].

Non-diabetic foot ulcers and arterial leg ulcers are most commonly due to peripheral arterial disease (PAD) leading to severe tissue ischaemia (lack of blood flow to the skin). The current UK prevalence of PAD is unknown but the prevalence rate in higher income countries is estimated to be 7.37% and increasing[15]. Approximately 10% of the PAD population will have critical limb ischaemia[16] (tissue loss and/or rest pain) but of these, a large proportion will **not** have diabetes. The size of the foot ulcer population with no diabetes is unknown but as half of all major lower limb amputations are in people that do not have diabetes[17], non-diabetic foot ulceration is likely to be at least as common as diabetic foot ulceration which is estimated to be at least 60,671 – 75,838 people in England at any given time[18]. Arterial leg ulcers are estimated to account for around 11% of the leg ulcer population. Therapy is based on:

- lifestyle modifications such as nutrition and medical optimisation and smoking cessation,
- surgical or interventional radiological revascularisation,
- pain management,
- minimising the risk of infection, and
- offloading/ pressure reduction[19].

Healing arterial foot and leg ulcers is challenging but people with untreated arterial foot and leg ulcers have an increased risk of amputation or premature death. Success is usually measured by avoidance of adverse outcomes such as infection and limb amputation.

Venous leg ulcers are the most common cause of leg ulceration and usually estimated to be around 65% of the leg ulcer population[20]. Therapy is based on improving venous return through:

- strong multi-layer graduated compression therapy[21] [22,23].
- endovenous ablation surgery[24].

[14] NWCSP Lower Limb Recommendations https://www.ahsnnetwork.com/wp-content/uploads/2020/05/@NWCSP-DRAFT-Lower-Limb-Recommendations-20.03.20.pdf
[15] Song, Peige; Rudan, Diana; Zhu, Yajie; Fowkes, Freya J I; Rahimi, Kazem; Fowkes, F Gerald R; Rudan, Igor. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis *Lancet Glob Health* 2019 Aug;7(8):e1020-e1030.
[16] Song, Peige; Rudan, Diana; Zhu, Yajie; Fowkes, Freya J I; Rahimi, Kazem; Fowkes, F Gerald R; Rudan, Igor. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis *Lancet Glob Health* 2019 Aug;7(8):e1020-e1030.
[17] Ahmad N, GN Thomas, Gill P et al. Lower limb amputation in England: prevalence, regional variation and relationship with revascularisation, deprivation and risk factors. A retrospective review of English hospital data. *J R Soc Med*. 2014 Dec;107(12):483-9
[18] Kerr M. Diabetic foot care in England: an economic study. Internet Document: Jan 2017. Available from: URL: https://www.diabetes.org.uk/Upload/Shared%20practice/Diabetic%20footcare%20in%20England,%20An%20economic%20case%20study%20(January%202017).pdf
[19] Bus et al. Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update). *Diab Metab Res Rev*. 2020. e3274.
[20] Cullum N, Buckley H, Dumville J, Hall J, Lamb K, Madden M, et al. Wounds research for patient benefit: a 5-year programme of research. *Programme Grants Appl Res* 2016;4(13).
[21] Nelson EA, Adderley U. Venous leg ulcers. *BMJ Clin Evid*. 2016;2016
[22] Ashby RL, Gabe R, Ali S, Adderley U, Bland JM, Cullum NA, et al. 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. *The Lancet*. 2014;383(9920):871-9.
[23] Nelson EA, Bell-Syer SEM. Compression for preventing recurrence of venous ulcers. *Cochrane Database of Systematic Reviews*. 2014(9)
[24] Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, Cullum N, et al. A Randomized Trial of Early Endovenous Ablation in Venous Ulceration. New England Journal of Medicine. 2018;378(22):2105-14.

With appropriate therapy, about three-quarters of people with venous leg ulcers should heal within 12 months, although about two-thirds should heal within 6 months [21].

Arterial/venous ('mixed') ulcers are estimated to account for 23% of the leg ulcer population[11] and are caused by a combination of venous and arterial insufficiency. Therapy is based on improving venous return through reduced compression therapy (at a level that will not impede arterial blood flow) and improving arterial blood flow through surgical revascularisation and lifestyle changes. Healing rates for mixed ulcers will depend on the severity of arterial insufficiency.

Chronic lower limb wounds can be caused by other conditions such as sickle cell anaemia, pyoderma gangrenosum and autoimmune conditions such as rheumatoid arthritis, but these forms of ulceration are much rarer.

Care Provision for chronic lower limb wounds

In England, care for people with chronic lower limb wounds is provided by a variety of health care providers including general practice, podiatry, community nursing services, care homes, secondary care in-patient and out-patient services which are all parts of the emerging integrated care systems in England. Mobile patients commonly receive wound care from practice nurses in general practice while the housebound receive care from community or district nursing services. Despite the high numbers of patients, this often translates into a low volume of chronic lower limb wound care per nurse and wound care is squeezed by competing priorities such as palliative care or respiratory care. As a result, the quality of care varies widely, and many patients never receive appropriate evidence-based care or experience significant delay in receiving the correct care.

In a few localities, there are dedicated chronic lower limb wound care services where care is provided by clinicians with the appropriate knowledge and skills who implement evidence-based pathways of care with established referral routes to escalate care as needed. Such services are delivered by a variety of providers, including community nursing services, general practice collaboratives, secondary care services, community interest companies or social models of care such as the Leg Club®.

It is worrying that across England, relatively few people with chronic lower limb wounds have access to services staffed by clinicians with sufficient knowledge and skills and time to provide appropriate care. The inequality of care for people with diabetic foot ulcers compared to those with non-diabetic foot ulcers is particularly worrying, especially in light of the emerging evidence that suggests that early access to 'at risk' foot clinics may significantly reduce the risk of major lower limb amputation at 12 months [25].

2.2 The scope for improvement

There is a well-established research-informed evidence base to inform the care of a people with venous leg ulceration. Although there is less research evidence to inform the care for people with foot ulcers or arterial leg ulceration but no diabetes, the principles of caring for these ulcers is the same as for diabetic foot ulcers (i.e. off-loading, infection control,

[25] Nickinson, A. T. O., Dimitrova, J., Rate, L., Dubkova, S., Lines, H., Gray, L. J., Houghton, J. S. M., Nduwayo, S., Payne, T. J., Sayers, R. D. & Davies, R. S. M. 2019. Adopting a new model of care for treating patients with chronic limb threatening ischaemia: early results of a vascular limb salvage clinic. *medRxiv,* 19013037.

debridement and early revascularisation) which makes the current inequity of care unacceptable. It is likely that improving diagnosis and care for all people with chronic lower limbs will improve outcomes for all types of wounds through enabling swifter access to appropriate care.

Numerous audit reports indicate ongoing unwarranted variation in England wound care services, underuse of evidence-based practices and overuse of ineffective practices [1,26, 27,28.] To ensure patients are receiving the best outcomes, the NWCSP recommends that people with chronic lower limb wounds should have:

- Early access to high quality evidence-based diagnostics and therapies
- Clinical care provided by clinicians with appropriate levels of knowledge and skills working within a co-ordinated multi-disciplinary team system with referral pathways into specialist services.
- Following healing, lifelong follow-up care to reduce the risk of recurrence.

Foot ulceration

The most common type of foot ulceration in people with no diabetes is due to peripheral arterial disease (PAD). Treatment is based on revascularisation surgery with the aim of reducing the risk of amputation and death. Revascularisation surgery is cheaper than amputation mostly due to lower rehabilitation costs[29] but also often leads to higher quality of life (although some patients will be best served by primary amputation followed by high-quality rehabilitation, rather than often repeated and ultimately unsuccessful attempts at revascularisation.[30])

The NICE clinical guideline for peripheral arterial disease 2012[31] makes numerous care recommendations including the need for multi-disciplinary assessment. However, evidence suggests that there appear to be missed opportunities for timely diagnosis of critical limb threatening ischaemia within general practice[32] and ongoing problems with referral pathways to vascular services. These often lead to lengthy delays in accessing appropriate care[33,34,35] and such delays are associated with poor limb-salvage outcomes[36]. Although there has been a national drive to implement interdisciplinary foot care services for people with

[26] Srinivasaiah N, Dugdall H, Barrett S, Drew PJ. A point prevalence survey of wounds in north-east England. *Journal of Wound Care*. 2007;16(10):413-9.
[27] Vowden K, Vowden P. The prevalence, management and outcome for patients with lower limb ulceration identified in a wound care survey within one English health care district. *Journal of Tissue Viability*. 2009;18:13-9.
[28] Gray TA, Rhodes S, Atkinson RA, et al 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*;8: e019440. doi: 10.1136/bmjopen-2017-019440
[29] Panayiotopoulos, Y. P., Tyrrell, M. R., Arnold, F. J., Korzon-Burakowska, A., Amiel, S. A. & Taylor, P. R. 1997. Results and cost analysis of distal [crural/pedal] arterial revascularisation for limb salvage in diabetic and non-diabetic patients. *Diabet Med*, 14, 214-20.
[30] Bradbury Aw, A. D., Bell J, Forbes Jf, Fowkes Fgr, Gillespie I, 2010. Multicentre randomised controlled trial of the clinical and cost-effectiveness of a bypass-surgery-first versus a balloonangioplasty- first revascularisation strategy for severe limb ischaemia due to infrainguinal disease. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial. Health Technology Assessment.
[31]NICE Guideline Peripheral arterial disease: diagnosis and management Clinical guideline [CG147] https://www.nice.org.uk/guidance/cg147/chapter/Recommendations
[32] Nickinson, A., Coles, B., Payne, T., Davies, R., Khunti, K. & Sayers, R. 2019. Missed Opportunities for Limb Salvage in Patient Undergoing a Major Amputation: A Cohort Study Using the Clinical Practice Research Datalink. *European Journal of Vascular and Endovascular Surgery*, 58, e569-e570.
[33] Nickinson A, Bridgwood B, Houghton J. et al. A systematic review investigating the identification, causes, and outcomes of delays in the management of chronic limb-threatening ischemia and diabetic foot ulceration. *Journal of Vascular Surgery*. 2020;71(2):669–681.e2. http://dx.doi.org/10.1016/j.jvs.2019.08.229.
[34] Normahani P, Mustafa C, Standfield NJ, et al. Management of peripheral arterial disease in diabetes: a national survey of podiatry practice in the United Kingdom. *J Foot Ankle Res*.2018;11:29.
[35] Pankhurst CJW, Edmonds ME. Barriers to foot care in patients with diabetes as identified by healthcare professionals. *Diabet Med*. 2018;35:1072-1077.
[36] Bradbury Aw, A. D., Bell J, Forbes Jf, Fowkes Fgr, Gillespie I, 2010. Multicentre randomised controlled trial of the clinical and cost-effectiveness of a bypass-surgery-first versus a balloonangioplasty- first revascularisation strategy for severe limb ischaemia due to infrainguinal disease. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial. *Health Technology Assessment*.

diabetes, there has been no national strategic effort to implement similar services for people with foot ulcers but no diabetes, even those there are at least as many patients facing similar limb and life threatening risk.

Some areas are establishing one-stop shop models of conjoined care where patients with lower limb chronic wounds but no diabetes have access to a team with multi-disciplinary expertise in assessing and managing lower limb ischaemia, venous disease and other potential co-morbidities. These are few but emerging evidence suggests that access to 'at risk' foot clinics appear to significantly reduce the risk of major lower limb amputation at 12 months [37].

Leg ulceration

The most common type of chronic lower limb wound is venous leg ulceration. There is rigorous evidence to suggest that evidence-based therapies greatly improve healing rates and prevent recurrence for these wounds. For example, compression therapy more than doubles the number of people with venous leg ulcers healed at one year compared to no compression[38]. Following healing, compression therapy reduces the likelihood of recurrence by more than half[39]. Endovenous ablation is a cost-effective adjunctive surgical therapy for both improving venous leg ulcer healing and preventing recurrence[40].

The NWCSP recommendations for chronic lower limb wound care echo the Royal College of Nursing[41] and SIGN[42] [43] clinical guidelines for venous leg ulcers which were first produced in 1998 and updated in 2010. However, these recommendations have never been implemented in a systematic way across England.

Studies in Canada[44] and the UK[45] showed that successful implementation of leg ulcer clinical guidelines requires services with organisational structures that allow the delivery of evidence-based practice. These services are characterised by:

- Dedicated services providing both clinic and home care staffed by registered clinicians with additional training in leg and foot ulcer care,
- Appropriate staffing levels and skill mix to ensure sufficient clinical time, expertise, and experience to provide quality care,
- High quality data capture and reporting to inform clinical care and enable quality improvement
- Adequate financing to ensure sufficient time and clinical equipment,
- Robust communication and referral routes between primary care, community services, secondary care and third sector health care organisations
- Expert clinical leadership

[37] Nickinson, A. T. O., Dimitrova, J., Rate, L., Dubkova, S., Lines, H., Gray, L. J., Houghton, J. S. M., Nduwayo, S., Payne, T. J., Sayers, R. D. & Davies, R. S. M. 2019. Adopting a new model of care for treating patients with chronic limb threatening ischaemia: early results of a vascular limb salvage clinic. *medRxiv,* 19013037.
[38] O'Meara S, Cullum N, Nelson EA, Dumville J. Compression for Venous Leg Ulcers. Cochrane Database of Systematic Reviews 2012. 2012;Issue 11(Art. No.: CD000265. DOI: 10.1002/14651858.CD000265.pub3.)
[39] Nelson EA, Bell-Syer SEM. Compression for preventing recurrence of venous ulcers. Cochrane Database of Systematic Reviews. 2014
[40] Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, Cullum N, et al. A Randomized Trial of Early Endovenous Ablation in Venous Ulceration. New England Journal of Medicine. 2018;378(22):2105-14.
[41] Royal College of Nursing. (1998) Clinical Practice Guidelines: the nursing management of patients with venous leg ulcers. 1998
[42] SIGN. The Care of Patients with Chronic Leg Ulcer. http://wwwsignacuk/pdf/sign26pdf. 1998.
[43] SIGN. Management of chronic venous leg ulcers - a national clinical guideline2010 04.09.2015. Available from: http://www.sign.ac.uk/guidelines/fulltext/120/.
[44] Harrison MB, Graham ID, Lorimer K, Friedberg E, Pierscianowski T, Brandys T. Leg-ulcer care in the community, before and after implementation of an evidence-based service. CMAJ : Canadian Medical Association Journal. 2005;172(11):1447-52.
[45] Moffatt CJ, Franks P. Implementation of a leg ulcer strategy. *Br J Dermatol* 2004;151:857-67.

Studies show that such services demonstrate greatly improved clinical outcomes and efficiencies, more than doubling healing rates and reducing nursing input by a third[43,44]. In England, there are some dedicated chronic lower limb wound care services, but they are few and provision is patchy. These services report high healing rates for venous leg ulcers and more cost-effective use of resources in line with those cited above.

Improving care for all lower limb chronic wounds

Addressing the variation in the delivery of care presents a golden opportunity to address the growing burden of wound care, improve the quality of life for people with chronic lower limb wounds and secure better value from existing health care resources. The most easily quantifiable improvements relate to venous leg ulcer care, but improvements in lower limb chronic wound services are likely to improve the care for all types of chronic lower limb wounds (such as non-diabetic arterial foot ulcers, mixed or arterial leg ulcers or chronic lower limb wounds due to more unusual conditions) by improving access to clinical expertise.

The knowledge and skills needed to assess and diagnose the causes of non-healing are similar for all types of lower limb chronic wounds. Therefore, dedicated chronic lower limb wound care services should be designed to meet the needs of people with all types of chronic lower limb wounds. The concept of 'tiers of care' that was established for the management of diabetic foot ulcers, lends itself well to other forms of chronic lower limb ulceration. The tiers of care range from community-based lower limb services which undertake initial assessment and provide ongoing care through to centres of excellence which provide specialist limb salvage services for complex cases. Such services could be in the form of a community hub staffed by clinicians with appropriate knowledge and skills with direct referral routes into relevant services such as vascular services, podiatry or dermatology, or as an integrated lower limb service that incorporates such speciality services.

It is a key recommendation of this business case that the commissioning process for chronic lower limb services should include care for other lower limb wounds besides venous leg ulcers. This will reduce the risk of inequality in care leading to poor quality of life with significant pain and morbidity. Improving the provision of lower limb chronic wound care will work towards a more equitable and clinically effective service for people with foot and leg ulcers, whatever the underlying cause of their ulceration.

2.3 Delivering the opportunity

To realise the opportunity in improving patient outcomes and reduce the future burden of chronic lower limb wound care, the NWCSP recommends taking a transformative approach to improving care by:

1. **Changing the model of care provision** to allow more people with chronic lower limb wounds to receive care in dedicated chronic lower limb services staff by clinicians with appropriate time, knowledge and skills and where there are established referral routes to escalate care as needed.
    - Increase early diagnosis and treatment

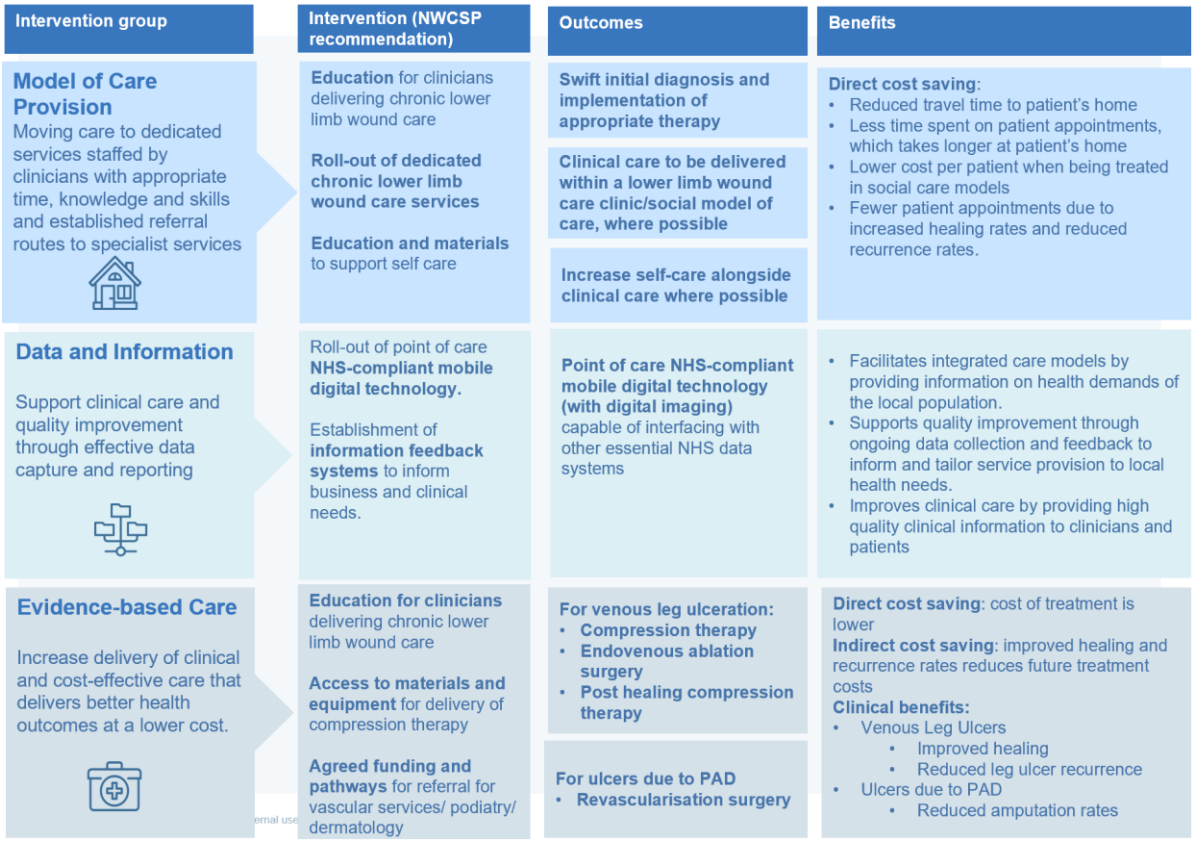
- Deliver care in a clinic setting, where possible
- Encourage supported self-care, where possible
- Referral routes for escalation of care as appropriate.

2. **Increasing the delivery of evidence-based care**
   - For arterial leg and foot ulcers
     - Offloading /casting for pressure relief
     - Rapid access to specialist vascular services for vascular reconstruction
     - Optimisation of co-morbidities including disease management
   - For venous leg ulceration:
     - Strong multi-layer compression therapy
     - Endovenous ablation surgery
     - Post-healing compression therapy

3. **Improving data and information** to support clinical decision making and enable quality improvement to be monitored.
   - Implementation of point of care, NHS compliant digital technology

Figure 1 below summarises the interventions that will be required to deliver these improvements.

Figure 1 Summary of NWCSP interventions



Such transformation would prevent chronic lower limb wound recurrence and harm, improve wound healing, increase staff productivity, and get better value from existing resources in line with the requirements of the recent NHS Long Term Plan[46].

Increasing the delivery of care through dedicated chronic lower limb services

Organisations that have moved to delivery of care to dedicated chronic lower limb services have achieved significant benefits, as illustrated by these examples:

Figure 2 Case study, Leeds Community Healthcare Trust

Introducing Lower Limb Wound Clinics
Leeds Community Healthcare Trust

In 2019, Leeds Community Healthcare Trust sought expressions of interest from their local GP practices to develop an integrated wound clinic within their Primary Care Networks (PCNs) utilising the skills of practice and community nurses. Many practices expressed interest which led to implementation of such clinics.

Patients with venous leg ulceration, who had not previously received a diagnosis or appropriate care are now in compression and healing. New ways of working have also led to success. For example, the Band 4 self-management facilitator has contributed to real improvements in self-care such as the elderly obese man with type 2 diabetes and an ulcer on the ankle, who now has normal blood sugar levels and whose ulcer has healed.

Patient satisfaction has been very positive with 99% are either likely or extremely likely to recommend the service to friends and family. Typical patient feedback is very positive:

"Very informative and gave me confidence they knew what they were doing"

"Fantastic - even the surgeon complimented the nurse on her expertise"

"Thank you for turning me into a human being with normal legs. I'll never forget your hard compassionate and competent work and for not giving up on me."

[46] NHS Long Term Plan 2019. Accessed at https://www.england.nhs.uk/long-term-plan/ 02.04.19

Where social models have been implemented, the benefits have extended beyond improved healing rates and efficient staff deployment, to deliver additional psychological benefits for patients.

Figure 3 Case study, The Adam Practice Leg Club, Poole

Significant benefits from social models of care
The Adam Practice Leg Club, Poole

In 2015, The Adam Practice in Poole, made the biggest transformational change to a service that it had seen in 25 years. By taking on the Leg Club® model and providing care in community settings such as church halls, with expert treatment from practice and district nurses, the lives of many patients have been transformed.

Leg Clubs® are a social model which see patients treated by nurses in non-clinical environments in accordance with strict clinical guidelines. They empower members to take control of their own conditions, giving them treatment as well as preventative advice while giving the opportunity to meet others in their situation. It is a model that addresses loneliness head on as well as helping to address a £5.3 billion annual cost.

There were challenges setting up the Leg Club, for example finding the right location, somewhere with storage – and eventually finding somewhere bigger when it outgrew its existing location. However, it has all been a huge team effort. Primary care nurses are now working side by side with community district nurses, sharing experience and information.

Gradually, the numbers at each session increased. The socially isolated became volunteers, making new friends who had been through the same challenges they had. They attended the weekly sessions for a coffee and a catch up, even if they no longer needed treatment for their legs. Many of them found a new focus, fundraising for this much needed community facility. In fact, enough money was raised to buy a minibus driven by volunteers which is used to pick up patients who are home-bound and would normally be treated by a district nurse.

Healing rates have been greatly improved with some patients finding their ulcers that normally took a couple of years to heal were healed within three to six months.

Increasing the delivery of evidence-based care

However, delivering lower limb chronic wound care through a dedicated service, is not in itself sufficient to achieve benefits. It is essential that care is underpinned by an evidence-based pathway and such services are staffed by registered clinicians with additional training in leg and foot ulcer leg care and the time to provide appropriate care.

Figure 4 Case study, North Lincolnshire and Goole NHS Foundation Trust

Importance of implementing evidence-based care
North Lincolnshire and Goole NHS Foundation Trust

North Lincolnshire and Goole NHS Foundation Trust has a GP-commissioned daily wound clinic delivered by the local community nursing service. The clinic has run since 2000 receiving referrals from primary care. An audit of 30 patients referred from general practice found that they had not received Doppler (ABPI) assessments or compression for long periods, sometimes years until they were eventually referred into the chronic wound clinic. Once in clinic they received full assessment including Doppler, and started compression. The average time to healing was 59 days from starting the pathway.
A second audit in 2017 of patients with leg ulcers in their own homes under the care of district nurses found only 40% of patients with a chronic lower limb wound were receiving a Doppler assessment and only 33% were in compression therapy. None of these were in full compression. A review of the service revealed low levels of skills and knowledge.
A new evidence-based care pathway was introduced in 2017, and staff were supported with education and training. Full holistic assessment was introduced for all people with lower limb wounds. Where appropriate, full compression therapy is offered, and self-care is actively encouraged. People receiving compression are mostly using hosiery or wraps, rather than bandaging. Healing rates have improved.
Patients engaging in self-care using dressings with compression hosiery kits and wraps report to this to have ‘changed their lives’.

Expert clinical leadership is also needed along with robust communication and referral routes between primary care, community services, secondary care and third sector health care organisations to ensure the delivery of evidence-based care and rapid access to appropriate clinical services.

Integrated services that incorporate relevant services such as vascular, podiatry or dermatology services or services staffed by clinicians with appropriate knowledge and skills who can directly refer into such services, enable timely and well-co-ordinated care.

Figure 5 Case study, Manchester University NHS Foundation Trust

Integrated wound care pathways

The Manchester Amputation Reduction Strategy (The MARS Project)

The MARS Project in Salford has piloted integrated and co-ordinated cross-discipline working to improve wound care for lower limb wounds. The team of over 30 clinicians, is led by a consultant podiatrist and provides evidence-based care in the community and two hospital settings.

The service now offers emergency appointments within one working day and A&E can book patients directly into the daily hospital foot clinic. People with leg ulcers can be booked into the foot multi-disciplinary team (MDT) clinic allowing all lower limb wounds access to MDT input. Closer collaborative working has resulted in the cross pollination of skillsets e.g. podiatrists learning compression bandaging and tissue viability nurses undertaking toe pressure vascular assessments. All staff use the same online assessment form, domiciliary visits can be augmented by real-time online MDT review and vascular investigations can be ordered by non-medical senior clinicians. Approximately 40% of their workload is for people with foot ulcers without diabetes.

Early results suggest that appropriate referrals for vascular surgical input have increased (from 61% to 93%) and there is now easier movement of patients between services, reduced duplication of care and a growing culture of multi-professional collaboration.

Figure 6 Case study, University Hospitals of Leicester NHS Trust,

Fast access to vascular services

Leicester Vascular Limb Salvage ('VaLS') clinic

The aim of the Leicester Vascular Limb Salvage ('VaLS') clinic is to reduce time-to-treatment (referral to revascularisation <14 days) and reduce major amputation rates. VaLS is a 'one-stop', nurse-led, rapid-access clinic offering a dedicated service for patients with critical limb threatening ischaemia (CLTI).

The clinic opened in February 2018 and is led by two full-time specialist nurses, an administrator, vascular scientist, and a consultant vascular surgeon. The clinic runs Monday-Friday (08:00-16:00) and provides four consultations per day. Referrals are accepted from any healthcare professional (community or primary/secondary care) who suspects CLTI and the clinic aims to see patients within two days of referral. At the clinic, patients undergo clinical assessment by a specialist nurse followed by imaging (e.g. duplex ultrasound). Treatment is planned in consultation with a supervising consultant vascular surgeon, with dedicated 'fast-track' endovascular and surgical revascularisation slots available.

The clinic is co-ordinated by the vascular surgery department in partnership with key stakeholders and is being evaluated in collaboration with the University of Leicester. Early results show that from 294 patients assessed within the clinic, 222 (75.5%) were managed for CLTI. Since the VaLS clinic was implemented, the rate of major amputation has reduced from 19.4% to 9.5% and amputation-free survival at 12 months has increased from 60.7% to 74%.

Improving data and information to support clinical decision making and enable quality improvement to be monitored.

Good quality data and information is essential to inform both clinical care and quality improvement, but current data and information for wound care is very poor. In the recent Carter review, it was reported that most trusts do not capture basic information on wound care including the number of patients with wounds, wound types, treatment plans or, most critically, wound healing rates and there is no reliable prospective data for chronic lower limb wounds, apart from diabetic foot ulcers.

Clinicians need good quality data to inform treatment decisions, enable continuity of care, support decision making and to enable audits to identify unwarranted variation and support improvement programmes. The business function of the NHS needs good quality data for commissioning and contract management, service management, business case development and performance management.

Organisations that have prioritised high quality data collection alongside quality improvement initiatives have been able to demonstrate significant improvements in both the quality of care delivered and the achievement of better outcomes.

Figure 6 Case study, Accelerate CIC

Data and information for quality improvement
Accelerate CIC

Accelerate CIC is a specialist community service that provides care for people with people who live with complex non-healing wounds and/or lymphoedema. Since 2019 Accelerate has been the direct provider of leg ulcer clinics, where previously it was the community nursing service. As part of contract management in Tower Hamlets Accelerate reports on healing rates across their service delivery as well as the impact their service has on outcomes within community nursing and primary care.

The Accelerate specialist service is delivered by Band 3-7 clinicians competent in both wound care and lymphoedema.

Care Delivery	Compression pre assessment	Assessment including ABPI	Compression post assessment	Healing at 12 weeks	Healing at 24 weeks
Leg ulcer clinics: Venous ulcers	26%	99%	99%	65%	91%
All CCG commissioned services*: Venous ulcers	28%	97%	98%	61%	90%
Leg Ulcer clinics: all other aetiologies*	25%	99%	97%	51%	79%

* Community Nursing, Primary Care, Leg ulcer clinics
**Examples of other aetiologies include mixed ulcers or ulcers associated with vasculitis, sickle cell disease or intravenous drug use

The impressive healing rates sit alongside a very high usage of both diagnostics and compression therapy. Unfortunately, this data was not collected previously so no comparison can be provided but the data shows the low use of compression at referral to specialist services for the more complex wound. A recent CCG wide audit found 70% of all lower limb wounds were receiving compression therapy. These results clearly demonstrate the improvement that is possible when appropriate care is delivered by knowledgeable and skilled clinicians.

Organisations that have introduced point of care high quality data and information systems have found benefits for both clinical practice and business functions.

Figure 7 Case study, Kent Community Health NHS Trust

Data and information for improving clinical care
Kent Community Health NHS Trust

In 2015 Kent Community Health NHS Trust needed a data and information system that could capture wound images and assessment information at the point of care to support their wound care patient pathway which were being delivered through their new 'Wound Medicine Centres'. These Wound Medicine Centres are staffed by tissue viability specialists to support community nurses caring for people complex wounds. The first of these centres was established in 2016 and there are now 5 across Kent.

The Kent data and information system allows community nurses to capture an image using a mobile device and record essential wound care data (such as diagnosis of wound type, wound tissue type, factors that may delay healing) in a structured assessment process. The technology can also measure wound surface area, length, width and volume and analyse the percentage of granulation, slough and necrotic tissue. The system is supported by a secure central storage solution that enables tissue viability clinician to provide phone advice to community nurse colleagues.

The data and information system supports a more consistent approach to wound assessment which, in turn, supports more accurate diagnosis and better treatment planning

The Wound Medicine Centres are already achieving better healing rates than other services, despite caring for people with more complex conditions, justifying the investment in the data and information system.

NHS pressures make it imperative that data collection should be secondary to operational practice to avoid creating additional administration. It is also essential that data systems should have the functionality to collect data and provide information at national, regional level, integrated care system level, local provider level and clinician level. For clinicians who deliver wound care, it is particularly important that such systems are also capable of handling digital images and can support opportunities for tele-health. The NWCSP is producing recommended specifications for mobile digital technology applications suitable for wound care. (Appendix 1)

Technological data solutions capable of meeting these needs are now available and offer the opportunity to support quality improvement for chronic lower limb wounds. With reliable information on the state of wound care, providers can tailor the care they provide to local conditions, adhere to best practice clinical pathways and monitor the progress of the interventions as part of ongoing quality improvement.

Although lack of evidence means it is not possible to quantitatively model the benefits of improving data capture, investing in data technology is a key enabler to improve chronic lower limb wound care. Furthermore, it is also recognised that many other areas of care would benefit from such investment made as part of the NWCSP recommendations.

3 Approach to understand the impact of the NWCSP recommendations

3.1 Summary of methodology

This analysis seeks to estimate the annual cost of chronic lower limb wound in England. The impact of the NWCSP recommendations has been assessed by firstly modelling the current state of chronic lower limb wound care in England (the 'baseline'), to then understand change in outcomes following the introduction of NWCSP recommendations (the 'To-be').

The analysis and underlying modelling have been developed in line with government appraisal guidance, particular with reference to the Green Book[47] and Comprehensive Investment Appraisal (CIA)[48] guidance, as detailed in section 8.2.

The below diagram summarises the methodology used to model the impact of the NWCSP recommendations. Further detail on the assumptions and methodology is in Section 8.1.

Figure 2 Summary of modelling approach

1. Project chronic lower limb wound prevalence	Chronic lower limb wound prevalence was taken from academic evidence following a review of available studies (approach is detailed in section 0) and was projected using an epidemiological stock-and-flow model, in which wounds accumulate over time based on the relative healing and recurrence of wounds on an annual basis. New wounds are grown based on demographic growth and it is assumed the healing and recurrence rates are constant over time. The presence of comorbidities is also likely to influence wound incidence; however, this could not be modelled due to a lack of data.
2. Estimate resource consumption per wound	The average amount of resources used to treat each type of wound on an annual basis was estimated. Estimates for clinical nurse time for wound care, compression therapy and dressings are based on bottom-up modelling of different types of treatment pathways. All other estimates, such as for drug prescriptions, hospital admissions, GP visits are taken from published academic evidence.
3. Apply unit cost and inflation	Unit costs for have been taken from standard sources such as PSSRU Unit Costs of Health and Social Care 2019, NHS Prescription Cost Analysis data and National Cost Collection data. Inflation assumptions are from NHSE/I Economic assumptions 2016/17 to 2020/21
4. Introduce intervention impacts and costs	A review of evidence was undertaken to understand how implementing the NWCSP recommendations would change key assumptions in the model. For example, this includes increasing the healing rate and reducing the recurrence rate to reflect clinical improvements, as evidenced by academic RCT studies. The associated costs of introducing these interventions were also estimated. The impact of the interventions is therefore the difference in outcomes with and without the interventions (i.e. To-be versus Baseline)

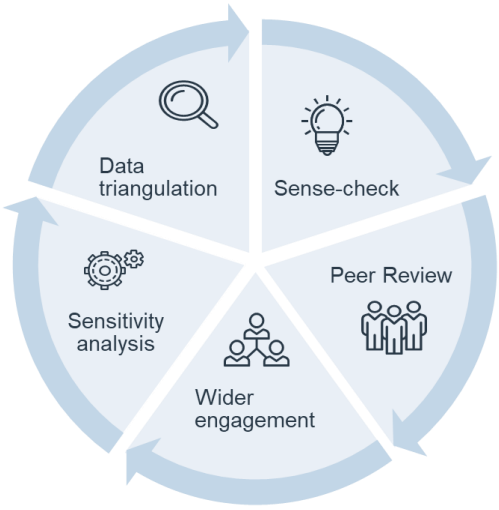
[47] HMT (2020), The Green Book: appraisal and evaluation in central government
[48] DHSC (2019), Comprehensive Investment Appraisal (CIA) Model and guidance

As the interventions modelled are largely based on available academic evidence and advice from clinical experts, the results in this report should be viewed as an approximation of the achievable outcomes and not interpreted as the precise outcomes that will result from these recommendations.

3.2 Approach to assumptions gathering

Throughout the analysis, a triangulation approach has been used to determine assumptions and inform modelling decisions. Assumptions and methodology have then been iteratively sense-checked with wound care experts, academics, clinicians, and stakeholders. The diagram below summarises this process.

Figure 3 Approach to assumptions gathering



Data triangulation

The assumptions underpinning the analysis have been triangulated from a range of sources.

Research evidence

A review of published research evidence was undertaken to obtain key assumptions where possible. However, limited resources prevented the completion of a series of full systematic reviews to search and critique all the existing relevant literature. Therefore, the following process was adopted to identify key literature:

1) Publications on the prevalence of chronic lower limb wounds

To obtain estimates on prevalence of chronic lower limb wounds a review was conducted of existing academic evidence. This initially adopted the results of a literature search for prevalence studies for an NIHR study[49] undertaken to March 2012. The search strategy was then repeated to search for publications from January 2012 to May 2020, as detailed in

[49] Cullum N, Buckley H, Dumville J, Hall J, Lamb K, Madden M, et al. Wounds research for patient benefit: a 5-year programme of research. *Programme Grants Appl Res* 2016;4(13).

Figure 4 below. This exercise identified 1098 possible studies of which 4 publications were potentially relevant [50,51, 52, 53].

Figure 4 Search strategy for leg ulcer prevalence

Search Strategy for Publications reporting Prevalence of Leg Ulceration
Using OvidSP, an electronic search in MEDLINE (January Week 1 2012 – May Week 1 2020) was undertaken as follows: 1. exp Skin Ulcer/ 2. exp Leg Ulcer/ 3. exp Pressure Ulcer/ 4. exp Foot Ulcer/ 5. exp Diabetic Foot/ 6. (skin ulcer$or foot ulcer$or diabetic foot or diabetic feet or leg ulcer$or varicose ulcer$or venous ulcer $or stasis ulcer$or arterial ulcer$or neuropathic ulcer$).tw. 7. ((ischaemic or ischaemic) adj (wound$or ulcer$)).tw. 8. (bed sore$or pressure sore$or pressure ulcer$or decubitus ulcer$).tw. 9. (chronic adj (wound$or ulcer$)).tw. 10. or/1–9 11. exp Epidemiology/ 12. exp Prevalence/ 13. (prevalence or audit or survey).tw. 14. 11 or 13 or 12 15. 10 and 14

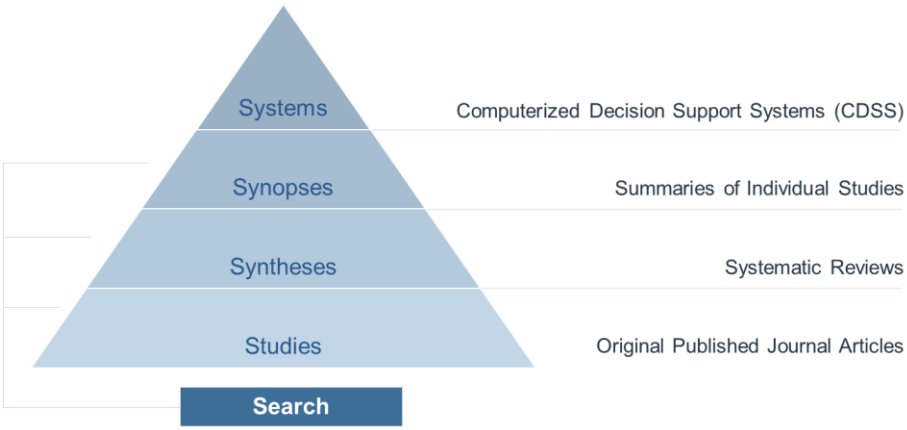
Further relevant publications were identified from suggestions from NWCSP Board and workstream members.

2) Interventions for treating chronic lower limb wounds

[50] Gray TA, Rhodes S, Atkinson RA, et al 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*;8: e019440. doi: 10.1136/bmjopen-2017-019440
[51] Onida S; Davies AH. Predicted burden of venous disease. [Review] *Phlebology*. 31(1 Suppl):74-9, 2016 Mar.
[52]Coull AF; Atherton I; Taylor A; Watterson AE. Prevalence of skin problems and leg ulceration in a sample of young injecting drug users. *Harm Reduction Journal*. 11:22, 2014 Aug 13.
[53] Nelson EA, Adderley U. Venous leg ulcers. Systematic review 1902. *BMJ Clinical Evidence*. 2016 January

To obtain assumptions on the potential impact of interventions resulting from the NWCSP recommendations, a 4S approach[54] was used to structure a search strategy as shown.

Figure 5 4S search strategy approach



- *Systems*: searched UK computerised decision support systems for chronic lower limb wounds. Two were identified relating venous leg ulceration[55, 56,] and one relating to peripheral arterial disease [57].

- *Synopses*: searched for summaries of the current state of knowledge about the prevention and treatment of chronic lower limb wounds. This identified two papers relating to venous leg ulceration [58, 59,] and one relating to peripheral arterial disease[60]. These are cited in the NWCSP Lower Limb Recommendations.

- *Syntheses*: searched the Cochrane Library of Systematic Reviews to identify reviews for chronic lower limb wounds leg ulcer treatment. 25 completed reviews were identified for leg ulceration. This found three reviews with robust evidence of the effectiveness of certain interventions for venous leg ulceration. These are all cited in the NWCSP Lower Limb Recommendations [61], [62, 63]. 45 reviews were identified that related to peripheral arterial disease, but none related to foot ulceration.

- *Studies*: searched the NIHR library for NIHR funded studies completed after publication of the relevant Cochrane systematic reviews for venous leg ulceration. Ten studies were identified relating to venous leg ulceration. Two found robust

[54] Haynes RB Of studies, syntheses, synopses, and systems: the "4S" evolution of services for finding current best evidence *BMJ Evidence-Based Medicine* 2001;6:36-38.
[55] NICE (2020) Leg ulcer – venous https://cks.nice.org.uk/leg-ulcer-venous
[56] NHS (2020) Venous Leg Ulcer https://www.nhs.uk/conditions/leg-ulcer/
[57] NICE (2018) Peripheral arterial disease https://cks.nice.org.uk/peripheral-arterial-disease
[58] Nelson EA, Adderley U. Venous leg ulcers. Systematic review 1902. *BMJ Clinical Evidence*. 2016 January
[59] SIGN. 2010. *Management of chronic venous leg ulcers - a national clinical guideline*. https://www.sign.ac.uk/sign-120-management-of-chronic-venous-leg-ulcers
[60] NICE (2018) Peripheral arterial disease: diagnosis and management https://www.nice.org.uk/guidance/cg147
[61] O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database of Systematic Reviews* 2012, Issue 11. Art. No.: CD000265. DOI: 10.1002/14651858.CD000265.pub3.
[62] Jull AB, Arroll B, Parag V, Waters J. Pentoxifylline for treating venous leg ulcers. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD001733. DOI: 10.1002/14651858.CD001733.pub3
[63] Nelson E A, Bell-Syer S. (2014) Compression for preventing recurrence of venous ulcers Cochrane Systematic Review

evidence of effectiveness[64], [65] and these are cited in the NWCSP Lower Limb Recommendations. A search for NIHR funded studies for treatments for critical limb threatening ischaemia found two studies[66, 67].

Further relevant publications were identified from suggestions from NWCSP Board and workstream members.

The retrieved literature for venous and mixed leg ulceration included sufficient robust research data to model improvements for this type of chronic lower limb wound. However, it was not possible to model improvements for other types of chronic lower limb wounds due to insufficient research data.

Most foot ulcers are associated with peripheral arterial disease (PAD) but a review of the literature found insufficient evidence to robustly estimate the potential improvements that could arise through avoided care costs and lower mortality. It is possible to estimate the prevalence of non-diabetic foot ulcers and the cost of amputation and life-time costs of post amputation care but there are significant gaps in relation to other necessary data such as lifetime cost of revascularization, avoided health system costs and survival rates relating to patients without revascularization surgery. Without such data, meaningful modelling is not possible. The literature search did retrieve some publications around the opportunities to improve the identification of PAD in primary care and the possible impact of quick access to 'at risk' foot clinics but, as the papers themselves state, these are early findings so insufficient upon which to base a financial case.

Therefore, the financial modelling in this report is only focused on venous and mixed leg ulceration. However, the inclusive approach proposed in this report is likely to lead to improvements for all types of lower limb chronic wounds because lower limb chronic wounds are typically managed by the same clinical teams and face the same issues of variation in practice and outcome as known to exist for leg ulcer care.

Sense-check

Throughout the development of the business case, assumptions and results were compared and contextualised against existing evidence and data to sense-check the assumptions and understand their real-world applicability. Where there was a lack of research data, the views of academics and clinicians were used to identify and agree on certain assumptions which were subsequently sense-checked across various stakeholder groups. Furthermore, all assumptions have been stress-tested to understand the potential impact of inaccuracies as part of the sensitivity analysis of the results. Outputs of the sensitivity analysis are located in Section 4.3.

[64] Ashby R, Gabe R, Ali S, Saramago P, Chuang L, Adderley U, et al. VenUS IV (Venous leg Ulcer Study IV): 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(57)

[65] Gohel MS, Heatley F, Liu X, Bradbury A, Bulbulia R, Cullum N, et al. A Randomized Trial of Early Endovenous Ablation in Venous Ulceration. *New England Journal of Medicine*. 2018;378(22):2105-14.

[66] Bradbury Aw, A. D., Bell J, Forbes Jf, Fowkes Fgr, Gillespie I, 2010. Multicentre randomised controlled trial of the clinical and cost-effectiveness of a bypass-surgery-first versus a balloonangioplasty- first revascularisation strategy for severe limb ischaemia due to infrainguinal disease. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial. Health Technology Assessment.

[67] Simpson, E. L., Kearns, B., Stevenson, M. D., Cantrell, A. J., Littlewood, C. & Michaels, J. A. 2014. Enhancements to angioplasty for peripheral arterial occlusive disease: systematic review, cost-effectiveness assessment and expected value of information analysis. Health Technol Assess, 18.

Peer Review & wider engagement

All assumptions and methodology were reviewed as part of an iterative peer review process to question the validity of the results against clinical practice experience and understand the extent to which given assumptions were likely to be subject to high levels of uncertainty.

The peer review process was carried out in 4 stages. The dates and participants of the peer review process is detailed in section 8.2.

Stage 1: **Consultation with academics and clinicians with direct experience of establishing lower limb wound clinics.**

This involved three academics and two clinicians who provided an initial sense-check of key assumptions and supported the collection of data for the modelling of the chronic lower limb wound clinics under the To-be scenario.

Stage 2: Consultation with clinicians delivering wound care

Fourteen clinicians from the NWCSP Expert Reference Group (whose members are nominated by NHS England's regional Chief Nurses) were invited to take part in the consultation. Four nurses accepted and were joined by the leads for the NWCSP Lower Limb workstream and a clinician involved in the NWCSP Data and Information workstream work relating to chronic lower limb wounds. This stage was carried out iteratively and was used to sense-check and refine the real-world applicability of key assumptions. A consensus approach was taken in response to feedback from participants, all of which was considered in the decisions relating to both the assumptions and modelling approach. Much of the feedback and queries resulting from this process has informed the discussion in this report regarding the assumptions and modelling approach.

Stage 3: Consultation with members of the NWCSP Lower Limb Workstream

All fifteen members of the NWCSP Lower Limb workstream were invited along with an additional member of the Leg Club®. Twelve members participated in the consultation which enabled a further sense check of the emerging key assumptions and provided feedback to inform the narrative of the report.

Stage 4: Consultation with registrants of the NWCSP Health and Care Professionals Stakeholder Forum.

A survey was conducted to seek consultation with registrants of the NWCSP Health and Care Professionals Stakeholder Forum on important clinical modelling assumptions relating to leg ulceration that other peer reviewers had questioned. 813 registrants who had expressed an interest in lower limb ulcer care were asked to indicate their views on healing rates, the frequency of leg ulcer appointments, the duration of leg ulcer appointments, and the potential share of patients eligible for certain types of care. 187 registrants provided data.

This data was used to sense-check the respective assumptions and provide alternative values that could be tested as part of the sensitivity analysis. A summary of the survey results of the 187 responses is in section 8.4

Sensitivity analysis

The results of the analysis were stress-tested through sensitivity analysis which seeks to understand the impact on the results of uncertainty in key assumptions and provide a level of confidence in the results. The tested assumptions were selected based on being both impactful to the results and having a high degree of uncertainty, as suggested by feedback from the peer review and wider engagement process. With such assumptions, the results were stress-tested based on their most reasonably pessimistic values. Where the results were highly sensitive, further refinement and review was carried out to limit the level of uncertainty associated with the assumption. The scenarios tested are detailed in section 8.7.

4 The impact of the NWCSP recommendations

This section describes the results of the modelling to understand the impact of implementing the NWCSP recommendations in England. Detail on the assumptions underpinning this analysis is in section 8.

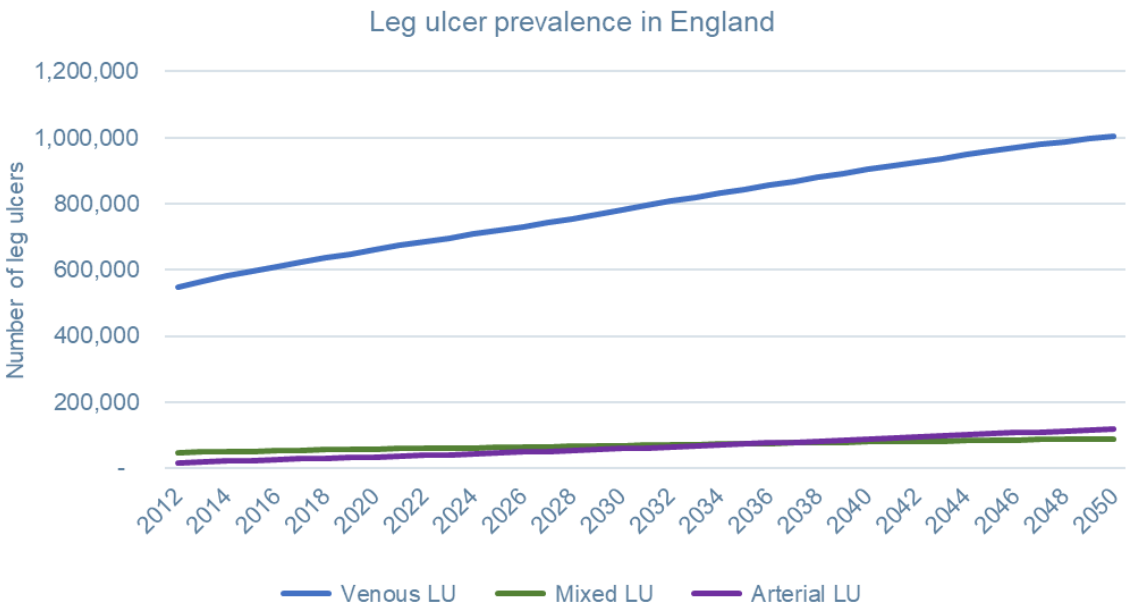
4.1 The current state of leg ulcer care in England

In 2019, there were an estimated 739,000 leg ulcers in England, of which 649,000 were venous leg ulcers, 57,000 were mixed leg ulcers and 33,000 were arterial leg ulcers.

Without intervention, the prevalence of total leg ulcers is expected to increase by around 4% annually, to over 1.0 million by 2036 (Figure 6 below). This growth is driven by an accumulation of leg ulcers that either do not heal or recur once healed. For example, more than half of venous leg ulcers fail to heal within 12-months and of those that do heal, more than half are likely to recur within 12 months. This accumulation of unhealed and recurred wounds over time means that over 80% of leg ulcers prevalent in 2019 are leg ulcers that existed in previous years. Therefore, improving healing and recurrence outcomes could have a significant impact in reducing overall leg ulcer prevalence.

This projection of leg ulcer volumes is in line with estimates from Guest et al (2017)[68] and Guest (2017)[69] who estimates there being 731,000 leg ulcers in 2012/13 across the UK.

Figure 6 Projected leg ulcer prevalence in England

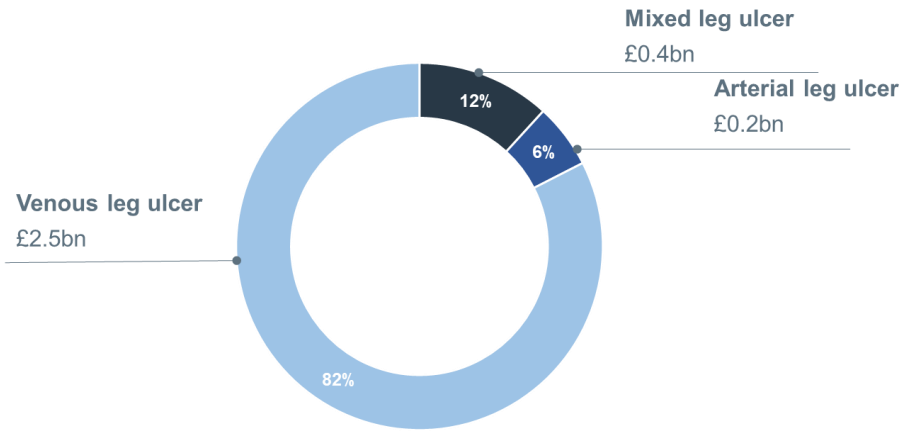


[68] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal. 2017

[69] Guest JF, Vowden K, Vowden P. The health economic burden that acute and chronic wounds impose on an average clinical commissioning group/health board in the UK. Journal of Wound Care. 2017 Jun;26(6):292-303. DOI: 10.12968/jowc.2017.26.6.292.

The NHS cost of leg ulcer care in England is estimated to be £3.1bn in 2019. As shown in Figure 7 below, over 80% of this cost relates to treatment of venous leg ulcers, with mixed and arterial leg ulcers making up the remaining total cost. This is in line with Guest et al (2016)[12] who estimates the 2012/13 cost as being £1.9bn across the UK, with the difference largely arising because of the steady growth in leg ulcers between 2012 and 2019.

Figure 7 NHS cost of leg ulcer care, 2019



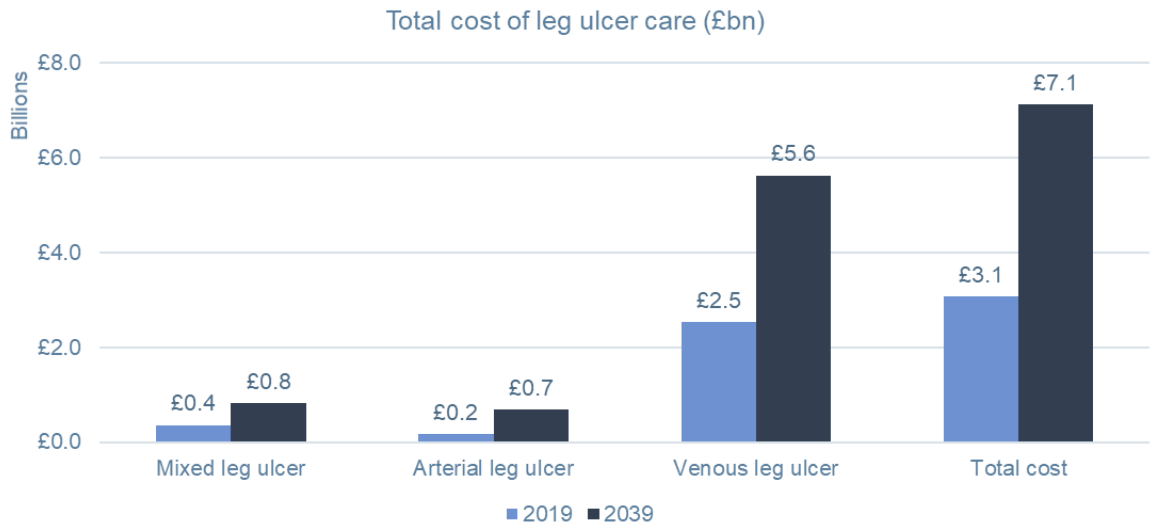
As shown in Figure 8 below, over 30% of the NHS cost of leg ulcer care in England is attributed to clinical time (community nurses, practice nurses, GP visits), of which over half is community nurse time. This high share of cost is because people with leg ulcers need dressing/bandage changes at least weekly, with each appointment lasting between 20 minutes to 35 minutes each. A large share of these appointments take place at the patient's home where appointments generally take longer than in a clinical setting and which also incur travel time for nurses.

Figure 8 Total NHS cost by item, 2019

Item	Total cost (£m)	Share of total cost
Hospital admissions	£1,057.5	34.4%
Community nurses	£488.5	15.9%
Prescriptions for anti-infectives	£277.5	9.0%
GP visits	£256.0	8.3%
Practice nurses	£198.0	6.4%
Dressings and bandages	£181.5	5.9%
Hospital outpatient visits	£171.5	5.6%
Prescriptions for analgesics	£122.6	4.0%
Laboratory Tests	£119.6	3.9%
Compression bandages	£107.6	3.5%
Devices	£69.9	2.3%
Compression hosiery	£13.3	0.4%
Other staff (Allied and specialist)	£9.9	0.3%
Total	**£3,073.4**	**100%**

Without intervention, the total cost of leg ulcer care in England is expected to more than double over the next 20 years, to £7.1bn (Figure 9 below).

Figure 9 Cost of leg ulcer care, 2019 vs 2039



This cost growth is driven by the c.4% annual growth in leg ulcer prevalence from the accumulation of unhealed and recurred leg ulcers along with demographic growth affecting the incidence of new leg ulcers. This annual growth in leg ulcer volumes is cautious compared to that from Guest et al (2017) who estimates c.9% growth per annum[12].

4.2 The impact of implementing the NWCSP recommendations

4.2.1 Improvements from intervention

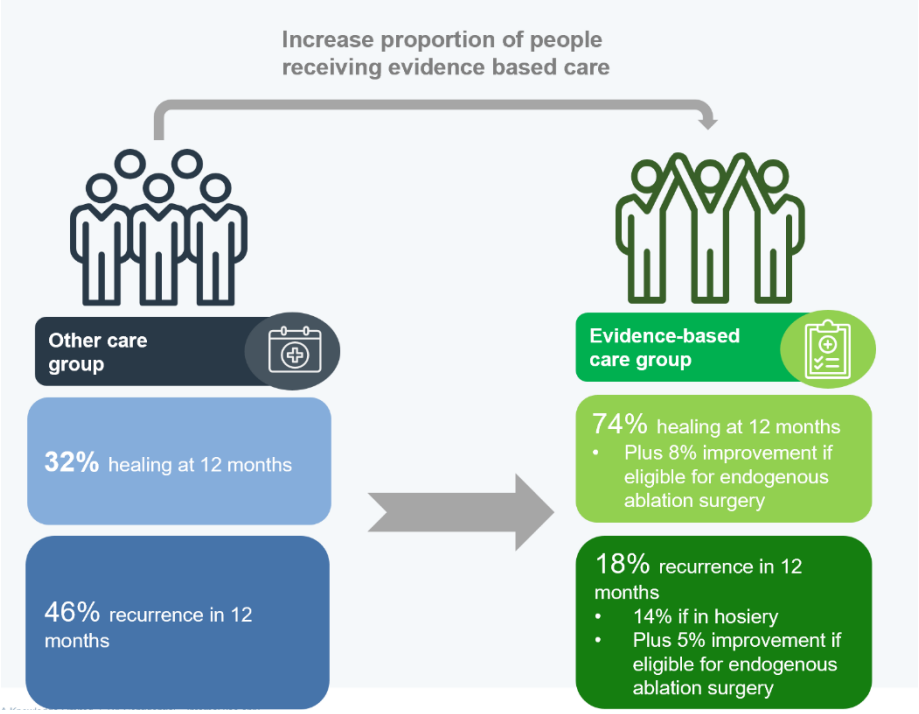
The NWCSP recommendations seek to increase the delivery of evidence-based care that delivers the best possible patient outcomes in terms of improved healing rates and reduced recurrence rates. This section outlines the expected clinical improvements from implementing the NWCSP recommendations. The underlying evidence and methodology underpinning these estimates are detailed in section 8.6.1.

Clinical improvements for venous leg ulcers

It is estimated that at present, 69% of current venous leg ulcer patients are treated with compression therapy (bandaging, hosiery or wraps) which is the mainstay of effective evidence-based care for both promoting healing and reducing the risk of recurrence. At least 74% of these patients are expected to heal within 12 months, with only 18% of healed leg ulcers recurring within 12 months. The chance of recurrence rate can be reduced further to 14% for patients who able to wear compression hosiery. For patients willing and able to undergo surgery (about 58% of all VLU patients) early endovenous ablation surgery can also lead to a further 8% improvement in the healing rate and a further 5% improvement in the recurrence rate.

However, 31% of patients currently receive other forms of care ('other care') that are not underpinned by such robust research evidence. For patients receiving such care, the healing rates will be much lower and the recurrence rates much higher than for patients who receive evidence-based care. For example, it is expected that only 32% patients receiving other forms of care will heal within 12 months and almost half (46%) of healed leg ulcers will recur within 12 months. Therefore, increasing the proportion of patients receiving evidence-based care could significantly improve clinical outcomes for a large number of patients. This is summarised in the diagram below.

Figure 10 Increase proportion of people receiving evidence-based care, VLU



As an ambition, increasing the share of people with venous leg ulceration receiving evidence-based strong compression care from 69% to 90% could enable over 20% more patients to receive better clinical outcomes. Increasing the number of people receiving endovenous ablation and post-healing compression hosiery will further increase healing rates and reduce recurrence rates. It is therefore estimated that improving leg ulcer care in this way could increase the average 12-month healing rate across the entire venous leg ulcer population from 47% to 60% and could reduce the recurrence rate from 48% to 37% (Figure 11 below)

Figure 11 average healing and recurrence rate across all VLUs

	Healing rate	Recurrence rate
Baseline (pre implementation)	47%	48%
To-be (post implementation)	60%	37%

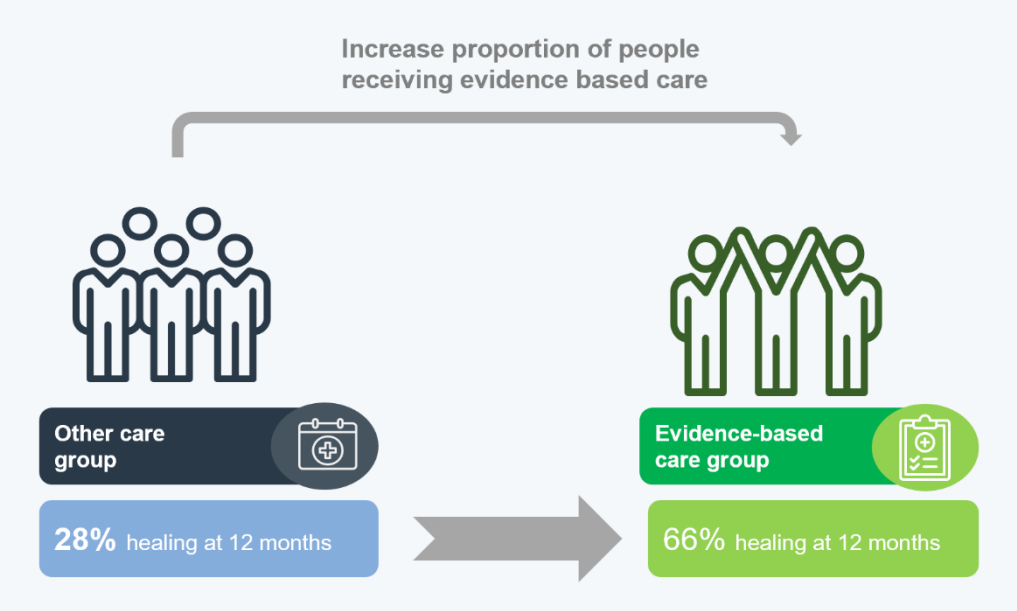
Improved healing and recurrence will enable more leg ulcers to heal and remain healed, therefore reducing the accumulation of leg ulcers, which in turn will reduce the cost of leg ulcer care to the NHS. It is recognised that these estimates are cautious, with there being numerous examples of much greater improvements available.

Clinical improvements for mixed leg ulcers

It is estimated that 36% of current 'mixed' (arterial/venous) leg ulcer patients are treated with effective evidence-based care, consisting of reduced compression therapy and revascularisation surgery (for those willing and able to undergo surgery). As a result of receiving the most effective care available, at least 66% of these patients are expected to heal within 12 months.

However, 64% of patients receive currently 'other care' that is not underpinned by evidence and best practice. These patients are likely to receive much worse healing outcomes of those receiving evidence-based care. For example, it is expected that only 28% patients receiving other forms of care will heal within 12 months. Therefore, by increasing the share of patients receiving evidence-based care, the NWCSP recommendations can significantly improve clinical outcomes for a large number of patients. This is shown in the diagram below.

Figure 12 Increase proportion of people receiving evidence-based care, mixed leg ulcer



As an ambition, being able to increase the share of patients receiving evidence-based compression therapy from 36% to 90% could enable over 54% more patients to receive better clinical outcomes. It is estimated that this could lead to the average 12-month healing rate across the entire mixed leg ulcer population to increase from 42% to 62% (

Figure 13 below)

Figure 13 average healing rate across all mixed leg ulcers

	Healing rate
Baseline (pre implementation)	42%
To-be (post implementation)	62%

Clinical improvements for arterial foot and leg ulcers

Treatment for arterial foot and leg ulcers is based on revascularisation surgery (for those willing and able to undergo surgery) and conservative management aimed at reducing the risk of infection and amputation. A significant proportion of patients with arterial foot and leg ulcers will have severe peripheral arterial disease and other co-morbidities that will form significant barriers to healing. The literature on arterial foot and leg ulcers suggests unacceptably high amputation rates[70]. Given that amputation is a highly expensive procedure and would involve significant rehabilitation and care costs, reducing the risk of amputation could lead to significant financial and health benefits. Although it has not been possible to model improvements for this group of patients due to a lack of data, service evaluation data suggests that providing care through structured services leads to better care outcomes and more effective use of health care resources.

Financial savings from cost-effective treatment

Dressings and wound care products

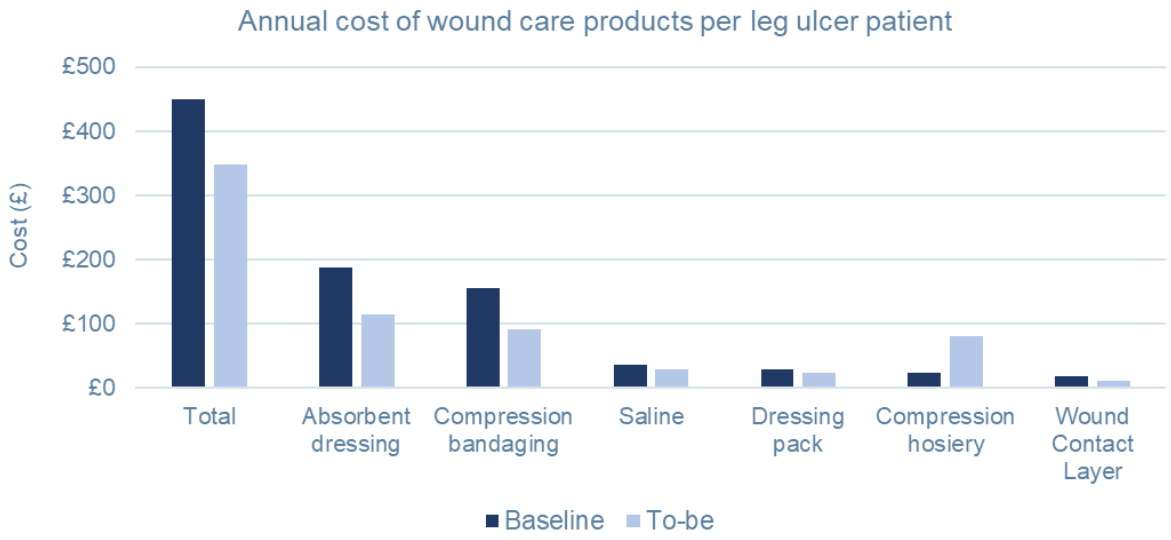
Currently, a large amount of the spend on leg ulcer care is related to wound care products such as dressings, bandaging and hosiery. It is estimated that at present, the average leg ulcer patient is likely to require over £400 of wound care products every year.

The dressings recommended for use with compression therapy (simple, low adherent dressings) cost less than the dressings typically used in the absence of compression so financial savings on dressing spend within the same year of implementation is likely. Furthermore, the increased use of compression therapy products will also improve patient healing and reduces recurrence, which too could reduce the amount spent on wound care products within the same year of implementation.

It is therefore expected that implementing the NWCSP recommendations could lead to an immediate in-year 11% reduction in the spend on dressings and wound care products. Furthermore, as shown in the diagram below, a 23% in-year saving could be achieved if rapid improvements are made in the delivery of evidence-based care which improves healing and recurrence outcomes.

[70] Ahmad N, GN Thomas, Gill P, et al. The prevalence of major lower limb amputation in the diabetic and non diabetic population of England 2003-2013. *Diab and Vasc Dis Research* 2016;13(5):348-53

Figure 14 Average annual cost of dressings per leg ulcer patient, 2023



Care at home

Providing leg ulcer care in a patient's home tends to be more expensive than at a clinic. This is partly because home appointments tend to take 25% to 35% longer than clinic appointments and clinicians will require time to travel to a patient's home. The recommendations of the NWCSP seeks to increase the treatment of patients in either a local clinic setting or through a social care model. This will help reduce the amount of clinical time spent on lower limb wound care and support the delivery of consistent care.

4.2.2 The implementation costs to realise these improvements

In order to increase the number of people receiving evidence-based care, it is necessary to change the delivery model of chronic lower limb wound care, as detailed in section 2. The below table summarises the interventions required to make this happen, along with the expected costs for implementation and ongoing running.

The costs outlined in this section apply to dedicated wound care clinics but do not include the costs of specialist services (such as vascular, podiatry or dermatology services) which may be integrated within such wound care clinics, or to which patients may be referred.

Further detail on the assumptions behind this costing is in section 8.6.3.

Figure 15 Summary of implementation costs

Item	Cost (£)	Detail
Non-recurrent costs		Implementation costs only incurred during the implementation period
Lower limb wound care education	Band 4 - £600 Band 5 - £786 Band 6 - £954 £7.7 in total, over 3 years	During implementation, lower limb wound care education will be provided for all clinical staff delivering lower limb wound care as a key part of their role. • 4 days of education for clinical staff working in wound clinics, leg ulcer social care models or delivering lower limb wound care at home (56%). • 1 day of education for clinical staff who only occasionally provide first line care for people with lower limb wounds (44%). Band 7 and 8 are assumed to have adequate knowledge so do not receive any training. The cost of training is based on clinician time spent at training.
Lower limb wound clinic set-up costs	£1.42 per patient, £0.5m in total	This largely relates to the cost of purchasing vascular Doppler machines, as rent (running costs) covers most equipment costs and the data capture costs (below) include imaging devices.
Hardware purchase for data capture	£0.6m per year over 3 years	Each room of the lower limb wound care clinic will need a 2D imaging device, which is £1,000 each.
Programme implementation	c. £17.4m per year over 3 years	It is assumed a Band 8c (Project Manager) and Band 5 (admin) will be employed over three years of implementation, to lead implementation across the CCGs undertaking the change.
Monitoring and evaluation	£3.5m over 3 years	Several years after implementation, evaluation of the success of the interventions, will be needed as part of ongoing quality improvement
Recurrent costs		Annual running costs of the intervention, phasing in at start of implementation and being incurred thereafter
Annual ongoing refresher education	Band 4 - £225 Band 5 - £295 Band 6 - £358 c. £0.3m each year	All clinical staff delivering lower limb wound care will be able to access a 1-day training refresher course. It is assumed 10% of the baseline clinician workforce each year will undertake the refresher education
Leg ulcer social care model	£80 per member per year c. £12.0m per year	Some members are treated in a social care model (such as a Leg Club®) • This is the incremental administrative cost of running a leg ulcer social care model. It is assumed members (people with leg ulcers) attend the leg ulcer social care model in the same way they would a clinic. • In practice, the cost of treating patients in a social care model is likely to be less than in a clinical setting, as people with leg ulcers are treated as a community in a collective environment so clinician time per member is likely to be less. However, it is not possible to estimate the clinician time savings due to lack of data.
Lower limb wound clinic running costs	£154 per patient per year c. £55m per year	This is the rent for clinical space for the wound care clinics and the cost of clerical support (Band 3 clerical). It is assumed clinical staff will be redeployed from existing services so no additional clinical cost will be incurred. This cost also does not include direct treatment costs, which are assumed constant across the different care settings. Very few wound care clinics provide patient transport, so travel costs have not been included in the model.
Annual software data capture cost	c. £10.0m per year	All clinicians who care for people with lower limb wounds will require a wound care app. It is estimated the mobile apps will cost £50,000 per 300,000 adult population per user.

To implement the recommendations across England, there is expected to be £225m of implementation costs during the implementation period

If the proposals are implemented over a three-year period, taking a staged approach with increasingly greater numbers of implementation sites (e.g. 2020-2022[71]) an estimated £225m of implementation costs is required[72]. Almost 50% of this cost is attributed to the cost of running the lower limb wound clinics (rental cost and administrative cost). This could be an overestimate as conservative assumptions have been used in relation to the cost of clinical rental space and a 30% optimism bias adjustment has been included.

Figure 16 Implementation period costs, 2020-2022

Costs (£m)	2020	2021	2022
Lower limb wound clinic set-up costs	£0.5	£0.0	£0.0
Lower limb wound clinic running costs	£18.5	£38.6	£60.3
Leg ulcer social care model	£4.1	£8.5	£13.3
Lower limb wound care education	£2.5	£2.6	£2.6
Programme management costs	£17.0	£17.4	£17.8
Annual software data capture cost	£3.2	£6.4	£9.8
Hardware purchase for data capture	£0.6	£0.6	£0.6
Total	**£46.3**	**£74.1**	**£104.5**

The total cost of implementing the NWCSP recommendations across England, including ongoing running costs until 2050, has a present value of £1.9bn. The majority of this relates to the set-up and running costs of the wound care clinics, as shown below.

[71] The findings of this report are based on an assumed national implementation programme that has a duration of three years, however there could be other models that take shorter or longer periods
[72] Includes 30% optimism bias as standard

Figure 17 Present value of implementation costs

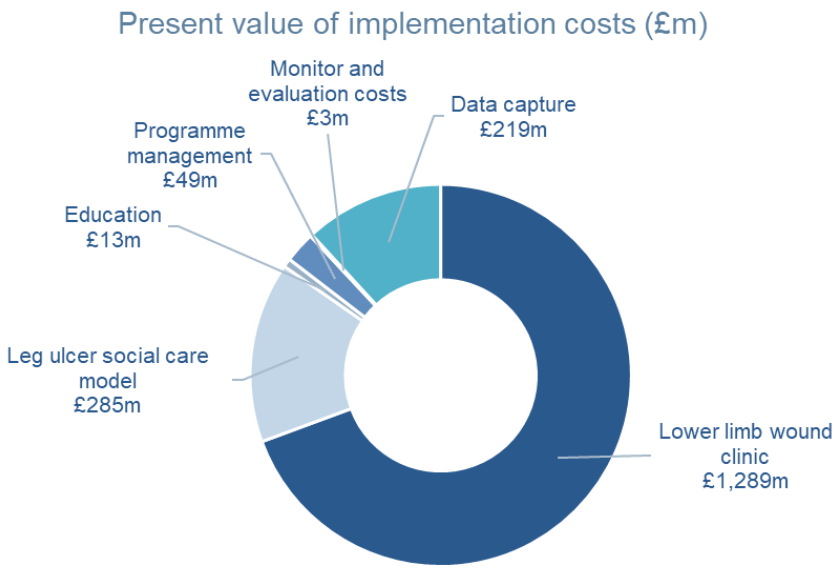


Figure 18 Case study, Leeds Community Healthcare Trust

Rolling out of wound clinics
Leeds Community Healthcare Trust

Leeds Community Healthcare Trust is implementing integrated wound clinics across their Primary Care Networks (PCN). Three waves of implementation are planned:

1. Wave 1: Some PCNs already had a service and were willing to adapt that service to a common model (which included use of a standard EMIS and SystmOne data template for data capture, a Band 5 nursing model, clinical governance arrangements to capture incidents, use of the citywide formulary, willingness to accept new patients from the neighbourhood teams within the local NHS trust and patient satisfaction surveys)

2. Wave 2: PCNs that did not have an existing service but wanted to develop a service as outlined above.

3. Wave 3: To develop weekend and evening opening hours and develop new clinics to cover any gaps in service.

4.2.3 The impact of the NWCSP recommendations

A c.30% annual reduction in leg ulcer prevalence in England

As described in section 4.2.1, implementing the NWCSP recommendations will increase the delivery of evidence based care to patients, enable faster healing and reduce recurrence. In turn, this will reduce the prevalence of leg ulcers.

As shown in diagram below, it is expected that implementing the NWCSP recommendations could achieve a c.30% reduction in the prevalence of leg ulcers in the long term. For example, in 2036 there is expected to be just over 1 million leg ulcers in England without intervention, but this reduces to 0.7 million following the implementation of the NWCSP recommendations.

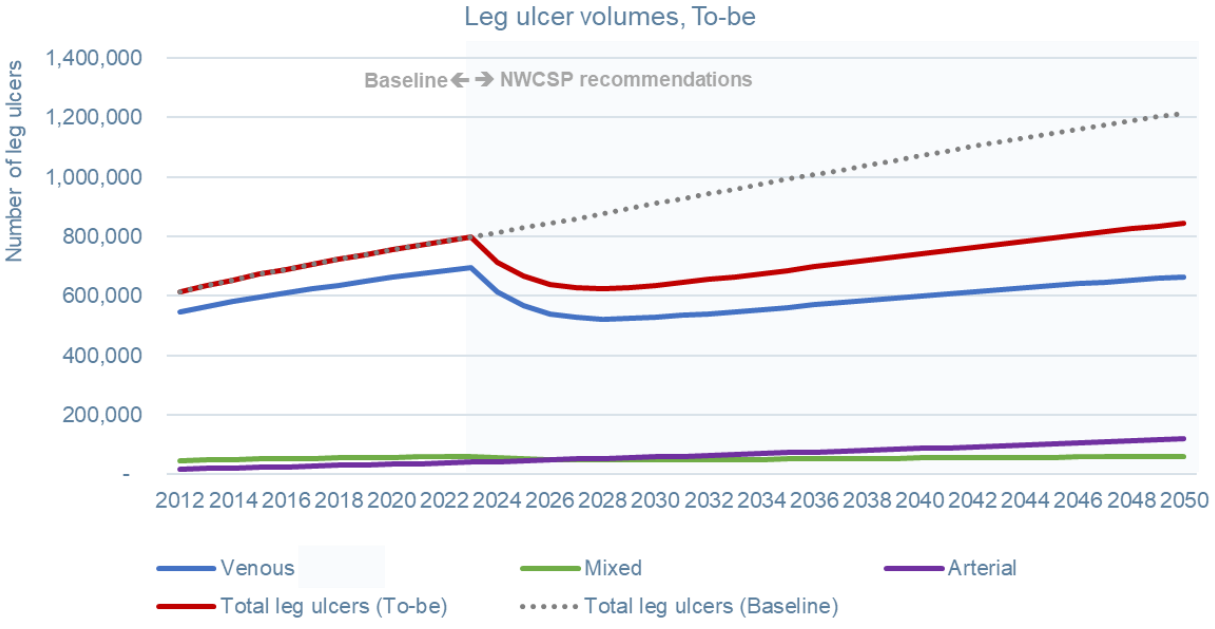
This large reduction in leg ulcer volumes is explained by the cumulative impact of clinical improvements from implementing the NWCSP recommendations. In particular:

I. a higher share of leg ulcers to heal each year (an additional 13% for VLUs) so there will be fewer unhealed wounds being treated in the following year.

II. a greater share of healed leg ulcers remaining healed within 12 months (an additional 11% for VLUs) due to the improved recurrence outcomes.

III. The impact of improved healing and recurrence in a single year will have a cumulative impact in all subsequent years. For example, the 13% improvement in the healing rate for VLUs in a single year will increase the volume of healed wounds for all subsequent years at a diminishing rate. Therefore, improved clinical outcomes will produce a cumulative reduction in the prevalence of leg ulcers, which results in a 30% annual reduction in the medium to long term.

Figure 19 To-be leg ulcer volumes



- **2020 to 2022:** the recommendations of the NWCSP recommendations are being implemented. As lower limb care is in transition during this period it is cautiously assumed benefits will not yet be delivered in this period.

- **From 2023**: within the first 12 months following implementation patients will begin to benefit from the interventions. The clinical improvements in terms of better healing and recurrence rates results in a sharp decline in the both the annual number and growth of leg ulcers, as disproportionally more leg ulcers are healing and not recurring than before.

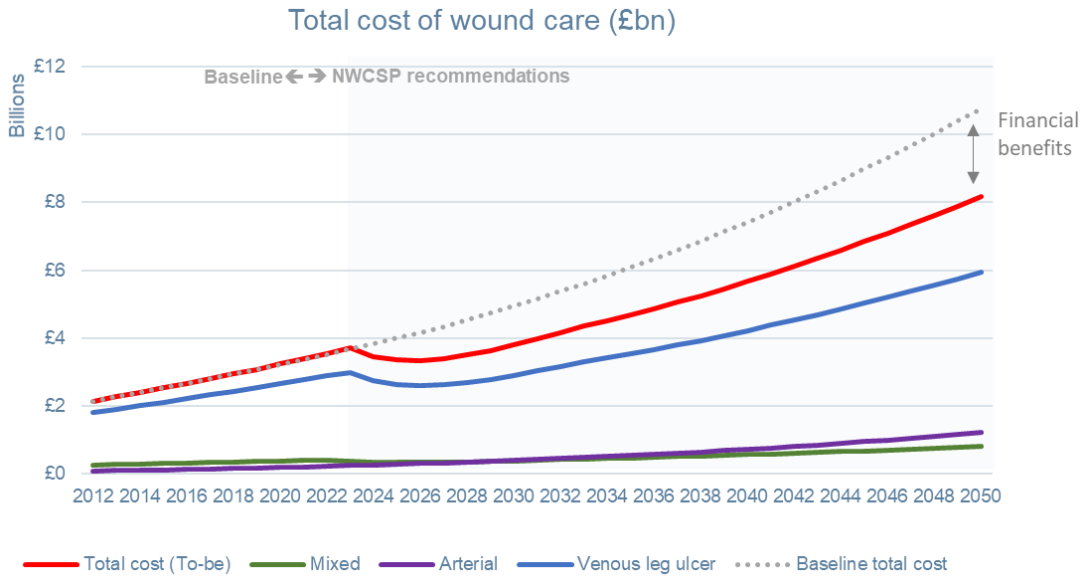
- **In the long term**: After 5 to 10 years following implementation, the relative number of healed and unhealed leg ulcers begin to balance out, causing the growth of leg ulcers to stabilise, at around 2030 onwards. The long-term growth of leg ulcers will be slightly lower than under baseline as more leg ulcers are remaining healed.

As the majority of leg ulcers are venous leg ulcers, the reduction in total leg ulcer prevalence is largely based on the reduction in venous leg ulcer volumes. For this reason, the relative share of leg ulcers that are venous is expected to fall over time[73].

A c.15% annual saving on the cost of leg ulcer care in England

The implementation of the NWCSP recommendations is expected to result in an annual reduction in the total cost of treating leg ulcers, as shown in the figure below. For example, the total cost of leg ulcer care to the NHS in 2030 is projected to be £4.9bn under baseline, however this reduces to £3.8bn following the implementation of the NWCSP recommendations. This reduction is largely driven by an estimated c.30% reduction in the volume of leg ulcers and includes the cost of implementation.

Figure 20 To-be cost of leg ulcer care



By 2030, the implementation of the NWCSP recommendations is expected to reduce leg ulcer related annual demand for clinical time by 23% and hospital admissions by 11%.

[73] The prevalence of arterial leg ulcers are unchanged compared to baseline because it was not possible to model clinical improvements due to a lack of robust data and evidence on arterial leg ulcers.

Prescriptions given to leg ulcer patients, equivalent to a cost of £400m in 2019, is expected to reduce by 30% under the To-be. This is driven by the reduction in both the prevalence and healing time of leg ulcers, as unhealed leg ulcers are expected to use almost four times as many items per annum than those that heal within 12 months.

The difference between the To-be total cost and the Baseline total cost is the annual savings from implementing the NWCSP recommendations. Figure 21 below displays this saving as a share of baseline total cost, including a 30% optimism bias. It shows that a 15% annual net saving on the cost of UK leg ulcer care could be achievable from implementation.

Figure 21 Annual savings, To-be vs Baseline

- **From 2020 to 2022**, the recommendations of the NWCSP will be implemented. During this time, implementation costs will be incurred, such as for the set-up of lower limb wound clinics and purchasing of hardware for data capture. As the delivery of lower limb wound care will be in transition during this period, it is assumed that the delivery of lower limb wound care will be the same as before implementation (i.e. the baseline), meaning that no benefits will be delivered at this stage. As a result, there is expected be a net cost incurred between 2020 and 2022, causing the negative saving rate shown in the diagram above.

- **2023 onwards**: following 3 years of implementation, from 2023 the benefits of the NWCSP recommendations will begin to be realised. In the first 2 years of benefits (2023-2024), the savings are relatively small. This is because it will take time for the clinical benefits from the improvement in lower limb wound care to feed through into patient outcomes, through better healing and recurrence, to ultimately reduce year on year costs. There is also a greater implementation cost from the operation of the lower limb wound clinics, which is largely responsible for the net cost at 2023. Net benefits accrue from 2024 and the full extent of the annual benefits is realised at around 2026, stabilising at around 15% of savings per annum.

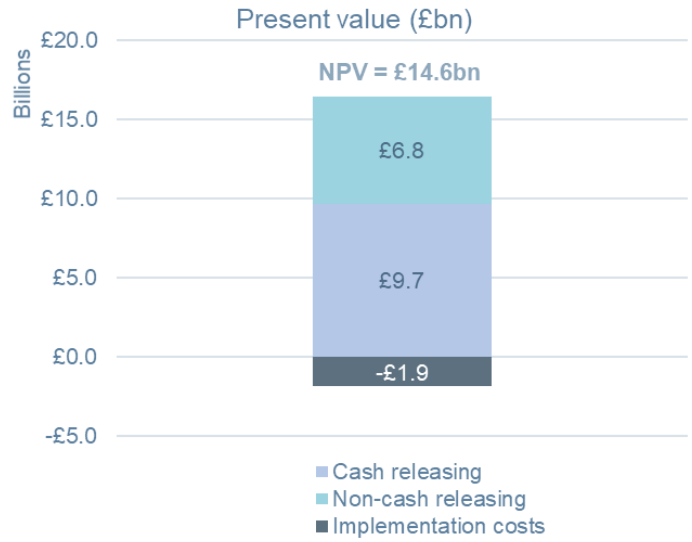
It should be noted that a conservative approach has been taken regarding the timing of benefits, such as assuming benefits will only occur after the period of implementation. However, some models of implementation enable swifter implementation and would thus accelerate the delivery of benefits, potentially during the implementation period.

The NWCSP recommendations is estimated to have a net present value of £14.6bn

It is estimated that the NWCSP recommendations has a net present value of £14.6bn over 30 years of implementation. This includes the cost of resources saved due to the NWCSP recommendations, all implementation costs and a 30% optimism bias adjustment. It does not include the value of health-related benefits, which is detailed further on.

A benefit cost ratio of 9.8 is implied, which suggests £9.8 of financial benefits are generated for every £1 invested.

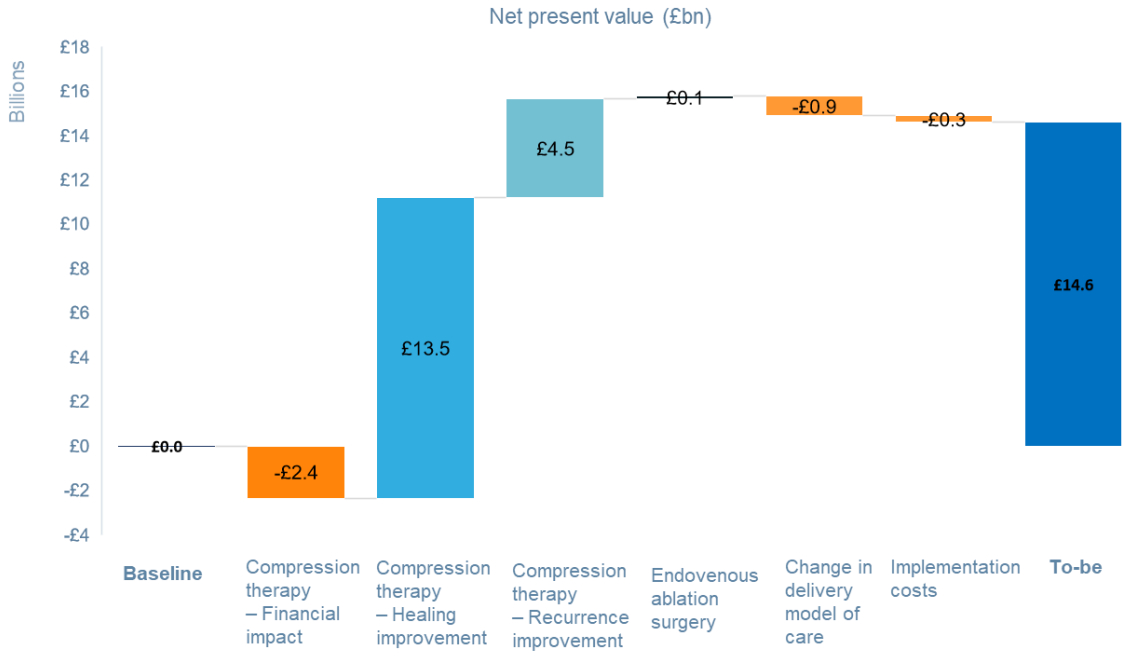
Figure 22 Present value of NWCSP recommendations



This net present value estimate proves robust against the sensitivity analysis detailed in section 3.5.1, even under extreme scenarios. For example, a £3.5bn NPV is still achievable if all clinical improvements relating to healing and recurrence are halved. Similarly, using leg ulcer prevalence estimates that are a tenth of that used in the modelling produces an NPV of £2.0bn. Basing nurse appointment times, a key assumption of the model, on survey data collected through the consultation produces an NPV of £15.8bn. Lastly, the NWCSP programme becomes cost-neutral if the optimism bias is increased from 30% to 88%.

Figure 23 below attributes the incremental impact each benefit driver to produce the £14.6bn NPV.

Figure 23 Breakdown of NPV



The diagram suggests that most of the benefits are driven by the improved healing and recurrence outcomes from more patients receiving evidence-based care for venous and mixed leg ulceration. In other words, simply reducing the variation in care will deliver significant cost savings and reduce the volume of venous leg ulcers and mixed leg ulcers. Furthermore, the cost of implementation (education, data capture, programme implementation and monitoring and evaluation costs) and changing the delivery model of care (through leg ulcer clinics) has a relatively small impact on the NPV.

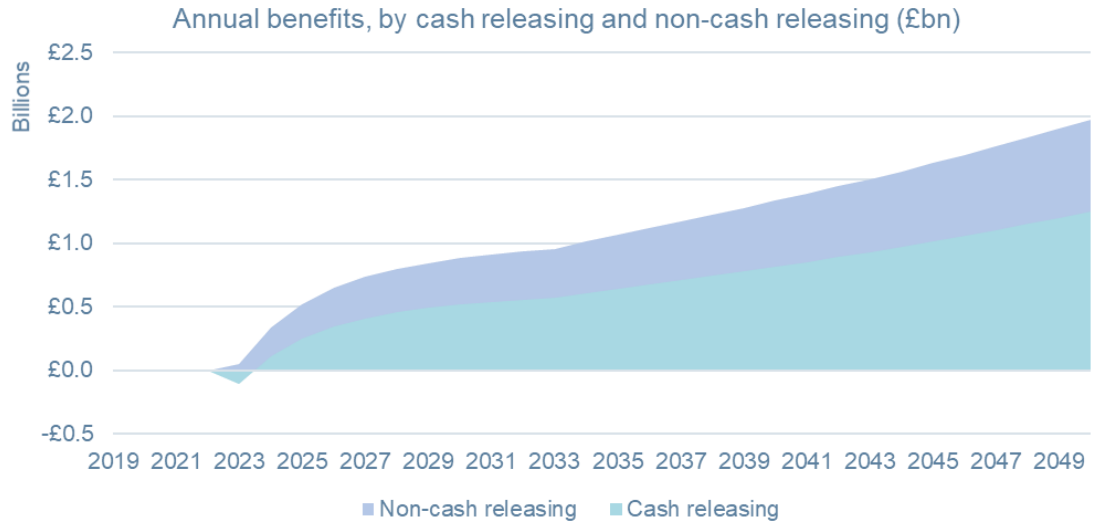
Cash releasing and non-cash releasing benefits

Cash releasing savings are identified as the saved costs relating to drug prescriptions, hospital admissions, dressings, bandages and hosiery.

Reduction in staff time from the interventions is assumed to be non-cash releasing. This is in recognition that most clinicians who care for people with chronic lower limb wounds also spend time caring for people with other clinical needs (such as respiratory disease, end of life care and continence and this will increase as more care is provided in the community under the NHS long Term Plan). This makes it impossible to estimate the FTE saved from reduced chronic lower limb wound care. Furthermore, modelling local resource structures is beyond the scope of this analysis, which would be required to properly assess whether a proportion of clinical time saved would be cash releasing. Therefore, the clinical time savings are interpreted as efficiencies (i.e. non-cash releasing benefits), whereby reducing clinical time spent on chronic lower limb wound care releases time to care for people with other clinical conditions.

Figure 24 illustrates the annual cash releasing and non-cash releasing savings from implementing the NWCSP recommendations (excluding implementation costs)

Figure 24 Cash releasing and non-cash releasing benefits[74]



In the first few years following implementation, most of the benefits are expected to be non-cash releasing. For example, in 2023 there is expected to be £156m of non-cash releasing benefits, rising to £226m in the following year. However, in 2023 the cash releasing benefits are negative, at -£107m. This is because there will be an initial increase in the amount of clinical time and equipment used from increasing the delivery of evidence-based care. However, after several years the reduction in leg ulcer prevalence will lead to a reduction in the consumption of clinical time and equipment, which will generate cash savings. For example, there is expected to be £108m and £249m of cash releasing benefits in 2024 and 2025 respectively.

After 2028, the estimated cash releasing benefits equate to about an 10% annual cash saving relative to baseline. This becomes an 9% annual cash saving once implementation costs are included. Further breakdown of the annual benefits is in section 9.

Break-even and payback period

The NWCSP recommendations are expected to break-even in 2026, four years after the end of implementation period. This suggests a payback period of six years.

This is based only on cash-releasing benefits and excludes clinical time efficiencies resulting from the NWCSP recommendations, which are assumed non-cash releasing. In practice, it is likely that the significant reduction in clinical time spent on treating chronic lower limb wounds is likely to result in at least some financial savings. For example, if it is cautiously assumed that just 35% of clinical staff time efficiencies are cash-releasing, the investment will break even in 2025, three years after the end of the implementation period.

A conservative approach has been taken regarding the timing of benefits, such as with the assumption that benefits only occur after the period of implementation. In practice, there are models of implementation that enable the benefits to be delivered sooner, for example during the implementation period to achieve a lower payback period.

[74] Note that this excludes the implementation cost given neither benefit types can be realised without incurring the full implementation cost. Includes a 30% optimism bias adjustment.

In addition to the NPV, there is at least £4.8bn to £16.0bn of QALY benefits

Quality-Adjusted Life Years (QALYs) is a measure of the improved health outcomes for patients because of an intervention. In summary, it is estimated that the NWCSP will generate at least £4.8bn to £16.0bn of QALY benefits. A range is provided to reflect the differences in monetary value estimates provided by NICE and Department for Health respectively.

This is based on an average 0.034 QALY improvement per patient as a result of the clinical interventions. Across all 800,000+ leg ulcer patients, it is estimated there will be c.13,000 QALYs gained per annum from implementing the NWCSP recommendations. This is likely to be a significant underestimate on the likely QALY benefits because these estimates are based on the only available QALY data which shows gains from introducing compression hosiery versus compression bandaging for people with venous leg ulceration. This, therefore, only measures improved health outcomes for one group of patients from one type of evidence-based care to another type of evidence-based care. It would be reasonable to anticipate that there would be higher QALY gains from moving a patient from other forms of care to evidence-based care which yields much higher healing and recurrence improvements, but data is lacking. Given the data imperfections, the NPV stated above excludes these QALY benefits estimates.

Non-quantifiable benefits

Implementing the NWCSP recommendations is likely to generate many types of benefits that are non-quantifiable and so cannot be included in the net present value but influence the wider determinants of health. These benefits should be equally considered alongside the quantified benefits detailed in the previous section.

Improved wellbeing and quality of life

In addition to generating QALYs, the NWCSP recommendations are likely to significantly improve the quality of life for people with chronic lower limb wounds by improving healing, reducing recurrence, and reducing amputation rates. Time spent attending clinical appointments becomes available for work or leisure activities and some people may be able to re-commence paid employment or take up leisure activities that were not possible with an open wound.

There are also financial benefits for patients as healing means that that it is no longer necessary to fund travel costs for clinic appointments or undertake additional laundry for soiled clothing or bed linen. Physical and psychological health will improve as healed wounds do not smell and are less likely to be painful, reduce mobility and impede sleep. Anxiety about malodour and leakage can lead to social isolation so healing is also associated with psychosocial benefits such as reduction in anxiety and greater willingness to socialise.

Cost savings from social care models

The analysis presented assumes that people with chronic lower limb wounds will require the same level of resources regardless of the care setting which they are treated in. In practice, people receiving care in a social care model setting are likely to require significantly less clinical time than in a clinical setting. Some aspects of care, such as advice, prevention, and

support in the Well Leg regime, may be delivered by appropriate fellow members sharing their lived experience. Therefore, social care models are likely to entail greater cost savings than suggested by the modelling, but lack of data meant that this could not be incorporated into the costing.

Accelerated healing associated with swifter diagnosis and treatment

Clinicians report that venous leg ulcer healing is accelerated if appropriate therapy is offered early in the patient journey. Currently, there is often delay between a patient first presenting with a non-healing limb wound, diagnosis of the causes of delayed healing and access to appropriate treatment. Implementation of the NWCSP lower limb recommendations should reduce the time between initial presentation and appropriate treatment and thus enable even faster healing than indicated in this business case. The absence of robust data has meant that it has not been possible to capture this in the modelling, but such improvements in both healing and recurrence may translate to even better patient outcomes and cost savings.

Improvements for lower limb wounds other than venous and mixed leg ulcers

Although the modelled clinical improvements focus on venous leg ulcers and mixed leg ulcers, it is likely that implementing the NWCSP recommendations will significantly improve care for all types of lower limb chronic wounds. Access to lower limb wound services will enable faster diagnostic care and ongoing treatment for many types of chronic lower limb wounds. Emerging evidence suggests that rapid access to vascular services significantly reduces the risk of amputation for people with critical limb threatening ischaemia[75] Therefore, people with non-diabetic foot ulcers are likely to get faster access to vascular imaging and surgical interventions and people with less common conditions, such as malignant ulcers or sickle cell ulceration, are likely to be identified earlier and referred to quickly and more appropriately.

These services will also improve care for conditions that lead to chronic lower limb wounds, such as chronic oedema, and are thus likely to prevent the incidence and recurrence of ulceration and reduce the number of people requiring hospitalisation for cellulitis associated with chronic oedema. Lower limb services are also likely to improve wound care knowledge and skills for clinicians and patients, leading to better healing and thus freeing up resources for use delivering other types of healthcare.

Benefits from increasing self-care

The analysis presented assumes that all care will be provided by a clinician but the NWCSP recommendations also supports patients to increasingly undertake a larger proportion of care themselves. This is partly driven by increasing availability of compression hosiery and wraps, supported by research evidence. This move has been further accelerated by the Covid-19 situation whereby many more people with lower limb wounds are expressing their preference to undertake more of their own care. Although the future is uncertain, it is possible that this pattern will continue post Covid-19. Due to a lack of data, the increasing use of self-care could not be included in the modelling.

[75] Nickinson, A. T. O., Dimitrova, J., Rate, L., Dubkova, S., Lines, H., Gray, L. J., Houghton, J. S. M., Nduwayo, S., Payne, T. J., Sayers, R. D. & Davies, R. S. M. 2019. Adopting a new model of care for treating patients with chronic limb threatening ischaemia: early results of a vascular limb salvage clinic. medRxiv, 19013037.

4.3 Sensitivity analysis and modelling considerations

4.3.1 Sensitivity analysis

This section presents the results of sensitivity analysis, which seeks to stress-test the results by understanding the impact of potential variation and uncertainty in important modelling assumptions. As such, the sensitivity analysis seeks to indicate a level of confidence in the robustness of the results.

The sensitivities tested are based on the outcomes of the peer review process and wider stakeholder engagement, as outlined in section 3.2. These processes identified highly impactful assumptions which were likely to be subject to both variation and uncertainty. Figure 25 presents the results of the sensitivity analysis. The tests are designed to represent highly pessimistic and extreme scenarios. Further detail on the rationale and methodology used to develop the sensitivities tested is section 8.7.

Figure 25 Results of sensitivity analysis

Test	Sensitivity	Net present value (£bn)	Benefit-cost ratio
	Core scenario	**£14.6**	**9.8**
1.	Leg ulcer prevalence (from Cullum et al 2014)	£2.0	5.2
2a	Survey consultation on nurse timings	£15.8bn	10.2
2b	Survey consultation on nurse timings and bandage change frequency	£20.2bn	11.0
2c	Survey consultation on nurse timings and clinical improvements	£7.9bn	5.2
3a	Halving of all clinical improvements	£3.5bn	3.0
3b	No healing improvement at all	£-2.8bn	-0.2
3c	No recurrence improvement at all	£8.2bn	5.5
4	88% optimism bias (highest level of optimism bias such that NPV is zero)	£0.0bn	1.0
5	Zero inflation post 2019/20	£9.1bn	8.5
6	Zero patients wearing compression hosiery	£12.9bn	8.6
7a	Failure to reduce share of VLU patients receiving sub-optimal care from baseline (at 31%)	£1.2bn	1.8
7b	Increase in share of patients in sub-optimal care to 33%, but all other patients receive better care.	£0.0bn	1.0
8a	Introducing general population mortality – leg ulcer patients are at risk of dying year on year	£11.0bn	7.4
8b	Impact of covid-19 proxy – all aged 70+ (62% of leg ulcers) die from 2020 and onwards.	£61.bn	10.3
9a	Long term trends on new leg ulcer incidence – assume 5% growth of new leg ulcers per annum	£24.0bn	10.3
9b	Long term trends on new leg ulcer incidence – assume 0% growth of new leg ulcers per annum	£12.1bn	9.4
10	Healthcare assistants provide 50% of leg ulcer care in general practice appointments in baseline only	£14.4	9.7

In summary, the sensitivity analysis suggest that the results are robust against extreme uncertainty and variation in key assumptions, with significant net benefits still available in most scenarios tested.

For example, Test 4 suggests that implementing the NWCSP recommendations could still deliver net benefits even if the incremental benefits were 88% less and the implementation costs were 88% higher than initially estimated. Furthermore, there are still substantial benefits generated even under scenarios where there is limited success in achieving the desired clinical improvements (Test 3) or partial failure to reduce variation in care (Test 7).

Scenarios were also tested to stress-test important modelling assumptions. For example, by using real-world data obtained through the survey consultation Test 2 corroborates the clinical time estimates used in the core modelling as being highly conservative. Scenarios which increase the average cost of treating a leg ulcer results in even higher financial benefits because it means there are more savings to be made per leg ulcer successfully healed.

The results also prove robust under extreme scenarios relating to the future state of the world, which could not be included in the core modelling due to a lack of robust evidence. This includes scenarios where there is an extreme impact on demographics from Covid-19 (Test 8b), cost inflation (Test 5), trends in leg ulcer incidence (Test 9) and patient mortality (Test 8a).

In conclusion, the results of the sensitivity analysis suggest that the implementation of the NWCSP recommendations can still deliver substantial benefits even under highly pessimistic scenarios.

4.3.2 Wider considerations

Throughout the development of this analysis, feedback has been received from experts, clinicians, academics, and stakeholders on both the assumptions and the external validity of the model. Although the sensitivity analysis in the previous section seeks to address some of these considerations, further discussion is provided below.

Variation in chronic lower limb wound prevalence

As chronic lower limb wound prevalence is likely to vary significantly across England and has a significant impact on the results, the model enables users to input their own prevalence estimates in order to reflect their local state of care. As seen in the sensitivity analysis, significant savings are still achievable at much lower levels of prevalence.

Applicability of RCT evidence to clinical practice

Many important assumptions used in the analysis are based on evidence from randomised control trials (RCTs), particularly those that evaluated therapies for healing and prevention of recurrence. However, the results from RCTs may not be achievable in clinical practice. In acknowledgement of this issue the following actions were taken to address this issue:

1. Evidence from ‘pragmatic’ RCTs was used as much as possible. Pragmatic RCTs are designed to measure whether an intervention works in real-life routine practice

conditions, as opposed to the well-defined and optimal conditions of more traditional explanatory RCTs which seek to establish whether an intervention works in theory. The results of pragmatic RCTs are therefore likely to generate results that have greater applicability and generalisability. Pragmatic RCT are not free of limitations but although results from a pragmatic RCT can only be interpreted as a ballpark estimate of a treatment's effectiveness, such evidence gives more reliable information than from other non-RCT research designs.

2. Estimates from RCTs were sense-checked using survey evidence. This included using available data and testing assumptions with clinicians through an iterative 4-step peer review process, as outlined in section 3.2. Data from the field, including survey data from the NWCSP Health and Care Professionals Stakeholder Forum (section 8.4), was used to provide alternative assumptions to be stress-tested as part of the sensitivity analysis.

3. A 30% optimism bias was applied to all incremental benefits and implementation costs to reflect potential uncertainty in the analysis. Therefore, the results provided assumes, by default, the results from RCTs will not be fully achievable.

4. Sensitivity tests were conducted to stress-test the impact of uncertainties in impactful assumptions. For example, this involves making highly pessimistic assumptions regarding the ability to deliver better wound care, particularly regarding assumptions where there could be concerns over achievability.

Time to implement changes to change the model of care provision

In the To-be scenario all lower limb wounds will receive care in dedicated chronic lower limb services staffed by clinicians with appropriate time, knowledge, and skills. It is recognised that it will take time to change the care delivery model and deliver the education to deliver the proposed dedicated chronic lower limb services delivered by an adequately skilled clinical workforce. However, clinicians who have implemented the changes proposed in this business case, are of the view that such change can be achieved surprisingly fast. Implementation will be addressed in stages, preceded by piloting to identify realistic timeframes.

A bigger challenge may be around developing sufficient capacity to enable eligible patients to access specialist services such as podiatry, vascular and dermatology services. Lack of robust data has meant that it has not been possible to model demand in relation to supply for endovenous ablation surgery and the Covid 19 situation has also had an impact since all non-urgent vascular surgery has been suspended for an unknown duration.

RCT evidence suggests that endovenous ablation is a clinically and cost-effective evidence-based intervention, but the cost-benefits from evidence-based therapy are mostly driven by compression therapy (see Diagram 15). Therefore, although endovenous ablation contributes to further improving venous leg ulcer healing rates, any delay in making endovenous ablation widely available is unlikely to impact significantly on achieving a meaningful net present value.

The impact of Covid-19 on care provision

As a large proportion of chronic lower limb wound patients are above the age of 60 and most wound care appointments are done face-to-face, concerns have been raised about the potential impact of coronavirus on the state of wound care in the future. For example, as noted previously, the need for social distancing during the Covid-19 outbreak could create an increase in self-care to enable patients to avoid contact with other people.

In response to these concerns, the impact of significant demographic change in the population has been modelled as a sensitivity. Although such a scenario would reduce the savings available by reducing the prevalence of chronic lower limb wounds, there are still significant savings to be made at much lower levels of prevalence.

A movement to self-care is part of the NWCSP recommendations but was not modelled due to a lack of data. However, it is likely that increased self-care will yield high levels of savings as it would significantly reduce the amount of clinical time spent on patient appointments. Therefore, increased self-care is likely to strengthen the business case for improved wound care.

Concern has been expressed that social care models such as Leg Clubs® may not be able to function or be acceptable to patients during Covid-19. However, these models of care are adopting the same infection control measures as other models of care and continue to provide care to their members who continue to attend.

Infected wounds

It has been reported that 50% of all leg ulcers can become infected. While this is theoretically possible, clinicians report that inaccurate diagnosis leading to inappropriate prescribing of antibiotics and antimicrobial dressings is widespread. A common error is to misdiagnose lack of healing and varicose eczema (due to untreated venous disease) as wound infection. Therefore, the infection data cannot be viewed as valid and reliable.

Similarly, although foot ulcer infection is an issue of clinical concern, the accuracy of diagnosis is a known issue of concern[76] so no modelling has been attempted in relation to this topic.

Healing rates for long-standing wounds

Currently, many leg ulcers are longstanding. The accumulation of unhealed and recurred wounds over time means that over 80% of leg ulcers prevalent in 2019 are wounds that existed in the previous year. Research evidence suggests that wounds that are more than 6 months old and larger than $10cm^2$ are less likely to heal within 24 weeks[77] but emerging clinical evidence suggests that many longstanding venous leg ulcers do heal when treated with evidence-based therapy such as strong compression[78].

[76] Gardner, S.E., Hillis, S.L. and Frantz, R.A. 2009. Clinical signs of infection in diabetic foot ulcers with high microbial load. Biological Research for Nursing. 11(2), pp. 119-128

[77] Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? The American Journal of Medicine. 2000;109(July):15-9.

[78] Atkin L, Kilroy-findley A, Schofield A. Updated leg ulcer pathway: improving healing times and reducing cost. British Journal of Nursing. 2019; 28 (20) S21-26

Therefore, it may be to the benefit of all patients to ensure that those with new leg ulcers receive early assessment and treatment to optimise healing rates, to quickly reduce demand on services and thus optimise service capacity to the benefit of all.

4.4 Limitations of analysis

This analysis sought to estimate the annual cost of leg ulcer care for venous leg ulcers, mixed leg ulcers and arterial foot and leg ulcers in England but lack of data meant that it has only been possible to model venous and mixed leg ulceration.

This analysis endeavours to use the best quality evidence available at the time of development. High quality published evidence is used to underpin assumptions as much as possible. Where such evidence is not available, data from a range of sources have been triangulated to produce appropriate assumptions, which has subsequently been tested through an iterative peer review process with NWCSP stakeholders, clinicians, nurses, experts and academics.

While every effort has been made to maximise and assure the robustness of the assumptions used, inevitably some stronger assumptions will need to be made to ensure a workable model can be developed within the resource constraints. The impact of large uncertainty in important assumptions is tested through sensitivity analysis.

This model captures the state of wound care at a point in time using evidence available at the point of development. It therefore does not seek to capture any trends or events that are not reflected in the evidence. Scenario analysis will be used to test the impact of probable scenarios on the results, where possible.

The analysis seeks to achieve a level of granularity that balances the trade-off between explanatory power, time constraints and data availability. Inevitably, there are many dimensions which are likely to be important to the cost of chronic lower limb wound care but have not been captured in the analysis. For example, this could include differences in resource consumption for infected wounds; differences in wound care profiles across England regions; deaths due to wounds; demographic differences; and the impact of comorbidities. Although the importance of these features is recognised, a lack of robust evidence and data makes it impossible to be captured in the modelling.

As the interventions were modelled in light of the NWCSP recommendations drafted at the time and are largely based on available academic evidence, the interventions modelled should be viewed as an approximation of the NWCSP recommendations and should not be interpreted as the precise interventions that will result from these recommendations.

The impact of uncertainty, robustness concerns and omission of potential modelling characteristics are managed in the following ways:

1. **Sensitivity and scenario analysis**: understanding the impact of the results under extreme/pessimistic assumption values. The results of this exercise are presented in Section 4.3.

2. **Optimism bias**: optimism bias is applied to both incremental savings and costs of implementation to capture levels of uncertainty in the assumptions.

3. **Customisability of the model:** the model is built such that users can customise important assumptions according to specific features of their local health geography (such as prevalence). This should help to mitigate any tensions between local versus national estimates.

4. **To-be versus baseline**: in some cases, the omission of certain modelling features are effectively nullified if the relevant assumptions are constant before and after the impact of the intervention. This is because the results effectively look at the difference in outcomes as a result of the intervention.

5. **Population-wide estimates**: this model is predominantly based on averages over a year. In many cases, any potential granular differences between groups within that population will be captured by population-wide estimates used in the analysis. For example, the healing rates used are based on population surveys and so would indirectly capture differences in wound age and infection incidence.

6. **Materiality**: in practice, some assumptions are immaterial to the results even under extreme circumstances. This has been tested as part of the sensitivity analysis as discussed in Section 4.3.

5 Achieving the vision – Implementation

Moving forward, the NWCSP intends to identify and work with a small number of '1st tranche implementation sites' to test this implementation model, provide additional evidence and gain experiential learning about the barriers and opportunities around implementing the NWCSP Lower Limb Recommendations. These initial implementation sites will enable the NWCSP to develop a blueprint for wider implementation and evidence to demonstrate how implementing the NWCSP Lower Limb Recommendations can deliver real and significant benefit in terms of health and well-being gains to people with lower limb wounds, healthcare efficiencies and resource savings in the NHS. The collection and analysis of robust evidence will be a key priority of this work.

To achieve this, the NWCSP will invite expressions of interest from health care organisations interested in becoming 1st tranche implementation sites as part of an initial implementation cohort.

Applicant organisations will be expected to demonstrate:

- A commitment to implementing the strategy recommendations
- Full commitment to developing an implementation case that describes resourcing, timelines and planned outcomes
- Full support from all relevant local partners including commissioners, provider organisations and Primary Care Networks ideally with full ICS/STP support
- Adoption of a recognised service improvement programme management methodology with a supporting timeline
- Commitment to release front line staff to undertake training and education
- Implementation of digital tools including the use of mobile technology to support the provision of evidence-based care and its measurement
- Commitment to work as part of a pathfinder collaborative group
- Commitment to evaluation of pathfinder work
- Commitment to sharing of learning outcomes of pathfinder status with other NHS organisations.

6 Conclusion

UK national clinical guidelines for improving lower limb chronic wounds have existed for more than 20 years but national implementation has not been achieved. This report outlines how the variation in lower limb care should be addressed and presents an enormous opportunity to tackle the growing burden of wound care, improve the quality of life for people with chronic lower limb wounds and secure better value from existing health care resources.

7 Appendix 1 – Data and Information Mobile Technology Specification - summary of attributes

This covers the key areas and provides top line guidance in relation to that attributes required for mobile technology for data and information. The attributes are separated into:

1. NHS requirements overview
2. Principles
3. Functional
4. Links
5. Measurements
6. Clinical attributes Outline Framework
7. Cyber Security

(items in **green** in sections 2-5 are key needs for the National Wound Care Strategy

Work in progress (with more detailed specification details are available)

9th June 2020

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1. **NHS Requirements Overview**

- Comply with existing and planned NHS developments:
  - Single NHS staff identifier (NHS passport compliant)
  - Compliant with NHSD and NICE Digital Standards
  - Allow full use of SNOMED CT terminology
  - Compliant Cloud based storage
  - Allow flow into NHS Digital (CSDS v2.0)
  - Instant access to all NHS data
  - Linkable with other H&SC data sources
- Interface (bidirectional) with essential systems:
  - GP systems: EMIS, Vision, Systm1 + document management systems
  - eRS (NHS Digital GP referral system) [API expected 18/19:Q2]
  - Secondary care EPR and legacy notes systems
- Replace rather than duplicate
  - Current Primary Care systems community templates
  - Secondary care to Community referral processes

2. Principles
Operational clinical systems should provide all management data

- **Single long-term record of all events in Community and Secondary care environments**
- Additional administrative load must be minimised
- Mobile technology supports live access to records and care plans.

- Mobile technology is intuitive and convenient for staff to use
- Systems should be resilient
- Systems should avoid installation and update burden
- Providers support staff in using the technology and adopting news ways of working
- Providers have oversight of key indicators to maximise benefits

3. Functional

Systems should be designed so that clinicians working in the community are able to do the following activities from any location

- **Ability to record care of multiple wounds, (types and locations)**
- **Secure 2D digital image capture**
- **Local formulary adherence**
- Allow remote working via tablet or laptop
- Real-time but with Store and Forward capability
- High level views with drill-down based on user security level
- Read and update patient records and care plans
- Record patient demographics, relevant medical history and social circumstance
- Record wound assessments and all important (wound MDS) clinical features
- Record the treatment plan and wound care materials employed
- No record locking
- Flags, Prompts and Alerts to match agreed pathways
- Access to Advice and Guidance
- Referral to multiple agencies
- Communicate securely with other professionals
- Supports Role Based Access
- Audit trail of all user activity by patient and user.

4. Links

The digital mobile working application should seamlessly interface with other relevant provider systems or replace them:

- Local health and care record (across organisations in the system)
- Local pathology ordering and reporting systems
- Local pharmacy systems
- Incident reporting systems
- On-line (non-prescription) ordering systems

5. Measurement

Measures that should be possible to extract from applications

- **Product evaluation**
- **Stock control with new Supply & Distribution wound product classification**
- **Allows the creation of a national image repository to support AI developme**nt
- Percentage of staff who have completed training for digital mobile working
- Advice and guidance audit log
- Cover all mandated community data requirements
- Allow record of adherence of staff / patient to A&G and treatment plan
- Average number of patient contacts per clinician per day
- Duration of logged in sessions
- Data quality and completeness of electronic patient record
- Proportion of clinicians who have logged on each day

6. Clinical Attributes Outline Framework

NHS Number	Wound Image (ID)	Wound Progress (fixed)
Patient ID (internal)	Calibration	Exudate Type (fixed)
Patient Name	Width (auto)	Exudate Colour (fixed)
DOB	Length (auto)	Exudate Level (fixed)
Gender	Area of each tissue type (auto)	Odour (fixed)
Postcode	Each Tissue Type % (auto)	Cleansing Agent (fixed)
CCG/Strategic Commissioner Area (fixed)	Depth (cms)	Primary & Secondary dressings (coded)
Site (fixed)	Comorbidities (fixed)	Dressing Change Frequency (fixed)
Team (fixed)	Tunnelling* (cms)	Pain Level (fixed)
Wound Type (Fixed)	Undermining* (cms)	Pain Frequency (fixed)
PU Category*	Medications (fixed)	Wound Bed (fixed)
3D Body Map	ABPI Scores (left and right leg)	Wound Edge (fixed)
Treatment Objectives	Swab sent and dates	Surrounding Skin (fixed)
Treatment Code (fixed)	Swab results and dates	Infection (Clinical signs) local /systemic (fixed)
*input field only visible if applicable to this type		Infection type (fixed)

7. Data Security

- Contain security controls for remote access users including use of cryptographic techniques and support two-factor authentication.
- Able to protect the confidentiality, authenticity or integrity of information by cryptographic means.
- Any data flowing to and from other health systems/server to be encrypted end to end and at rest.
- Able to retain previous versions of the assessment for audit purposes.
- Not contain any features which prevent any organisation from being fully compliant with the requirements of all UK legislation and professional obligations
- With Support for:
    - Network Access Controls.
    - Input Data validation and correction procedures.
    - User/time/date stamp for any modifications to data.

8 Appendix 2 – Modelling assumptions and methodology

8.1 Scope of analysis

This analysis seeks to estimate the annual cost of wound care for venous leg ulcers, mixed leg ulcers and arterial leg ulcers in England.

8.2 Alignment with government appraisal guidance

The analysis and underlying modelling have been developed in line with government appraisal guidance, particularly with reference to the Green Book[79] and Comprehensive Investment Appraisal (CIA)[80] guidance. The below table summarises the ways in which this has been done.

Figure 26 Alignment with government appraisal guidance

Appraisal guidance feature	Detail on how this has been aligned in the modelling
Discounting	All monetised non-QALY and QALY benefits have been discounted as per Green Book and CIA guidance, to calculate present values.
Optimism bias	A 30% optimism bias is applied to both the net savings (benefits) and implementation costs as standard. Although it is acknowledged that this is a high degree of optimism bias, it is viewed as prudent given the level of uncertainty and challenge with some of the assumptions.
Time horizon	Costs and benefits are calculated up to 2050 (28 years from the start of implementation) in recognition that benefits are still achievable in later years and the interventions are not intended to be for the short-term. Although benefits are still achievable beyond 2050, a longer time horizon was not used given the uncertainty in projecting outcomes over such a long period.
Implementation cost and benefits phasing	The analysis assumes that the implementation period will last three years (2020-2022), with the first year of benefits occurring in 2023. Although it is likely that local health organisations would be able to realise benefits much sooner, a later phasing of the benefits is used in recognition that different healthcare organisations could be starting implementation in different years. Although partial take-up was considered as a phasing assumption of the benefits, there was little evidence on what this partial take-up could look like. Therefore, a conservative approach was taken to delay benefits by an additional year to 2023.
Transition costs	Although implementation will not be complete by 2023, it is assumed that some implementation costs will be incurred during the implementation period to reflect the potential double-running of services during transition. This includes the early set-up of the leg ulcer clinics, initial leg ulcer compression education costs and the purchase of hardware for data capture.
Avoidance of double counting	To avoid double counting benefits due to differences in cost of treatment between baseline and to-be, it is assumed that the implementation costs relating to the leg ulcer clinics and social models of care does not include the cost of treatment and instead only includes administrative costs. It is therefore assumed that all treatment costs are the same across all care settings. Although this may underestimate the cost savings

[79] HMT (2020), The Green Book: appraisal and evaluation in central government
[80] DHSC (2019), Comprehensive Investment Appraisal (CIA) Model and guidance

	resulting from social models of care, this approach was viewed to be prudent given potential risk of double counting the reduction in treatment costs from the interventions.
Cash releasing and non-cash releasing monetary benefits	In acknowledgment that leg ulcer care is likely to be one aspect that nurses spend their time on, this analysis does not attempt to estimate the FTE savings and therefore the cash releasing savings realised from reducing demand on clinical time. Although the interventions could reduce the amount of time nurses spend on leg ulcer care, it is unclear whether this could free up individual FTE across the entire system to realise a cash releasing saving (i.e. there is an opportunity cost to consider). To be conservative, it is therefore assumed that the benefits is non-cash releasing and relates to efficiencies in terms of reducing resource consumption.
Societal and non-quantifiable benefits	Societal benefits (QALYs) have been estimated as part of this analysis. Recognition is also given to other equally important benefits that are not quantifiable
Sensitivity analysis	Extensive sensitivity analysis has been conducted to evaluate the impact of uncertainty and risk in the model (see section 4.3). An active approach was used to identify scenarios to test by using feedback from extensive peer review and consultation (see section 3.2) to identify assumptions which could be subject to material variability and uncertainty.

8.3 Peer review process and wider engagement

All assumptions and methodology were reviewed as part of an iterative peer review process to question the real-world validity of assumptions and understand the extent to which such assumptions were likely to be subject to high levels of uncertainty.

The table below lists the participants who, with thanks from the NWCSP, dedicated time providing feedback on the modelling assumptions and methodology as part of the peer review process.

Figure 27 Peer review process reviewers

Stage	Reviewers
Peer Review 1 6th April 2020	Reviewers: Professor Nicky Cullum (University of Manchester) Professor Jo Dumville (University of Manchester) Professor Julian Guest (Catalyst Consultants and Kings College, London) Brenda King (Sheffield Teaching Hospitals NHS Trust) Nikki Stubbs (Leeds Community Healthcare NHS Trust)
Peer Review 2 7th May 2020	Invited NWCSP Expert Reference Group and NWCSP Lower Limb Workstream Leads. Accepted: Laura Hallas (South West Yorkshire Partnership Trust) Kerry Grimshaw (Taunton & Somerset NHSFT) Brenda King (Sheffield Teaching Hospitals NHS Trust) Nicky Morton (Lancashire Care NHS Foundation Trust) Alison Schofield (Northern Lincolnshire and Goole NHS Foundation Trust) Nikki Stubbs (Leeds Community Healthcare NHS Trust) Kate Williams (Leeds Community Healthcare)
Peer Review 3 18th May 2020	Invited 15 NWCSP Lower Limb Workstream Members and 1 Lindsay Leg Club member. (Unfortunately, an administrative error meant that some members did not receive the invite and thus were unable to attend. Following discovery of this error, these members contributed feedback at a later date.) Accepted: Dr Leanne Atkin (Mid Yorks NHS Trust/University of Huddersfield) Professor Frances Game (Royal Derby Hospital, University Hospitals of Derby and Burton NHS FT) Sarah Gardner (Oxford Health NHS Foundation Trust) Alison Hopkins (Accelerate CIC) Brenda King, Ellie Lindsay (Lindsay Leg Club) Professor Andrea Nelson (Glasgow Caledonian University) Mr David Russell (Leeds Teaching Hospitals NHS

	Trust) Margaret Sneddon (University of Glasgow) Professor Peter Vowden (University of Bradford) Dr Neil McIntyre (Lindsay Leg Club) 11th June: Dr Paul Chadwick (College of Podiatry)
Peer Review 4 14th May – 21st May 2020	Online consultation with 813 NWCSP Health and Care Professionals Stakeholder Forum There were 187 responses to the survey. A summary of the results of the survey is in section 8.4.

8.4 Results of the online survey consultation

As outlined in section 3.2 a survey consultation among the NWCSP Health and Care Professionals Stakeholder Forum (HCP Forum) was conducted to obtain evidence to test key modelling assumptions. A summary of the survey results is presented in the table below. There were 187 responses to the survey.

- Survey 1 - Test survey with Expert Reference Group
- Survey 2 - Survey with HCP Forum
- Survey 3 - Survey with HCP Forum, updated to clarify travel time should be excluded from estimates

Figure 28 Results summary of HCP survey

#	Question	Survey 1 (n=9)	Survey 2 (n= 82)	Survey 3 (n=96)
		Mean Score	Mean Score	Mean Score
3	How long does it typically take to do a home visit for someone with a leg ulcer whose only treatment is a dressing on their leg? (mins)	34.17	27.12	29.69
4	How long does it typically take to do a home visit for someone with a venous leg ulcer on one leg, who is receiving compression bandaging? (mins)	39.17	36.51	40.23
5	How long does it typically take to do a home visit for someone with a venous leg ulcer on one leg, who is receiving compression hosiery? (mins)	34.17	28.06	30.52
6	How long does it typically take to do a home visit for someone with a mixed leg ulcer on one leg, who is receiving reduced compression bandaging? (mins)	37.50	30.00	38.31
8	How long does it typically take to do a clinic visit for someone with a leg ulcer whose only treatment is a dressing on their leg? (mins)	25.50	24.56	22.61
9	How long does it typically take to do a clinic visit for someone with a venous leg ulcer on one leg, who is receiving compression bandaging? (mins)	35.00	33.10	33.90
10	How long does it typically take to do a clinic visit for someone with a venous leg ulcer on one leg, who is receiving compression hosiery? (mins)	31.67	26.08	26.51

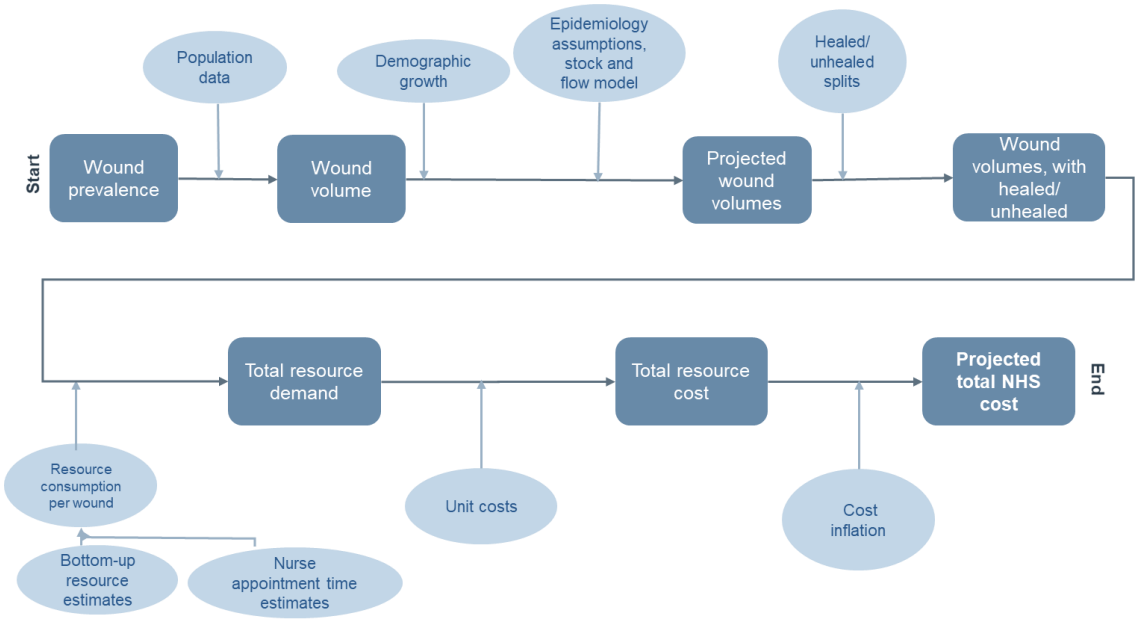
11	How long does it typically take to do a clinic visit for someone with a mixed leg ulcer on one leg, who is receiving reduced compression bandaging? (mins)	34.17	32.88	32.90
12	On average, how often do you change dressings for someone with a venous leg ulcer who is receiving compression bandaging? (times per week)	1.57	1.90	2.08
13	Thinking of your patients with venous leg ulcers, what percentage do you estimate would be willing to be treated with compression hosiery (or wraps) once initial oedema and excess exudate has been brought under control? (%)	57.14	68.20	69.40
14	Thinking of your patients with venous leg ulceration what percentage do you estimate heal within 12 months of being referred to your service? (%)	71.43	72.28	70.70
15	Thinking of all your patients with venous leg ulceration who have healed and have been provided with compression hosiery, what percentage do you estimate are still healed after 12 months of healing? (%)	56.00	65.16	64.31

8.5 Baseline methodology

The current state of wound care in England has been modelled (the 'baseline'). This modelling seeks to understand the current and future NHSE cost of treating leg ulcers in England without any improvement or intervention in wound care. The baseline therefore acts as a starting point, from which interventions can result in a relative improvement.

The diagram below summarises the broad structure of the baseline modelling.

Figure 29 Baseline model architecture

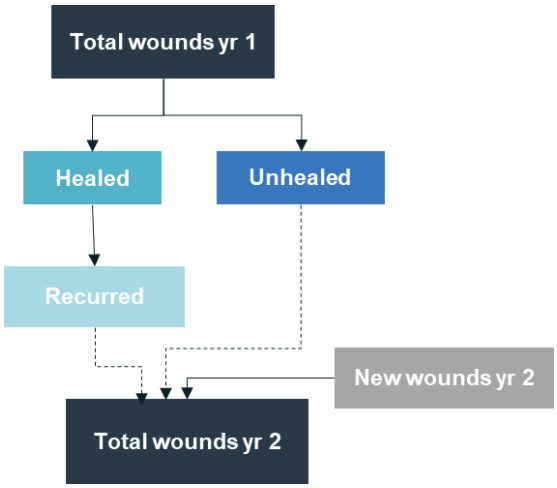


8.5.1 Projecting leg ulcer prevalence in England

The prevalence of ulcers follows a stock-and-flow model, where the incidence of unhealed and recurred wounds results in an accumulation of wounds over time. This is in line with the approach referenced in Guest et al (2017)[81] and Ashby et al (2014)[82].

This stock-and-flow model consists of the following logic and is illustrated in Figure 30.

Figure 30 Stock-and-flow model logic



It is assumed that for each type of wound, in year 1:

1. Wounds are either healed or unhealed within a 12-month period.
2. Unhealed wounds are then treated in year 2
3. A proportion of healed wounds will recur after 12 months, which are then treated in year 2.
4. New wounds in year 2 are grown by demographic growth

Therefore, total wounds in year 2 therefore consist of new wounds, and unhealed and recurred wounds from year 1. Unhealed and recurred wounds from year 1 will be carried forward to year 2 and will heal/recur according to the same healing/recurrence rate as in year 1 (which is the same as for new wounds).

This process continues repeats for every year throughout the model.

Detail on the respective assumptions underpinning this system is provided in the following sections. These assumptions were a key focus area in the peer review process as described in section 3.2. In short, these assumptions (including prevalence, healing rates, recurrence rate) outlined stated in the remainder of this sections are a product a lengthy iterative process in which clinicians, academics and experts were consulted upon with a view to reach an agreed approach that was deemed conservative and enabled progress with the modelling.

[81] Guest JF, Vowden K, Vowden P. The health economic burden that acute and chronic wounds impose on an average clinical commissioning group/health board in the UK. Journal of Wound Care. 2017 Jun;26(6):292-303. DOI: 10.12968/jowc.2017.26.6.292.
[82] Ashby R, Gabe R, Ali S, Saramago P, Chuang L, Adderley U, *et al.* VenUS IV (Venous leg Ulcer Study IV): 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(57)

Leg ulcer prevalence

The model considers leg ulcers and costs on an annual basis. Leg ulcer annual prevalence estimates for 2012/13 have been taken from Guest et al (2015), as shown in the second column of the table below. Non-diabetic foot ulcers were not reported in this paper so have not been included.

To ensure unspecified leg ulcers are captured in the analysis, they have been proportionately redistributed across venous, mixed and arterial leg ulcers. The resulting 2012/13 UK prevalence rate (shown in the last column of the table below) is calculated by using the volume of wounds (following the redistribution of unspecified leg wounds) and dividing it by UK adult population data.

Figure 31 UK leg ulcer prevalence estimates 2012/13[83]

Wound type	Annual number of leg ulcer in UK, 2012/13	Inferred annual prevalence rate (UK adult population)
Leg ulcer (arterial)	8,888	0.04%
Leg ulcer (mixed)	24,442	0.11%
Leg ulcer (unspecified)	419,956	N/A
Leg ulcer (venous)	277,749	1.30%

It is assumed that the prevalence rate is the same between the UK and England, to enable an England-specific focus for this work.

It is acknowledged that there is likely to be significant variation in the leg ulcer prevalence and care across England, with some areas potentially having much lower or much higher prevalence than that stated in the table above. As leg ulcer prevalence is likely to affect the scope for improvement, users of the model accompanying this implementation case are able replace these prevalence estimates with their own estimates specific to their health geography to help customise their own implementation.

Due to a lack of data, it is assumed that each patient will have one wound. In practice, this assumption becomes redundant as the epidemiology assumptions and costings are done on a per wound basis.

These assumptions were a key focus area in the peer review process as described in section 3.2. In short, the prevalence assumptions stated here are following a lengthy iterative process in which clinicians, academics and experts were consulted upon with a view to reach an agreed approach that was deemed conservative and enabled progress with the modelling.

Healing rates

In the baseline, leg ulcers are assumed to heal as per the assumptions in the table below. For example, 47% of VLUs heal within 12 months.

[83] Guest JF, Ayoub N, McIlwraith T et al. Health economic burden that wounds impose on the National Health Service in the UK. BMJ Open 2015

Figure 32 Baseline healing rates[84]

Wound type	Healing rate (12 months)
Arterial leg ulcer	0%
Mixed leg ulcer	42%
Venous leg ulcer	47%

Due to a lack of robust evidence, the model does not seek to distinguish differences in healing rate with regards to characteristics such as gender, age, wound size, wound age and whether the wound becomes infected. This is somewhat overcome given that, as detailed in Guest et al (2017) [85], the above healing estimates are based on an average healing across a population sample of patients with these different characteristics.

It is assumed that these healing rates are constant over time. Although there could be reason for the healing rate to change over time, perhaps due to underlying technology improvements and the presence of comorbidities, there is a lack of data on these trends for it to be modelled robustly.

Recurrence rates

It is assumed that a proportion of leg ulcers that heal may recur within 12 months following healing. The rate at which wounds may recur within the same year of healing is provided by the table below, taken from Kapp Sayers (2008).

Figure 33 Baseline recurrence rates[86]

Leg ulcer type	Lower bound	Upper bound	Midpoint (used in model)
Venous	26%	69%	48%
Mixed	26%	69%	48%
Arterial	0%	0%	0%

For venous leg ulcers, a range of recurrence estimates is provided, so the midpoint is taken for the purpose of the modelling. Recurrence rates for mixed leg ulcers is not available so it is assumed to be the same rate at for venous leg ulcers. Recurrence rates for arterial leg ulcers are not available, however this can be assumed to be zero given the assumed healing rate is zero.

[84] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal. 2017
[85] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal. 2017
[86] Kapp, S and Sayers, V. Preventing Venous Leg Ulcer Recurrence: A Review [online]. Wound Practice & Research: Journal of the Australian Wound Management Association, Vol. 16, No. 2

New wounds

At year 1 of the model, it is assumed that the volume of new leg ulcers is calculated based on the shares of total wounds as per the table below.

Figure 34 Share of new wounds[87]

Ulcer type	Share of wounds that are new
Leg ulcer (arterial)	40%
Leg ulcer (mixed)	50%
Leg ulcer (venous)	52%

It is assumed that the likelihood of a person receiving a new leg ulcer is constant over time for a given age band. Therefore, the incidence of new leg ulcers is driven by demographic growth – that is, the growth in the population and the increasing shift of people into the older age brackets. This is to reflect the greater prevalence of wounds at older age groups.

Although the presence of comorbidities can also affect the incidence of new wounds, the impact of comorbidities is not captured due to a lack of evidence on this relationship. Its omission is unlikely to have a material impact on the results, particularly as the presence of comorbidities is unlikely to change regardless of whether the NWCSP recommendations are implemented such that there is minimal difference. The potential impact of comorbidities is tested as part of sensitivity analysis.

The growth rate of new wounds (shown in Figure 35 below) is a weighted average of England population growth by adult age band, weighted by share of complex wounds for each adult age band (Figure 36). This is to capture the differences in wound prevalence at each age band. Historical and projected population estimates by age band are from the ONS[88,89].

Figure 35 New wound annual growth

2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
1.7%	1.5%	2.0%	1.4%	1.7%	2.0%	1.7%	1.9%	1.4%	1.2%	1.4%	1.6%

Figure 36 Share of wounds age band[90]

Age band	% with complex wounds
0 - 9	0.3%
10 - 19	1.8%

[87] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal. 2017
[88] ONS (2020), Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland
[89] ONS (2019), Principal projection - England population in age groups
[90] Cullum, Nicky & Buckley, Hannah & Dumville, Jo & Hall, J. & Lamb, Karen & Madden, Mary & Morley, Richard & o'meara, Susan & Saramago, Pedro & Soares, Marta & Stubbs, Nikki. (2016). Wounds Research for Patient Benefit::a 5 year programme of research. Health Technology Assessment.

20 - 29	2.7%
30 - 39	4.5%
40 - 49	5.5%
50 - 59	9.0%
60 - 69	12.4%
70 - 79	23.2%
80 - 89	28.3%
90-99	10.0%
100+	0.4%
Missing	1.9%

Deaths and model exiting

Ideally, the model would include patient mortality in which some patients exit the model based on the risk of dying at different age groups, which changes due to healing improvement and general demographic growth of England population. However, this could not be modelled due to a lack of evidence on the relationship between improved leg ulcer healing and mortality.

Although introducing general population mortality projections (without any relationship to leg ulcer healing) was considered, little data exists on leg ulcer incidence by age band and how this changes over time. Continuing to model mortality with a static allocation of leg ulcers by age band, for example as provided by Cullum et al (2016) outlined in Figure 36, would mean that the increasing share of mortality above the age of 100 would be highly under-represented. This would therefore suggest a rapidly declining average mortality rate over time, across the entire leg ulcer population, which would be incorrect. Furthermore, ONS data on mortality projections and population projections above the age of 100 are less reliable, making it harder to accurately model mortality for older age groups who are at greater risk of leg ulcers.

In recognition that mortality could still have a material impact on the results, mortality has been included as a sensitivity in section 4.3 using the imperfect information available.

England leg ulcer volume projections

Applying the stock-and-flow model with the healing, recurrence and new wound assumptions detailed above, the model predicts the following growth rates of total England leg ulcers:

Figure 37 England wound volume projections

Venous leg ulcers

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Growth	0.0%	3.3%	2.8%	2.6%	2.3%	2.1%	2.1%	2.0%	2.0%	1.8%	1.7%
Vol (000's)	547.8	565.8	581.7	596.7	610.3	623.3	636.4	649.2	662.0	674.1	685.4

Mixed leg ulcers

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Growth	0.0%	3.7%	3.2%	2.9%	2.5%	2.3%	2.3%	2.1%	2.1%	1.9%	1.8%
Vol (000's)	47.3	49.0	50.6	52.0	53.4	54.6	55.8	57.0	58.2	59.3	60.4

Arterial leg ulcers

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Growth	0.0%	11.3%	10.3%	9.5%	8.8%	8.3%	7.8%	7.3%	7.0%	6.6%	6.3%
Vol (000's)	17.7	19.7	21.8	23.9	26.0	28.1	30.3	32.5	34.8	37.1	39.4

8.5.2 Resource consumption per leg ulcer

Assumptions on average amount of annual NHS resources required to treat leg ulcers is required to both calculate the per annum NHS cost and how changes to the delivery of care from the NWCSP recommendations can affect these costs.

The table below outlines all the resource items that are considered in the modelling and how the respective resource consumption estimates have been obtained.

Figure 38 Approach for resource consumption estimates

Resource item	Approach used to obtain estimates on average annual resource consumption per wound
GP visits Specialist nurse visits Allied-healthcare visits Hospital outpatient visits Hospital admissions Laboratory tests Devices Drug prescriptions	**Approach 1** These estimates have been taken from Guest et al (2017)[91]. See section 'Approach 1' below for further detail.
Practice nurse visits Community nurse visits Wound care related products (e.g. dressings, compression bandages, compression hosiery)	**Approach 2** These have been estimated using a bottom-up approach which builds a picture of the different treatment pathways in leg ulcer care and the associated equipment used. Two broad types of treatment have been identified: other care and evidence-based care. This reflects how some patients are currently receiving care ('other care') that is not based on evidenced best practice and could lead to lower patient outcomes than what is possible. See section 'Approach 2' below for further detail

[91] Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. International Wound Journal. 2017

Approach 1: resource estimates from Guest et al

For venous, mixed and arterial leg ulcers, resource consumption per wound is estimated by dividing the total 2012/13 wound consumption estimates from Guest et al (2017) with total number of wounds stated in the paper[91]. The table below details the inferred annual resource consumption per wound.

Figure 39 Inferred annual resource consumption per wound

Wound type	GP visits	Specialist nurse visits	Allied health-care visits	Hospital outpatient visits	Hospital admissions	Laboratory Tests	Devices	Drug prescriptions
Arterial	2.25	0.00	0.25	0.74	0.75	6.75	366.79	0.56
Mixed	7.36	0.00	0.18	0.90	0.73	50.32	37.64	102.28
Venous	3.28	0.02	0.16	1.64	0.38	19.19	130.48	55.37

Resource breakdowns

The table above includes 'drug prescriptions'. To increase the level of granularity in the model, this item has been broken down further using data from Guest et al (2017) [92] to estimate the respective shares of analgesics and anti-infectives:

Figure 40 Split for drug prescriptions

Breakdowns	VLU	Mixed	Arterial
Prescriptions for analgesics	61%	61%	61%
Prescriptions for anti-infectives	39%	39%	39%

Unhealed cost uplifts

The resource consumption estimates from Guest et al (2017) detailed above do not distinguish resource consumption between a wound that is healed and not healed. As this distinction will have a cost implication, the difference in resource consumption between a healed versus an unhealed leg ulcer has been inferred from Guest et al (2017)[93] by calculating the resource uplift (i.e. the ratio of healed versus not healed resources), given in the table below. Uplifts for mixed and arterial leg ulcers are assumed to be same as VLU due to lack of data.

Figure 41 resource consumption uplifts

Resource	Average resource consumption per wound			Uplift for not healed wounds
	Total	Healed	Not healed	
Bandages	9.69	1.78	10.59	**5.95**
Community nurse visits	149.15	34.62	155.54	**4.49**

[92] Guest, J.F., Fuller, G.W. and Vowden, P. (2017), Venous leg ulcer management in clinical practice in the UK: costs and outcomes
[93] Guest, J.F., Fuller, G.W. and Vowden, P. (2017), Venous leg ulcer management in clinical practice in the UK: costs and outcomes

Compression hosiery	13.81	5.73	23.99	**4.19**
Compression systems	37.25	18.11	61.36	**3.39**
Dressings	150.7	26.43	169.74	**6.42**
GP visits	1.68	0.7	1.7	**2.43**
Hospital admissions	0.2	0.1	0.2	**2.00**
Hospital outpatient visits	0.88	0.13	1.3	**10.00**
Laboratory Tests	0.32	0.7	0.35	**0.50**
Practice nurse visits	15.35	3.7	16.26	**4.39**
Prescriptions for analgesics	9.19	2.7	9.62	**3.56**
Prescriptions for anti-infectives	5.93	1.69	6.14	**3.63**

Note that the uplifts are applied such that the weighted average of the healed/unhealed resource consumption with the baseline healing rates equal the total resource consumption estimates given in Figure 39. In other words, the uplifts do not affect the total resource consumption across all leg ulcers.

Approach 2: bottom-up consumption estimates

A bottom-up approach is used to estimate the resource demand for practice nurses, community (district) nurses, dressings, compression hosiery and bandages. The bottom-up resource assumptions outlined in this section was a key focus area in the peer review process as described in section 3.2. In short, the assumptions stated here are following a lengthy iterative process in which clinicians, academics and experts were consulted upon with a view to reach an agreed approach that was deemed conservative and enabled progress with the modelling.

The demand for community and practice nurse time is based on the average time taken to conduct each type of leg ulcer care appointment. These appointment time estimates are given in the table below. Differences in duration of at-home and in-clinic appointment, as well as travel time, are also captured.

Figure 42 Nurse appointment times, home and clinic (mins)

Wound care appointment type	Home (mins)	Clinical setting (mins)	Source
Compression hosiery	34.20	25.40	Table 6, Ashby et al (VenUS IV)
Multi-layer compression bandaging	36.20	30.10	
Dressing only	25.00	20.00	Based on consensus from peer review process
Additional time per appointment due to travel time	+10.00	+0.00	Based on consensus from peer review process

In the baseline, it is assumed that 60% of patients are treated at home and 40% are treated in a clinical setting, based on estimates from Ashby et al (2014) [94] and feedback through the peer review process.

For the purpose of costs, it is assumed that all compression bandaging is four-layer bandaging. Although it is recognised that other types of multi-layer compression bandaging are commonly used, there is a lack of effectiveness on relative effectiveness. Given the costs for both product cost and application time are similar between four layer and other types of multi-layer compression bandaging, it is reasonable to use four-layer bandaging as the basis for costing.

VLU bottom-up resource estimation

A bottom-up approach is used to estimate the resource requirements for VLUs in terms of practice nurse, community nurses, dressings, compression hosiery and bandages. We identify three types of VLU care:

1. ***Other care*** - this represents care that is not underpinned by good quality research and so could lead to lower patient outcomes than is possible
2. ***Evidence-based care V1*** - this represents one form of care underpinned by good quality research, in which patients are treated with compression bandages.
3. ***Evidence-based care V2*** - this represents another form of care underpinned by good quality research, in which patients are treated with compression hosiery.

The baseline VLU costings is assumed to be a mixture of these three different types of care, each delivering a different healing rate, as per below:

Figure 43 VLU care types, patient share and healing rates

Care type	Wound care product used	Healing rate	Share of baseline VLU patients[95]
Other care	Dressings	32%[96]	31%
Evidence-based care V1	Compression bandaging to healing followed by compression hosiery to prevent recurrence	74%[96]	63%
Evidence-based care V2	Compression hosiery kit for healing. Once healed compression hosiery to prevent recurrence	74%[97]	7%

[94] Page 57, Ashby R, Gabe R, Ali S, Saramago P, Chuang L, Adderley U, et al. VenUS IV (Venous leg Ulcer Study IV): 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(57)
[95] Cullum, Nicky & Buckley, Hannah & Dumville, Jo & Hall, J. & Lamb, Karen & Madden, Mary & Morley, Richard & o'meara, Susan & Saramago, Pedro & Soares, Marta & Stubbs, Nikki. (2016). Wounds Research for Patient Benefit::a 5 year programme of research. Health Technology Assessment.
[96] Nelson EA, Adderley U. Venous leg ulcers. Systematic review 1902. BMJ Clinical Evidence. 2016 January
[97] Ashby et al (2014) found no difference in healing outcomes compared to 4LB so assumed same as 4LB

In effect, estimates from Cullum et al (2016) suggest that 31% of patients in the baseline receive care that is not underpinned by robust research evidence and therefore do not achieve the clinical outcomes that are possible with evidence-based care. This estimate is similar to the 20% and 93% for VLU and Mixed LUs respectively from Srinivasaiah et al (2007) [98] and 25% for VLUs from Guest et al (2017)[99].

The following tables detail the bottom-up assumptions used to estimate the average annual resource consumptions per VLU, by each care type.

Figure 44 VLU Other Care resource consumption per wound

VLU Other Care ***Resource requirements per appointment***		
Dressing materials	**Quantity**	**Rationale**
Dressing Pack	1	Although legs are often washed in tap water and buckets, this is difficult to cost so cost has been based on a dressing pack and saline capsules.
Saline (Irripod)	2	
Adhesive absorbent dressing (expensive)	1	A variety of dressings may be used, including those that are not cost effective. For costing, we have used an average of two dressings from the two ends of the cost range: ActiveHeal Foam Adhesive 15 x 15 cm = £2.15 and Allevyn Ag Adhesive 17.5 x 17.5cm= £14.20.
Clinician Time	**Quantity**	**Rationale**
Home Visit – Community Nurse • 60% of cases	25mins + 10mins travel	Nurse time per dressing change is based on an approximation and consensus from peer review process due to lack of data. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice - Practice Nurse • 40% of cases	20mins	
Frequency of appointments/ dressing changes	1.5 times a week	Based on consensus from peer review group

Figure 45 VLU evidence-based care V1 resource consumption per wound

VLU evidence-based Care V1 (Compression Bandaging) ***Resource requirements per appointment***		
Dressing materials	**Quantity**	**Rationale**
Dressing Pack	1	For the sake of simplicity, costed as for other care.
Saline (Irripod)	2	BNF unit costs, Prescription Cost Analysis data

[98] Srinivasaiah, Narasimhaiah & Dugdall, H & Barrett, S & Drew, Philip. (2007). A point prevalence survey of wounds in north-east England. Journal of wound care. 16. 413-6, 418. 10.12968/jowc.2007.16.10.27910.
[99] Guest, J.F., Fuller, G.W. and Vowden, P. (2017), Venous leg ulcer management in clinical practice in the UK: costs and outcomes

Simple, low adherent wound contact Layer	1	For costing, we have used a product which clinicians say is commonly used: Atrauman 10 x 20 cm
Multilayer, graduated compression bandaging kit	1	Cost based on Urgo K Four kit (18-25 cm and 25.-30 cm kit), BNF unit costs, Prescription Cost Analysis data
Clinician Time	**Quantity**	**Rationale**
Home Visit – Community Nurse • 60% of cases	36.20mins + 10mins travel	Nurse times are from Ashby et al (2014), VenUS IV. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice - Practice Nurse • 40% of cases	30.10 mins	
Frequency of appointments/ dressing changes	1.0 times a week	Based on consensus from peer review group

Figure 46 VLU evidence-based care V2 resource consumption per wound

Evidence-based Care V2 (Compression Hosiery) ***Resource requirements per appointment***		
Dressing materials (changed weekly)	**Cost**	**Rationale**
Dressing Pack	1	For the sake of simplicity, costed as for other care.
Saline (Irripod)	2	BNF unit costs, Prescription Cost Analysis data
Foam	1	BNF unit costs, Prescription Cost Analysis data
Compression hosiery for healing kits (every 12 weeks)	2	BNF unit costs, Prescription Cost Analysis data
Clinician Time	**Cost**	**Rationale**
Home Visit – Community Nurse • 60% of cases	Weekly dressing change: 25mins + 10mins travel time Hosiery change per 12 week: 34.20mins + 10mins travel	Nurse times are from Ashby et al (2014), VenUS IV. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice – Practice Nurse • 40% cases	Weekly dressing change: 20mins Hosiery change per 12 week: 25.40	
Frequency of appointments/ dressing changes	Dressings: 1.0 times a week Hosiery: every 12 weeks	Based on consensus from peer review group and Ashby et al (2014), VenUS IV.

To capture differences in resource consumption between healed and unhealed wounds, it is assumed that VLUs heal according to the below healing profile. In effect, of the venous leg ulcers that heal in 12 months, 83% heal at 6 months. Such leg ulcers will not require direct wound care treatment following healing at 6 months.

Figure 47 VLU healing profile[100]

Cumulative Healing rate	0 month	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months
Healed within 12 months	0%	55%	58%	68%	74%	79%	83%	87%	91%	94%	96%	98%	100%
Unhealed within 12 months	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

Mixed LU bottom-up resource estimation

A bottom-up approach is used to estimate the resource requirements for Mixed LUs in terms of practice nurse, community nurses, dressings, compression hosiery and bandages. We identify two types of Mixed LU care:

1. ***Other care*** - this represents care that is not underpinned by good quality research and so could lead to lower patient outcomes than is possible
2. ***Evidence-based care*** - this represents another form of care underpinned by good quality research, in which patients are treated with reduced compression bandages. Some of these patients would also be eligible for revascularization surgery, however in the absence of data this has not been costed.

The baseline is assumed to be a mixture of these different types of care, each delivering a different healing rate, as per below:

Care type	Wound care product used	Healing rate	Healing rate source	Share of baseline patients[101]
Other care	Dressings	28%	In the absence of equivalent data as with VLU, these healing rates have been estimated by proportionately scaling the respective VLU healing rates by the ratio of baseline Mixed and VLUs healing rates. This was sense-checked as part of the peer review process.	64%
Evidence-based care	Reduced Compression bandage	66%		36%

The following tables detail the bottom-up assumptions used to estimate the average annual resource consumptions per mixed leg ulcer, by each care type.

[100] Based on rebased healing profile from Guest, J.F., Fuller, G.W. and Vowden, P. (2017), Venous leg ulcer management in clinical practice in the UK: costs and outcomes

[101] Based on rebasing of patient shares to exclude NDS from Srinivasaiah, Narasimhaiah & Dugdall, H & Barrett, S & Drew, Philip. (2007). A point prevalence survey of wounds in north-east England. Journal of wound care. 16. 413-6, 418. 10.12968/jowc.2007.16.10.27910.

Figure 48 Mixed LU standard care resource consumption per wound

Mixed LU Other Care ***Resource requirements per appointment***		
Dressing materials	**Quantity**	**Rationale**
Dressing Pack	1	Although legs are often washed in tap water and buckets, this is difficult to cost so cost has been based on a dressing pack and saline capsules.
Saline (Irripod)	2	
Adhesive absorbent dressing (expensive)	1	A variety of dressings may be used, including those that are not cost effective. For costing, we have used an average of two dressings from the two ends of the cost range: ActiveHeal Foam Adhesive 15 x 15 cm = £2.15 and Allevyn Ag Adhesive 17.5 x 17.5cm= £14.20.
Clinician Time	**Quantity**	**Rationale**
Home Visit – Community Nurse • 60% of cases	25mins + 10mins travel	Nurse time per dressing is based on an approximation due to lack of data. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice - Practice Nurse • 40% of cases	20mins	
Frequency of appointments/ dressing changes	1.5 times a week	Same per appointment cost as VLU Other Care V1

Figure 49 Mixed LU standard care resource consumption per wound

Mixed LU evidence-based care (Reduced Compression Bandaging) ***Resource requirements per appointment***		
Dressing materials	**Quantity**	**Rationale**
Dressing Pack	1	For the sake of simplicity, costed as for sub-optimal care.
Saline (Irripod)	2	BNF unit costs, Prescription Cost Analysis data
Simple, low adherent wound contact Layer	1	For costing, we have used a product which clinicians say is commonly used: Atrauman 10 x 20 cm
Reduced Multi-layer compression bandaging kit	1	BNF unit costs, Prescription Cost Analysis data
Clinician Time	**Quantity**	**Rationale**
Home Visit – Community Nurse • 60% of cases	36.20mins + 10mins travel	Nurse times are from Ashby et al (2014), VenUS IV. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice - Practice Nurse • 40% of cases	30.10 mins	

Frequency of appointments/ dressing changes	1.5 times a week	Same per appointment cost as VLU Optimal Care V1

To capture differences in resource consumption between healed and unhealed wounds, it is assumed that mixed leg ulcers heal according to the below healing profile. In the absence of data, the healing profile as for venous leg ulcers is used.

Figure 50 Mixed leg ulcer healing profile[102]

Cumulative Healing rate	0 month	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months
Healed within 12 months	0%	55%	58%	68%	74%	79%	83%	87%	91%	94%	96%	98%	100%
Unhealed within 12 months	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

Arterial LU bottom-up resource estimation

A bottom-up approach is used to estimate the resource requirements for Arterial LUs in terms of practice nurse, community nurses, dressings, compression hosiery and bandages.

We identify two types of arterial LU care:

1. ***Revascularisation or other surgical care followed by dressings:*** this care is offered to patients who are able to undergo surgery.
2. ***Dressings only:*** this care is offered to patients who are unable to undergo surgery.

Figure 51 Arterial care types, healing rates and patient shares

Care type	**Wound care product used**	**Healing rate**	**Healing rate source**	**Share of baseline patients**
Dressings only	Dressings	26%	Based on baseline healing from Guest et al (2016), assuming suboptimal healing rate is not higher than optimal care healing	100%
Revascularisation or other surgical care followed by dressings.	Revascularisation or other surgery and dressing changes	Due to lack data on both the cost, effectiveness and prevalence of revascularisation surgery, this has not been modelled.		

Figure 52 Arterial standard care resource consumption per wound

Arterial standard Care

[102] Based on rebased healing profile from Guest, J.F., Fuller, G.W. and Vowden, P. (2017), Venous leg ulcer management in clinical practice in the UK: costs and outcomes

Resource requirements per appointment		
Dressing materials	**Quantity**	**Rationale**
Dressing Pack	1	Although legs are often washed in tap water and buckets, these are difficult to cost and this probably doesn't happen in a typical general practice nurse / clinic setting
Saline (Irripod)	2	
Adhesive foam (expensive)	1	A variety of dressings may be used, including those that are not cost effective. For costing, we have used an average of two dressings from the two ends of the cost range: ActiveHeal Foam Adhesive 15 x 15 cm = £2.15 and Allevyn Ag Adhesive 17.5 x 17.5cm= £14.20.
Clinician Time	**Quantity**	**Rationale**
Home Visit – Community Nurse • 60% of cases	25mins + 10mins travel	Nurse time per dressing is based on an approximation due to lack of data. Nurse cost per minute is based on unit cost data from PSSR 2019-20 and Nurse band by band data from Royal College of Nursing (2013). Split of cases between Home and Clinic is based on Cullum et al (2016), adjusted for recent trends based on feedback from clinicians. Clinician time costs are a weighted average of the associated cost of providing care at home and in the clinic, weighted by the respective share of cases
General Practice - Practice Nurse • 40% cases	20mins	
Frequency of appointments/ dressing changes	1.5 times a week	Same per appointment cost as VLU Other Care

Because of a lack of data about the cost, effectiveness and prevalence of both types of care improvement from the different types of care has not been modelled.

Summary of annual resource consumption per wound

Based on the methodology presented in this section above, the below table summarises the average annual resource consumption per VLU.

Figure 53 Summary of annual quantity of resources consumed per wound for VLUs

Resource	Healed	Not healed
GP visits	1.9	4.5
Specialist nurse visits	0.0	0.0
Allied health-care visits	0.1	0.2
Hospital outpatient visits	0.3	2.8
Hospital admissions	0.3	0.5
Laboratory Tests	26.1	13.1
Devices	92.7	164.0
Prescriptions for analgesics	14.3	50.8
Prescriptions for anti-infectives	9.1	32.9
Dressing pack	15.9	59.9
Saline	31.7	119.9
Foam dressing	0.9	3.4
Foam Adhesive dressing (sub-optimal)	6.3	23.8

Compression bandaging 4-layer	8.6	32.7
Compression hosiery	0.2	0.6
Community nurses (mins)	359.8	1359.5
Practice nurses (mins)	164.0	619.0
Wound Contact Layer	8.6	32.7

Post healing leg ulcer therapy

Under evidence-based care, healed legs should still be regularly reviewed to reduce the risk of recurrence. This review involves assessment of arterial status and provision of new hosiery in a 60min appointment every 6 months for VLUs and every 3 months for mixed LUs, once the original wound heals, either until the patient dies or the wound recurs. This does not apply for arterial wounds which are assumed to not heal.

Given the nature of this review and for simplicity, it is assumed this review only occurs in a clinical setting. For the baseline, it is assumed that only 10% of patients receive this treatment as a conservative assumption, in the absence of data.

The table below details the resource consumption estimates per wound.

Figure 54 Post healing wound therapy resource consumption

Evidence-based post healing care (Compression Hosiery) – Clinic only ***Costs per appointment (2018/19)***		
Dressing materials (changed weekly)	**Quantity**	**Rationale**
Dressing Pack	1	For the sake of simplicity, costed as for sub-optimal care.
Saline (Irripod)	2	BNF unit costs, Prescription Cost Analysis data
Compression hosiery for healed legs	2	BNF unit costs, Prescription Cost Analysis data
Clinician Time	**Quantity**	**Rationale**
Clinic – Registered Nurse • VLU: Hosiery change every 6 months • Mixed: Hosiery change every 3 months	60min appointments	N/A
Frequency of appointment	VLU: every 6 months Mixed: every 3 months	

These costs are incurred from the point at which a patient's wound heals until the patient either dies or the wound recurs. The average age of a person with a wound is 70.6 years[103].

[103] Cullum, Nicky & Buckley, Hannah & Dumville, Jo & Hall, J. & Lamb, Karen & Madden, Mary & Morley, Richard & o'meara, Susan & Saramago, Pedro & Soares, Marta & Stubbs, Nikki. (2016). Wounds Research for Patient Benefit::a 5 year programme of research. Health Technology Assessment.

Based on an average age at death of 81.3[104], it is estimated that a person will receive 10 years of post-healing therapy before dying, or until the wound recurs (as per baseline recurrence rates).

8.5.3 Unit costs

The below unit costs are used to calculate costs using the resource consumption estimates detailed in the previous section.

Figure 55 Unit costs 2018/19

Item	Unit cost	Source
Allied healthcare visits	£74.48	These unit costs have been taken from Guest et al (2018)[105] due to a lack of detail on what these items are composed of. The unit costs are applicable across all wounds.
Specialist nurse visits	£69.64	
Devices	£0.69	
Laboratory Tests	£7.55	
Bandages (non compression)	£1.59	NHS Business Services Authority (2018), Prescription Cost Analysis (PCA) data
Compression hosiery	£23.20	
Compression bandages	£7.04	
Dressings	£3.14	
Prescriptions for analgesics	£4.64	
Prescriptions for anti-infectives	£16.26	
Saline	£0.39	
Foam dressing	£2.65	
Foam Adhesive dressing (sub-optimal)	£8.16	
Wound Contact Layer	£0.80	
Dressing pack	£0.60	
Hospital outpatient visits	£147.84	NHSI (2019), 2018/19 National Cost Collection data
Hospital admissions	£3,293.00	
Community nurse visits	£0.63 per min	PSSRU (2019) Unit Costs of Health and Social Care 2019 and appointment time data from VenUS IV
GP visits	£96.17	
Practice nurse visits	£0.62 per min	

[104] ONS (2019), Life expectancy in selected countries, 2015 to 2017
[105] Guest, J.F., Fuller, G.W. and Vowden, P. (2018), Diabetic foot ulcer management in clinical practice in the UK: costs and outcomes. Int Wound J, 15: 43-52. doi:10.1111/iwj.12816

Clinical time unit costs

Unit costs for community and practice nurses are based on data on time per wound care visit and cost per minute. Time estimates are detailed in Figure 42. Unit costs of nurse time by nurse band is given in the following table:

Figure 56 Nurse unit costs by band

Salary bands	Community nurse share of wound care [106]	Community nurse cost per hour[107]	Practice nurse cost per hour[107]
5	95%	£37.00	-
6	7%	£46.00	-
7	0%	£55.00	-
8a	0%	£64.00	-
N/A	-	-	£37.00

Prescription cost analysis data

Some of the unit costs are from NHS Business Services Authority (2018), Prescription Cost Analysis (PCA) data. The table below provides the definitions used to find the unit costs.

Figure 57 PCA unit cost definitions

Item	Note	Drug name	BNF chemical name	BNF Chapter name	BNF Sub para
Compression bandages 4LB	-	'compress' and "four"	'bandages'	-	-
Compression hosiery	-	'hose' or 'hosiery'	'Venous ulcer compression'	-	-
Bandages	Assumed this is non compression related	*Does not include* 'compress'	'bandages'	-	-
Anti-infectives	-	-	-	'infections' and 'skin'	'antibacterial'
Analgesics	-	-	-	-	'Analgesics'
Dressings	Dressings searched for: anti bacterial, foam, NLA, Polymer, Hydrogel, Silver, Alignate'	-	'[dressing name]'	'anti bacterial, foam, NLA, Polymer, Hydrogel, Silver, Alignate.'	-

[106] Royal College of Nursing (2013), Survey of district and community nurses in 2013
[107] PSSRU (2019) Unit Costs of Health and Social Care 2019

Saline	-	-	'irrigation solution'	-	-

8.5.4 Inflation assumptions

Inflation rates are available for 2016 to 2020 from NHSE/I. Inflation outside this period is assumed to be the average of the rates within this period, in the absence of better estimates or rationale for a different approach.

Figure 58 Annual inflation assumptions[108]

Cost type	2016	2017	2018	2019	2020
Pay and pensions	3.3%	2.0%	1.6%	1.6%	2.9%
Drugs	4.5%	4.6%	3.6%	4.1%	4.1%
Capital costs	3.1%	3.2%	3.2%	3.1%	3.1%
Other operating costs	1.7%	1.8%	2.1%	1.9%	2.0%
Overall	3.1%	2.3%	2.0%	2.0%	2.9%

[108] NHSE/I Economic assumptions 2016/17 to 2020/21

8.6 To-be methodology

The assumptions outlined in the following sections are for the purpose of estimating the potential impact of implementing NWCSP recommendations in England. It does not seek to provide guidance on the precise way in which leg ulcer care should be delivered.

8.6.1 Clinical improvements from evidence-based care

Evidence suggests that a significant share of leg ulcers treated are currently treated with care ('other care') that is not underpinned by good quality research ('evidence-based' care). These wounds are half as likely to heal and have more than double the chance of recurring compared to evidence-based care. Furthermore, the cost of standard care tends to be higher than evidence-based care, as healing takes longer and uses less effective therapies.

Therefore, increasing the share of patients receiving evidence-based care can result in better healing and recurrence rates, as well as financial savings.

The following sub-sections outline the assumptions underpinning the expected benefits from delivering evidence-based care. The To-be assumptions outlined were a key focus area in the peer review process as described in section 3.2. In short, the assumptions stated here are following a lengthy iterative process in which clinicians, academics and experts were consulted upon with a view to reach an agreed approach that was deemed conservative and enabled progress with the modelling.

Clinical improvements for venous leg ulcers

It is assumed that venous leg ulcers can receive one of three types of care:

1. ***Other care*** – this represents care that is not underpinned by good quality research and so could lead to lower patient outcomes than is possible
2. ***Evidence-based care V1*** – this represents one form of care underpinned by good quality research, in which patients are treated with compression bandages
3. ***Evidence-based care V2*** – this represents another form of care underpinned by good quality research, in which patients are treated with compression hosiery.

It is assumed that moving more patients from 'other care' to either of the 'evidence-based care' will yield benefits in the following ways:

- Healing rates – other care yields a lower healing rate than evidence-based care, so moving more patients to evidence-based care will increase the average healing rate
- Recurrence rates – other care has a yields recurrence rate than evidence-based care, so moving more patients to evidence-based care will reduce the recurrence healing rate
- Cost of delivering care – the resource modelling suggests other care can be more expensive than evidence-based care, so moving more patients to evidence-based care could lead to a lower average treatment cost per patient.

The below table illustrates the share of VLU patients allocated to the three care types, along with the respective healing and recurrence rates.

Figure 59 care type mix

Care type	Patient share by care type		Healing rates[109]	Recurrence rates
	Baseline[110]	To-be[111]		
Other care	31%	10%	32%	46%[112]
Evidence-based care V1 (compression bandaging)	63%	35%	74%	18%[113]
Evidence-based care V2 (compression hosiery)	7%	55%	74%	14%[114]

It is assumed that 60.9% of compression patients will be eligible for hosiery. This is based on analysis of patient drop-outs in VenUS IV trials[111]. Not all patients will be eligible for hosiery, for example because they may either find it uncomfortable or due to a clinical consideration. However, once compression bandaging has reduced swelling and excess exudate is reduced, a proportion of patients in compression bandaging may move into compression hosiery before healing. It is not known what proportion of patients may move from compression bandaging into compression hosiery before healing, so this has not been included in the modelling assumptions.

Compression wraps are also in use for venous leg ulceration but the effectiveness of these devices for promoting healing is currently unknown so these devices have not been included in the modelling assumptions.

In effect, moving a portion of the 31% of baseline patients from standard care to evidence-based care will enable these patients to achieve a higher healing rate of 74% and an improved recurrence rate (either 18% or 14% depending if they are eligible for hosiery). As a result, the average healing and recurrence rate across all VLU patients will improve (by precisely 9% and -7% respectively). The below tables describe this improvement in the average healing rate across all patients, by moving patients from standard care to evidence-based care:

[109] Average taken of from statistically significant trials reviewed in Nelson EA, Adderley U. Venous leg ulcers. Systematic review 1902. BMJ Clinical Evidence. 2016 January
[110] Cullum, Nicky & Buckley, Hannah & Dumville, Jo & Hall, J. & Lamb, Karen & Madden, Mary & Morley, Richard & o'meara, Susan & Saramago, Pedro & Soares, Marta & Stubbs, Nikki. (2016). Wounds Research for Patient Benefit::a 5 year programme of research. Health Technology Assessment.
[111] Based on analysis of patient drop-outs in VenUS IV, which suggests 60.9% of compression will be eligible for hosiery. This assumption can be customised. Suboptimal share is based on reasonable expectation, which has been sense-checked with clinicians. This assumption can be customised.
[112] Nelson EA, Bell-Syer SEM. Compression for preventing recurrence of venous ulcers. Cochrane Database of Systematic Reviews 2014, Issue 9. Art. No.: CD002303. DOI: 10.1002/14651858.CD002303.pub3.
[113] Average taken of estimates from VenUS I and VenUS IV trials: VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers. / Iglesias, C; Nelson, E A; Cullum, N A; Torgerson, D J; VenUS Team; Ashby R, Gabe R, Ali S, Saramago P, Chuang L, Adderley U, et al. VenUS IV (Venous leg Ulcer Study IV): 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(57)
[114] Ashby R, Gabe R, Ali S, Saramago P, Chuang L, Adderley U, et al. VenUS IV (Venous leg Ulcer Study IV): 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(57)

Figure 60 VLU healing improvement

Care type	Baseline	To-be
Inferred healing rate *(weighted average of patient shares and healing in Figure 59)*	61%	70%
Incremental healing rate improvement from care pathway mix	**+9%**	

Figure 61 VLU recurrence improvement

Care type	Baseline	To-be
Inferred recurrence rate *(weighted average of patient shares and recurrence in Figure 59)*	26%	19%
Incremental recurrence rate improvement from care pathway mix	**-7%**	

Clinical improvement from endovenous ablation

Further improvements in VLU healing and recurrence are available if patients undergo endovenous ablation surgery.

Figure 62 Endovenous ablation assumptions

	Assumption[115]
Eligibility *(share of patients in evidence-based care receiving ablation surgery)*	64%
Incremental healing improvement *(for those receiving ablation)*	**+8%**
Incremental recurrence improvement *(for those receiving ablation)*	-5%

It is assumed that only those patients that are receiving evidence-based care will be eligible for ablation surgery. Furthermore, due to a lack of data, it is assumed no patients in baseline are receiving ablation surgery. As a result, the average improvement resulting from endovenous ablation surgery across all VLU patients are given in the table below.

[115] Gohel, M. S., Heatley, F., Liu, X. et al. (2018) A Randomized Trial of Early Endovenous Ablation in Venous Ulceration. New England Journal of Medicine.

Figure 63 Healing and recurrence improvement from ablation surgery

	Assumption
Effective healing improvement rate *(average across all VLU patients)*	**+5%**
Effective recurrence improvement rate *(average across all VLU patients)*	**-3%**

Summary of total clinical improvement for VLUs

Adding all the incremental healing and recurrence improvements given in Figure 60, Figure 61 and Figure 63 to the baseline healing/recurrence rates gives the To-be healing/recurrence rates:

Figure 64 To-be VLU healing rate

Steps	Healing rate
Baseline VLU healing rate	**47%**
Care pathway mix incremental improvement (Figure 60)	+9%
Endovenous ablation incremental improvement (Figure 63)	+5%
To-be VLU healing rate	**60%**

Figure 65 To-be VLU recurrence rate

Steps	Recurrence rate
Baseline VLU recurrence rate	**48%**
Care pathway mix incremental improvement (Figure 61)	-7%
Endovenous ablation incremental improvement (Figure 63)	-3%
To-be VLU recurrence rate	**37%**

Clinical improvements for mixed leg ulcers

It is assumed that venous leg ulcers can receive one of two types of care:

1. ***Other care*** – this represents care that is not underpinned by good quality research and so could lead to lower patient outcomes than what is possible
2. ***Evidence-based care*** – this represents one form of care underpinned by good quality research, in which patients are treated with reduced compression bandages

It is assumed that moving more patients from ‘other care’ to ‘evidence-based care’ will yield benefits in the following ways:

- Healing rates – other care yields a lower healing rate than evidence-based care, so moving more patients to evidence-based care will increase the average healing rate
- Cost of delivering care – the resource modelling suggests other care can be more expensive than evidence-based care, so moving more patients to evidence-based care can lead to a lower average treatment cost per patient.

It is assumed that there will not be any improvement in mixed LU recurrence from the interventions due to a lack of evidence.

The below table illustrates the share of mixed leg ulcer patients allocated to the two care types, along with the respective healing rates. In the absence of robust evidence on the healing rates for other care and evidence-based care of mixed LUs, it is assumed that the healing rates are a proportional scaling of the VLU healing rates, based on the ratio between the baseline mixed and VLU healing rates. These healing rates have then been sense-checked with clinicians, nurses and experts to ensure they are reasonable.

Figure 66 Care type mix, mixed leg ulcers

Care type	Patient share by care type		Healing rates[116]
	Baseline[117]	To-be[118]	
Other care	64%	10%	28%
Evidence-based care	36%	90%	66%

In effect, moving a portion of the 64% of baseline patients from other care to evidence-based care will enable these patients to achieve a higher healing rate of 66%. As a result, the average healing across all mixed patients will improve (by precisely 20%). The below tables describe this improvement in the average healing rate across all patients, by moving patients from other care to evidence-based care:

Figure 67 Healing improvement, mixed leg ulcers

Care type	Baseline	To-be
Inferred healing rate *(weighted average of patient shares and healing in Figure 66)*	42%	62%
Incremental healing rate improvement from care pathway mix	+20%	

[116] Based on a scaling of VLU healing rates, based on the relative ratio of baseline mixed versus VLU healing rate.
[117] Srinivasaiah et al (2007), A point prevalence survey of wounds in north-east England
[118] Based on reasonable expectation, which has been sense-checked with clinicians. This assumption can be customised.

Summary of total clinical improvement for mixed leg ulcers

Applying all the incremental healing and recurrence improvements given in Figure 67 to the baseline healing rate gives the To-be healing rate:

Figure 68 To-be VLU healing rate

Steps	Healing rate
Baseline mixed healing rate	**42%**
Care pathway mix incremental improvement (Figure 60)	+20%
To-be mixed leg ulcer healing rate	**62%**

Post healing wound therapy

Under evidence-based care, healed wounds would still need to be reviewed periodically to help avoid recurrence. This involves review of arterial status and provision of new hosiery in a 60min appointment every 6 months for VLU and every 3 months for Mixed LUs, once the original wound heals, either until the patient dies or the wound recurs. This does not apply for arterial wounds which are assumed to not heal.

It is assumed that the recurrence improvements from post healing wound therapy is implicitly captured in the recurrence improvements from evidence-based care (as outlined earlier in this section) and so has not been explicitly calculated. In the absence of data, it is assumed 10% of patients receive post-healing therapy at baseline.

Figure 69 Post healing wound therapy patient shares

	Baseline	To-be
Share of patients receiving post healing wound therapy	10%	85%

Summary of total clinical improvements

For completeness, the below table summarises all the Baseline versus To-be healing and recurrence rates, as discussed in the previous sections.

Figure 70 VLU baseline vs To-be clinical outcomes

VLU	Healing rate	Recurrence rate
Baseline	47%	48%
To-be	60%	37%

Figure 71 Mixed LU baseline vs to-be healing rates

Mixed LU	Healing rate
Baseline	42%
To-be	62%

These clinical improvements were a key focus area in the peer review process as described in section 3.2. In short, the assumptions stated here are following a lengthy iterative process in which clinicians, academics and experts were consulted upon with a view to reach an agreed approach that was deemed conservative and enabled progress with the modelling.

8.6.2 Patient care settings

It is assumed that there are four care settings in which leg ulcer care is delivered: at home, in General Practices by practice nurses, in leg ulcer clinics and in social models of care. Patient outcomes and clinical resource requirements are assumed to be the same across all care settings, however each care setting may involve administrative running costs. In effect, clinical staff will be redeployed from existing services so little additional staffing costs will be incurred.

The table below details the share of patients treated in each of the four wound care settings.

Figure 72 Care setting mix

Care setting	Share of patients	
	Baseline[119]	To-be[120]
Home visits	60%	40%
General practice appointments	40%	10%
Wound care clinic	0%	35%
Social care model	0%	15%

For example, it is estimated that 60% of patients are currently treated at home. However, this is envisaged to be reduced to 40% under To-be. Treating patients at home tends to be more expensive because patient appointments take longer to complete than in the clinic and nurses need to spend time travelling to a patient's home, leading to greater clinician costs. Therefore, reducing the share of patients being treated at home could lead to financial savings.

It is assumed home visits are carried out by community clinicians and general practice appointments are mostly carried out by practice nurses. The assumptions for wound care clinics and social care models are detailed in the subsequent sections.

[119] Based on estimates from Ashby et al (2014) and feedback through the peer review process
[120] Based on reasonable expectation, which has been sense-checked with clinicians. This assumption can be customised.

Social models of care

Some patients will be in an informal group setting through social models of care. The assumptions below are based on data provided by the Lindsay Leg Club®.

The below table outlines the average cost of providing social care models. Note that these costs are the administrative running costs and not the cost of providing wound care in the care setting. This administrative/running cost is the cost of band 7 clinician time dedicated to a social care model. The band 7 requirements outlined below may underestimate the administrative cost as it does not include time spent organising sessions, due to a lack of data.

Figure 73 Social care model assumptions

Assumption	Value	Notes
Average care session (mins)	215 mins	The average members per session can vary considerable depending on geographical location i.e. town or rural community
Average clinician time per session	821 mins	
Share of time by Clinician band 7 (management nurse time)	7%	This is the session time dedicated to band 7's and is the cost of ongoing clinical oversight/administration to deliver a social care model. This may underestimate the administrative cost as it does not include time spent organising sessions.
Average members per session	21	
Average cost per member per session	£2.51	Applying PSSRU clinician costs.
Average compression changes per year for a patient with a new wound	41	Based on bottom-up resource estimates and above healing rate.
Average annual cost per member	**£103**	Assume changes per year translates into number of sessions. It is assumed total administrative cost of social care models cost is based on the share of patients allocated to social care models in a given year. This is the incremental average annual administrative cost for a social model of care, per patient. This does not include general cost of wound care in social care models.

Due to a lack of data, it is assumed that the amount of clinical time and wound care products a patient incurs in a social care model is the same as all other care settings. Given social care models treat patients in a group setting, it is likely that social care models are likely to demand significantly less clinical time than other care settings requiring one-on-one patient appointments (e.g. wound care clinics, GPs, at home). Therefore, moving patients to social care models can yield financial savings, albeit this cannot currently be estimated.

It is assumed the annual cost of providing the social care model is uniformly phased in during the implementation period and incurred thereafter

Lower Limb wound clinics

Lower Limb wound clinics will be set-up to specifically deliver wound care, such as those already existing in Manchester and Leeds. It is envisaged these clinics will predominantly serve patients in urban areas.

Lower limb wound clinic set-up costs

The below table details the assumptions underpinning the set-up costs of wound care clinics. Based on existing wound care clinics, most equipment and furniture will be included in the rental space costs. It is assumed this cost will be incurred at the very start of the implementation period, as a one-off.

Figure 74 Wound care clinic set-up cost assumptions

Assumption	Value (per clinic)	Notes
Estimated caseload patients per year	476	Based on existing patient caseloads.
Dopplers required per clinic	3	
Total-set up cost per clinic	£600	Most cost equipment and furniture costs will be included in the rental (running) costs.
Average set-up cost per patient	**£1.42**	It is assumed total clinic set-up costs is based on the share of baseline patients allocated to wound care clinics.

Lower Limb wound clinic running costs

The below table details the assumptions underpinning the annual running cost of wound care clinics. This details the incremental administrative cost of running the clinic and not the cost of wound care, which is assumed constant regardless of the care setting. Clinical staff will be redeployed from existing services so little additional staffing cost will be incurred.

Figure 75 Wound care clinic running cost assumptions

Item	Value (per clinic)	Notes
Band 3 clerical worker	0.4 WTE	This is the cost of clinician administration and oversight to run the clinic. The cost of delivering wound care itself is assumed constant across all care settings. Clinical staff will be redeployed from existing services so little additional staffing cost will be incurred.
Band 3 support worker	0.5 WTE	
Daily rental costs (including most equipment, IT, maintenance, cleaning costs)	£110/day	Assumed clinics are open 5 days a week every week
Total annual running costs per clinic	£73,506	
Average annual running cost per patient	**£154**	This is applied to all patients allocated to wound care clinics, each year, to produce the annual total clinic running cost.

It is assumed the clinic running costs are uniformly phased in during the implementation period and incurred thereafter.

8.6.3 Implementation costs

Lower limb wound care education

One-off training cost

During the implementation period, lower limb wound care education will be given to all clinicians below band 7 who are involved in lower limb wound care. Clinicians whose role is predominantly lower limb wound care (e.g. they work in a social care model, wound care clinic or regularly deliver care to patients at home) will receive a full four-day training course, while all other clinicians who are occasionally involved in lower limb wound care will receive a one-day course.

It is assumed that the cost of the training will be the cost of clinician time dedicated to taking the training course, as well as oversight from a band 8. The course itself will be delivered at no cost to the participants or their organisations by tissue viability specialist clinicians working within their organisations, supported by companies who supply the compression therapy wound products used within that organisation.

Figure 76 Lower limb wound care education cost assumptions

Item	Value	Notes
Clinician time spent on education	4 days (56% of clinicians) or 1 day (44% of clinicians)	Shares are based on the care setting mix assumptions in Figure 72
Trainees per session	12.5	10-15, so midpoint taken
Clinician oversight (1 x band 8)	4 days (56% of clinicians) or 1 day (44% of clinicians)	1x band 8 is required per 12.5 trainees per session
Other training costs	£0.00	Compression products supplied by product supplier companies.
Total training cost per clinician (by band)	**Band 4 – £600** **Band 5 – £786** **Band 6 – £954**	This cost is incurred for every clinician FTE required for wound care (based on resource consumption modelling) to produce total training cost. These costs will be evenly distributed over the implementation period

Ongoing refresher education

After implementation, clinicians will be able to receive a one-day refresher education course on an annual basis.

Figure 77 Ongoing refresher training cost

Item	Value	Notes
Clinician time spent on training	1 day	Shares are based on the care setting mix assumptions in Figure 72
Trainees per session	12.5	10-15, so midpoint taken
Clinician oversight (1 x band 8)	1 day	1x band 8 is required per 12.5 trainees per session
Share of all wound care clinicians receiving refresher courses every year	10%	Total number of clinician is based on FTE estimates from bottom-up resource consumption estimates for 2019.
Total training cost per clinician (by band)	**Band 4 – £225** **Band 5 – £295** **Band 6 – £359**	This is applied for each clinician being trained, on an annual basis.

Programme implementation management costs

There will be costs incurred of having dedicated staff to implement the interventions, which will be spread evenly across the implementation period. These costs are assumed to mainly be of staff time.

Figure 78 Programme implementation cost assumptions

Assumption	Value	Notes
Implementation team	1 x Band 8c 1 x Band 5	Unit cost is salary obtained from PSSRU unit cost 2019 data.
Years of implementation team required	3	
Number of CCGs implementing change	135[121]	Assumed each CCG implementing the recommendations will require an implementation team. This may change as the health system moves towards an Integrated Care System structure,
Annual cost (all CCGs)	**c. £17.4m per year over 3 years**	This cost is evenly spread across the implementation period.

Data capture costs

Hardware and software costs will be incurred from implementing data capture technologies to record and monitor patient wound care data.

One-off hardware costs

It is assumed each clinic will require hardware as a one-off initial cost (e.g. 2D imaging cameras)

[121] About CCGs, https://www.nhscc.org/ccgs/

Figure 79 hardware cost assumptions

Assumption	Value	Notes
Hardware cost for 2D imaging, per unit	£1,000	Provided by NHS procurement specialist based on wound care technology tenders
Hardware required per clinic	3	Assumed 3 rooms per clinic, each requiring hardware
One-off hardware cost	**£0.6m per year over 3 years**	Number of clinics estimated based on clinic costings. Cost assumed equally distributed over 3 years of implementation period.

Annual software costs

It is assumed each community nurse who spends a significant proportion of their time on wound care will require an app to record data. The cost of the app will be the associated licence fee of the software.

Figure 80 Software cost assumptions

Assumption	Value	Notes
Annual app software cost, per 300,000 adult population	£50,000	Based on software costs provided by by NHS procurement specialist.
Total community nurses delivering wound care	This is based on the resource consumption modelling and is assumed constant over time for the purpose of data capture costings for simplicity.	
Annual software cost	**£13.5m**	This cost is uniformly phased in during the implementation period and incurred thereafter

Monitoring and evaluation costs

Costs will be incurred several years after implementation to monitor and evaluate the success of the interventions, as part of ongoing quality improvement.

Figure 81 Monitoring and evaluation cost assumptions

Assumption	Value	Notes
Cost per monitoring and evaluation process	£20,000	Based on an approximation
Number of CCGs implementing change	135[122]	
Total monitoring and evaluation cost	**£3.5m**	Costs incurred seven years after the end of the implementation period and are spread over three years,

[122] About CCGs, https://www.nhscc.org/ccgs/

8.6.4 General modelling assumptions

Figure 82 General modelling assumptions

Assumption	Value	Notes
Implementation period	3 years, from 2020	
First year of benefits	2023	
Optimism bias[123]	30%	Applied to both implementation costs (as standard) and incremental benefits.
Discount rates[123]	3.5% for non-QALY benefits 1.5% for QALY benefits	Used to calculate the present values

8.7 Sensitivity analysis assumptions

This section describes the scenarios tested in the sensitivity analysis presented in section 4.3. These scenarios were informed by feedback from the peer review process and wider engagement described in section 3.2.

Test 1: leg ulcer prevalence

Estimates of leg ulcer prevalence have a large impact on the results but there is variation across different sources of data. The prevalence estimates used in the core analysis are based on the Guest et al (2017)[124] Burden of Wounds study. However, other data sources suggest much lower levels of prevalence. In recognition of this, prevalence estimates from Cullum et al (2016)[125] based on a study in Leeds have been used to test the scenario for populations where prevalence may be lower.

Test 2: Survey consultation

As outlined in section 3.2, a survey was conducted to seek consultation with registrants of the NWCSP Health and Care Professionals Stakeholder Forum on important clinical modelling assumptions. Scenarios 2a, 2b, 2c are based on the data provided by the survey , to test the core assumptions used in the model which are based on research evidence. A summary of the survey results is in section 8.4. Test 2a is based on the results for questions 2 to 11, test 2b is based on the results for questions 2 to 12, and test 2c is based on the

[123] HMT The Green Book: appraisal and evaluation in central government
[124] Guest JF, Vowden K, Vowden P. The health economic burden that acute and chronic wounds impose on an average clinical commissioning group/health board in the UK. Journal of Wound Care. 2017 Jun;26(6):292-303. DOI: 10.12968/jowc.2017.26.6.292.
[125] Cullum, Nicky & Buckley, Hannah & Dumville, Jo & Hall, J. & Lamb, Karen & Madden, Mary & Morley, Richard & o'meara, Susan & Saramago, Pedro & Soares, Marta & Stubbs, Nikki. (2016). Wounds Research for Patient Benefit::a 5 year programme of research. Health Technology Assessment.

results for questions 2 to 11, 13 to 15[126].

Test 3: healing and recurrence improvements

Most of the net benefits are from the clinical improvements from evidence-based care, in terms of improved healing and recurrence rates. Although most of the improvements are based on robust evidence from 'pragmatic' randomised control trials, there is some uncertainty in these estimates, both in terms of whether the improvements are fully achievable and the extent to which patients are eligible for the respective treatments. In acknowledgment of this, test 3a tests the scenario where all healing and recurrence improvements are half as effective specified in the core model. Tests 3b and 3c assumes zero improvement in the healing and recurrence rates respectively.

Test 4: optimism bias

A 30% optimism bias is applied to both implementation costs and incremental saving benefits to capture inaccuracies and uncertainties in benefits estimated. To understand the level of confidence in the results, a test is applied which seeks to determine the value of the optimism bias required to achieve a zero net present value.

Test 5: zero inflation

To understand the impact of inflation on the results this scenario removes all inflation post 2019/20. In effect, all costs in subsequent years are in 2019/20 prices.

Test 6: eligibility of patients wearing hosiery

There is uncertainty regarding the share of patients that would be willing and able to wear compression hosiery. To test this issue, as an extreme scenario, this test assumes no patients are treated with compression hosiery

Test 7: failure to increase patients receiving evidence-based care

A critical element to improve leg ulcer care across England is to shift more patients receiving other care to receive evidence-based care. It is assumed that 31% of VLUs are treated in other care in the baseline but this is expected to reduce to 10% under the To-be. Moving 21% of all VLU patients from 'other care' to evidence-base care could be ambitious, so a highly pessimistic scenario is tested (test 7a) in which there is a complete failure to achieve this swing (To-be remains at 31% of patients in suboptimal care while care improves for those already receiving evidence-based care).

Test 7b determines how much the share of patients in suboptimal care would need to increase in the To-be to produce a zero net present value.

Test 8a: patient mortality

Ideally the core modelling would include patient mortality in which some patients die based on the risk of dying at different age groups, which changes due to healing improvement and general demographic growth of England population. However, this could not be modelled

[126] The data from survey 3 was used to avoid the ambiguity over whether travel time was included in the estimates provided for survey 1 and 2.

due to a lack of evidence on the relationship between improved leg ulcer healing and mortality. Although introducing general population mortality projections (without any relationship to leg ulcer healing) was considered in the analysis, little data exists on leg ulcer incidence by age band and how this changes over time. Continuing to model mortality based on a static allocation of leg ulcers by age band (outlined in Figure 36), would mean that the increasing share of mortality above the age of 100 would be highly underrepresented. This would therefore suggest a rapidly declining average mortality rate over time, across the entire leg ulcer population, which would be misleading. Furthermore, ONS data on mortality projections and population projections above the age of 100 becomes less reliable, making it harder to accurately model mortality for older age groups who are at greater risk of leg ulcers.

In recognition that mortality could still have a material impact on the results, it is necessary to still test the potential scale of this impact using the imperfect information available. In this test, it is assumed that at the end of each year, some patients with unhealed and recurred wounds will die. The share of patients dying is a weighted average of the mortality rates by age band (mortality projections by age are from the ONS[127]) and the share of wounds by age band (outlined in Figure 36). This is to capture the greater presence of elderly people with a wound are more likely to die. In 2019, the estimated average mortality rate is 5.7% (the share of patients with an unhealed or recurred leg ulcer in 2019 will die before they receive treatment in 2020)

Test 8b: impact of coronavirus on demographics

Given leg ulcers are more prevalent at older age groups, concerns were raised about the potential impact of Covid-19 to change the age profile of the United Kingdom and what this means for the results of this analysis. A highly extreme scenario was used to test this scenario, in which all leg ulcer patients above the age of 70 would pass away in 2020 and onwards. As a result, the average age of a leg ulcer patient reduces from 20-79 to 50-59. Although this scenario is unrealistic, its extreme nature is used to demonstrate the ability of the results to withstand significant stress.

Test 9: Long term trends on new leg ulcer incidence

The core modelling assumes the incidence of new wounds is purely driven by demographic growth. Although the presence of comorbidities can also affect the incidence of new wounds, it is not captured in the modelling due to a lack of evidence on this relationship. In the absence of data on how comorbidities may affect both the absolute growth rate and the direction of trend of new wounds over time, tests 9a and 9b respectively provides extreme scenarios on the growth is much higher (5% per annum) or much lower (0% per annum) than as per the core modelling.

Test 10: Clinicians in General Practice care

It is assumed that some leg ulcers are treated in general practice, mostly by practice nurses. As some of this care might also be delivered by health care assistants who incur a different unit cost, this test seeks to understand this cost impact. Due to a lack of data on the extent to which patients are treated by healthcare assistants, a simplistic assumption of a 50:50

[127] ONS (2019), Mortality rates (qx), principal projection, England and Wales

split between practice nurses and healthcare assistants is assumed. Unit cost data for healthcare assistants is based on band 4 community nurses[128].

[128] PSSRU (2019) Unit Costs of Health and Social Care 2019

9 Appendix 3 – Presentation of annual benefits

The table below presents the annual benefits and costs from implementing the NWCSP recommendations across England, as a supplement to the net present value estimates presented in section 4. The benefits and costs include a 30% optimism bias adjustment.

Figure 83 Summary of annual benefits

Year	Financial Benefits (£m)		Implementation costs (£m)		Discounted net cash flow (£m)[129]	Discounted non-cash releasing benefits (£m)	Discounted total net benefits (£m)[130]
	Non-cash releasing	Cash releasing	Recurrent costs	Non-recurrent costs			
2012	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2013	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2014	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2015	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2016	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2017	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2018	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2019	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0	**£0.0**
2020	£0.0	£0.0	-£26.8	-£20.6	-£45.8	£0.0	**-£45.8**
2021	£0.0	£0.0	-£55.8	-£20.6	-£71.3	£0.0	**-£71.3**
2022	£0.0	£0.0	-£86.9	-£21.0	-£97.4	£0.0	**-£97.4**
2023	£156.4	-£106.7	-£90.5	£0.0	-£171.9	£136.3	**-£35.6**
2024	£226.2	£107.7	-£84.3	£0.0	£19.7	£190.4	**£210.1**
2025	£272.8	£249.2	-£81.2	£0.0	£136.6	£221.9	**£358.5**
2026	£304.4	£343.8	-£80.3	£0.0	£207.1	£239.3	**£446.3**
2027	£326.3	£408.3	-£80.8	£0.0	£248.7	£247.8	**£496.5**
2028	£342.7	£454.7	-£82.4	£0.0	£273.2	£251.4	**£524.6**
2029	£355.2	£489.4	-£84.6	£0.0	£287.0	£251.8	**£538.8**
2030	£364.6	£515.2	-£87.3	-£1.5	£292.1	£249.8	**£541.9**
2031	£372.2	£536.3	-£90.2	-£1.5	£294.2	£246.3	**£540.5**
2032	£378.4	£554.8	-£93.4	-£1.5	£294.0	£242.0	**£536.0**
2033	£383.9	£572.0	-£96.7	£0.0	£293.7	£237.2	**£530.8**
2034	£405.5	£608.8	-£100.1	£0.0	£303.6	£242.0	**£545.6**
2035	£425.4	£643.6	-£103.7	£0.0	£311.4	£245.3	**£556.7**
2036	£444.1	£677.2	-£107.4	£0.0	£317.5	£247.5	**£565.0**
2037	£462.3	£710.4	-£111.2	£0.0	£322.6	£248.9	**£571.5**
2038	£480.6	£744.6	-£115.2	£0.0	£327.4	£250.0	**£577.4**
2039	£499.1	£779.7	-£119.3	£0.0	£331.9	£250.8	**£582.8**
2040	£517.6	£815.1	-£123.5	£0.0	£335.8	£251.3	**£587.1**
2041	£536.3	£851.6	-£127.9	£0.0	£339.5	£251.6	**£591.2**
2042	£555.6	£889.8	-£132.3	£0.0	£343.4	£251.8	**£595.2**
2043	£575.4	£929.7	-£136.9	£0.0	£347.2	£252.0	**£599.2**
2044	£595.6	£970.8	-£141.6	£0.0	£350.9	£252.0	**£602.9**
2045	£616.1	£1,013.3	-£146.4	£0.0	£354.4	£251.9	**£606.3**

[129] Discounted net cashflow is Net Cashflow (Cash releasing benefits + recurrent costs + non-recurrent costs), discounted at 3.5%.
[130] This is used to calculate the reported NPV and includes cash releasing benefits, non-cash releasing benefits and implementation costs (i.e. Discounted net cashflow + Discounted non-cash releasing benefits)

2046	£637.1	£1,057.2	-£151.3	£0.0	£357.8	£251.6	**£609.5**
2047	£658.3	£1,102.6	-£156.3	£0.0	£361.2	£251.3	**£612.4**
2048	£679.9	£1,149.6	-£161.4	£0.0	£364.4	£250.7	**£615.1**
2049	£701.9	£1,198.2	-£166.6	£0.0	£367.5	£250.1	**£617.6**
2050	£724.5	£1,248.9	-£172.0	£0.0	£370.7	£249.4	**£620.1**
				Present value (£m)	**£7,767**	**£6,762**	**£14,530**

Health Impact Assessment

National Wound Care Strategy Programme

KSS Insights

September 2020

Contents

1. Introduction

1.1. The National Wound Care Strategy Programme

The National Wound Care Strategy Programme (NWCSP, 2020) has produced a report assessing the potential impact of national service changes aiming to improve the care and health outcomes of patients with chronic lower limb wounds. In addition to patient benefits such as improved wound healing rates and reduction in recurrence, the report suggests the programme could provide benefits for the workforce and financial benefits for the system.

Across England there were an estimated 739,000 leg ulcers in England in 2019, at an estimated cost to the system of around £3.1 billion annually (NWCSP, 2020). Chronic lower limb ulcers can have multiple physical, psychological, and social impacts on patients, affecting their daily lives (Phillips et al., 2017). Inequalities in access to evidence-based care and early access to diagnosis and treatment may exacerbate the rate of wound healing and recurrence.

Currently, care for chronic lower limb wounds is provided through multiple healthcare providers across different settings, such as general practice, care homes, or own homes. Care is often provided by practice or district nurses, with wound care frequently competing with other care priorities. The NWCSP looks at moving towards greater self-management of wound care, through lower limb specialist services providing care through clinics/social care models and at home. The key proposals outlined within the NWCSP report include changing the model of care provision to reduce unwarranted variation and support provision of equitable care, increasing the delivery of evidence based care, and improving data capture to support clinical decision making and monitoring of outcomes. In addition to the patient benefits of improvements in care and health outcomes, the report suggests after initial costs incurred through implementation, a potential net present value of £14.6bn over 30 years of implementation.

1.2. Health impact assessments

Kent, Surrey, Sussex Academic Health Science Network (KSS AHSN) have been commissioned to produce a health impact assessment based on the implementation case proposed by the NWCSP. A health impact assessment (HIA) is a tool used to support the decision-making process surrounding implementation of new programmes, through identifying the potential health impacts both positive and negative (Davenport et al., 2006). The HIA encourages individuals to consider whether the general population, or more specific cohorts, may be affected by the programme. Health impact assessments are often conducted for local projects, where there is often greater clarity and certainty on interventions (Davenport et al., 2006). The outcome of the HIA includes oversight of the potential health impacts of the intervention or programme, alongside recommendations on policy improvements or elements to consider.

2. Method

A desktop assessment approach was used to conduct the HIA, following the framework outlined by the Department of Health (2010) which uses a process of five stages (Figure 84). In addition to the implementation case, literature was sought for greater guidance and understanding.

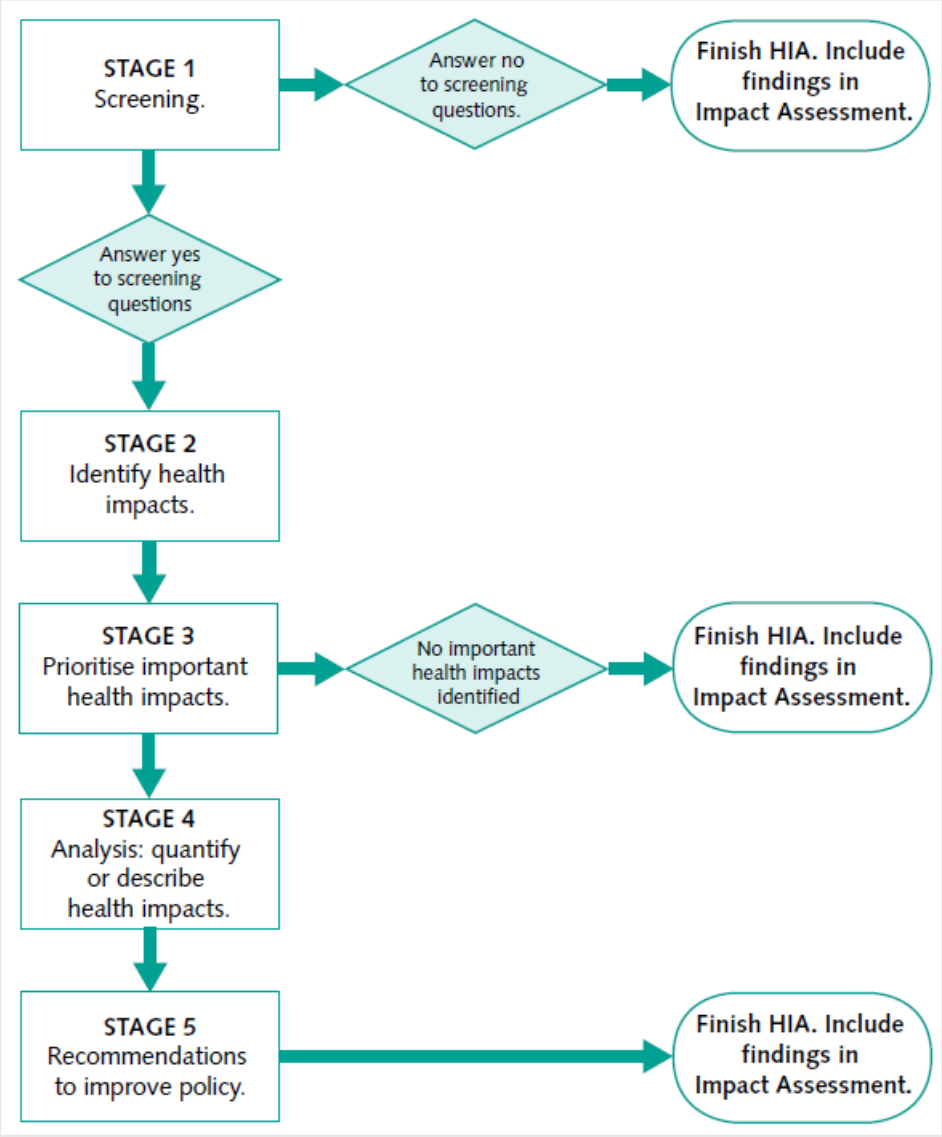


Figure 84: The five stages of a health impact assessment as outlined by the Department of Health (2010).

3. Stage 1: Screening

The following questions have been reviewed to determine whether to proceed with a HIA (Department of Health, 2010). Where the answer is yes, factors discussed shall be further explored in other stages of the assessment.

1) Will the proposal have a direct impact on health, mental health and wellbeing?

Yes, there will likely be a direct impact on individuals with chronic lower limb wounds through the NWCSP. As lower limb wounds are more prevalent amongst older people (Darwin et al., 2019), this cohort will be the most affected. Evidence also suggests that prevalence is higher amongst women (O'Meara et al., 2014). The programme aims to improve wound healing rates and reduce the recurrence of wounds, which may reduce pain and mobility issues whilst improving general wellbeing through absence of an unhealed wound. There may be wider benefits of improving independence through promotion of self-management and reducing social isolation through removing the unpleasant side effects of chronic wounds.

Venous leg ulcers account of 60-80% of lower limb ulcers (NICE, 2020), with UK prevalence estimated between 0.1-0.3% and increasing with age (Scottish Intercollegiate Guidelines Network, 2010). **Figure 85** highlights the estimated number of leg ulcers predicted over the next 30 years, with and without implementation of the NWCSP recommendations. Without intervention, evidence suggests the scale of the problem will annually increase.

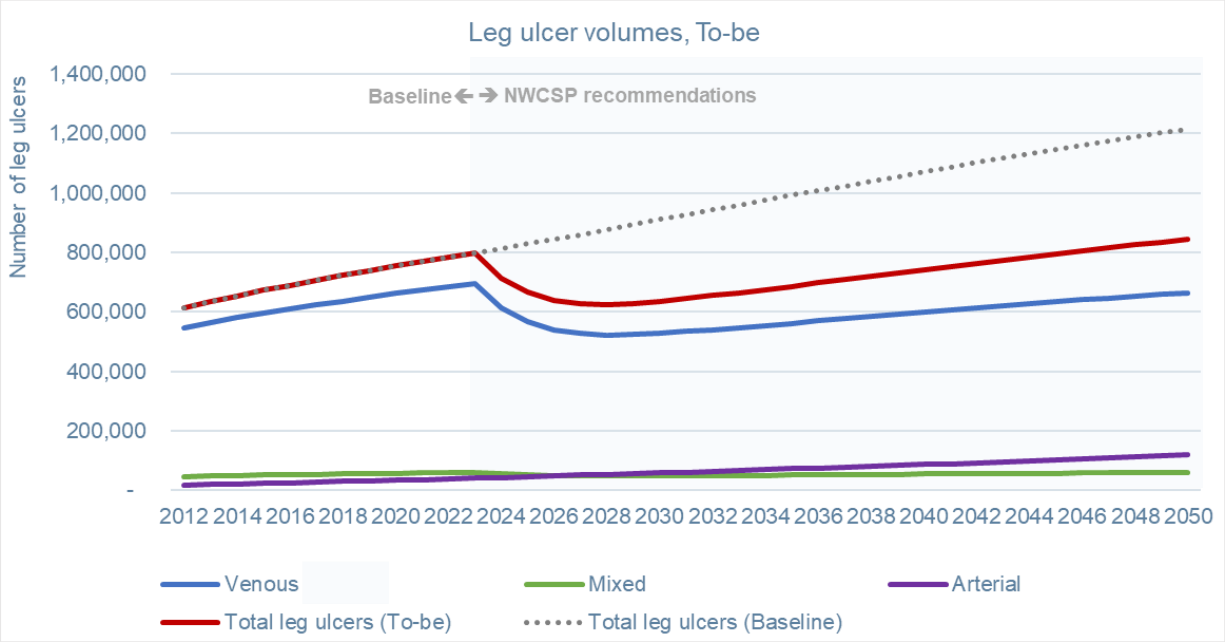


Figure 85: The estimated number of leg ulcers projected with continuation of current services, and with implementation of the NWCSP recommendations at a 30% annual reduction (Figure obtained from: NWCSP, 2020)

The proportion of older adults in local populations varies across England, with some areas having a higher proportion than others. As prevalence of lower limb wounds increases with age (Darwin et al., 2019), impact of NWCSP implementation may be greater within certain areas of the UK. **Figure 86** shows the variation across England in the proportion of adults aged 65 years or over, with northern England and coastal areas having a higher proportion. This also highlights the predicted increase in older adults by 2043 through population estimates.

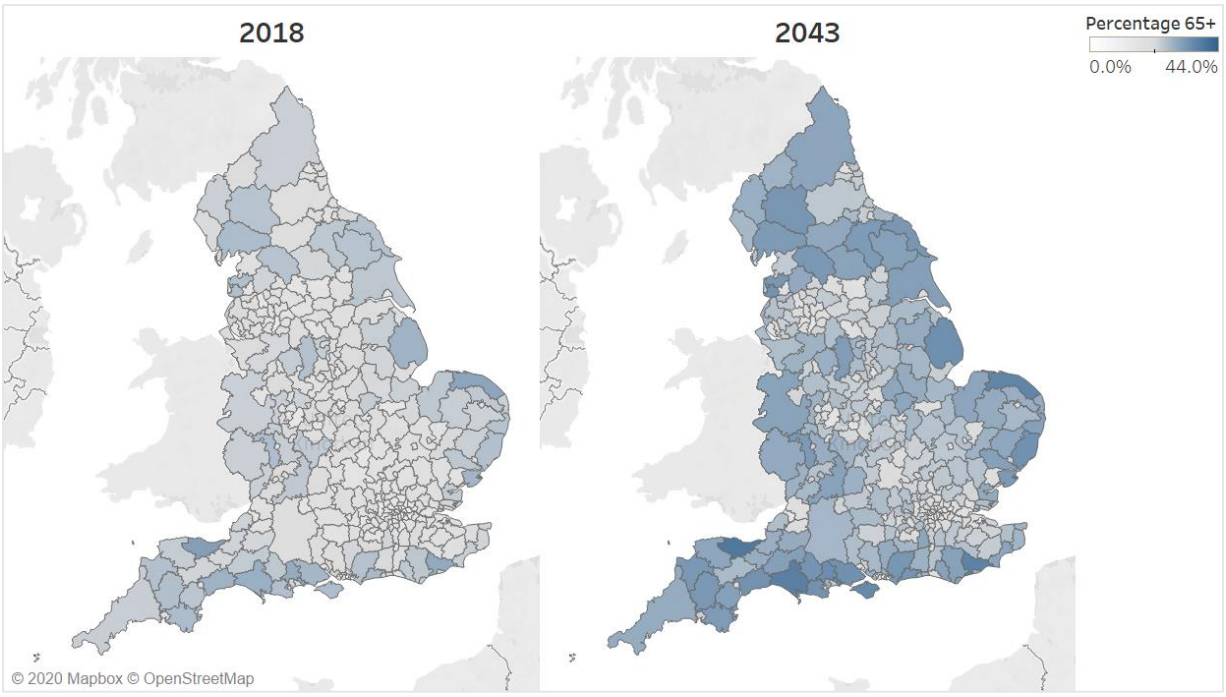


Figure 86: The proportion of adults aged 65 years and over by local authority across England, as of 2018 and projected for 2043 (Office for National Statistics, 2020).

Figure 87 shows the areas rated by level of deprivation across England, from least to most deprived. Research suggests that leg ulcers amongst patients from the most deprived areas take longer to heal and have a higher likelihood of recurrence (Scottish Intercollegiate Guidelines Network, 2010). The impact of the programme could be greater for this population cohort, with potential opportunity to address these poorer health outcomes.

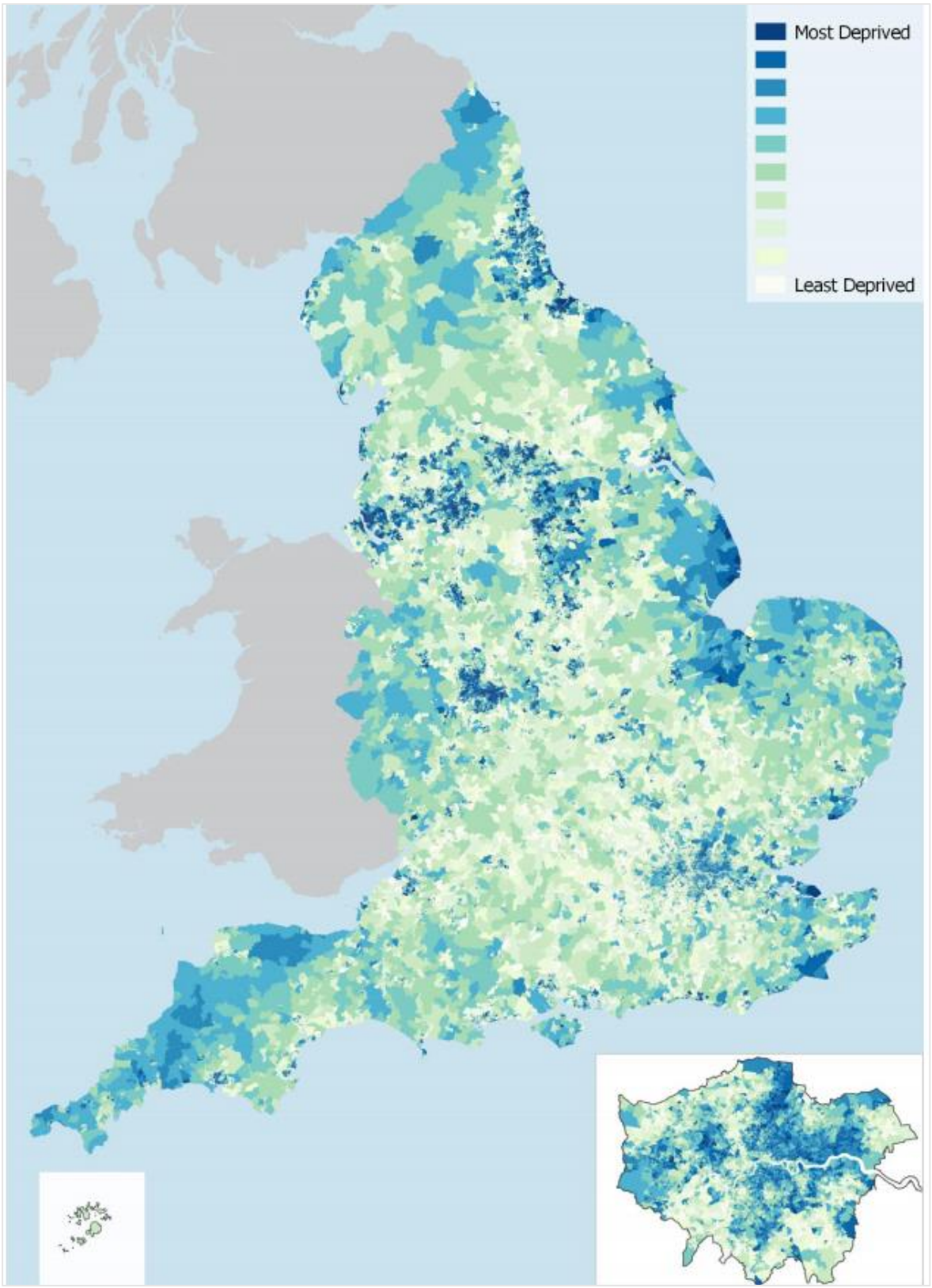


Figure 87: English Index of Multiple Deprivation map (Figure obtained from: Ministry of Housing, Communities & Local Government, 2019)

2) Will the policy have an impact on social, economic, and environmental living conditions that would indirectly affect health?

Yes, providing further education for clinicians and upskilling the workforce may lead to greater job opportunities, and promote motivation and wellbeing within the workforce. Research has highlighted the need for consistent, high quality training interventions for staff involved in wound care treatment to build confidence in their decision making and improve the care provided (Gray et al., 2019). Previous research suggests that the skill of staff, and adoption of evidence-based care, is of greater importance than the setting in which wound care is delivered (Anderson, 2017), however other research has found greater outcomes in clinic settings (Scottish Intercollegiate Guidelines Network, 2010). After six months of treatment in specialist clinics healing rates of 70% were identified, compared to 45% from treatment in a community setting.

In any case, reducing variation in wound care and improving efficiencies within the system would likely provide opportunities for other areas of healthcare to benefit.

3) Will the proposal affect an individual's ability to improve their own health and wellbeing?

Yes, where appropriate, individuals will receive education on managing and caring for their lower limb wounds, encouraging a self-care approach. Depending on the materials within the resources, individuals may be encouraged to make lifestyle changes to ease symptoms of underlying conditions to help prevent recurrence. Individuals at higher risk of poor health are likely to have low health literacy (Rowlands et al., 2015), with those with a greater need for health information often having the least access. In addition to being unable to access the information, they may lack the health literacy required to understand the information and adopt the suggestions (Furler et al., 2011). Designing health materials at a suitable health literacy level may support equitable access to information on wound care.

The programme may support individuals to improve their wellbeing; healing chronic wounds may improve individuals' mental state through removing the unpleasant physical, psychological, and social side effects of open sores. This may enable individuals to spend more time socialising and seeking opportunities to engage in activities which they enjoy.

4) Will there be a change in demand for or access to health and social care services?

Yes, through a change in service provision it appears there may initially be greater demand for care within a clinical setting. This would occur during the process of wound treatment, and as part of the lifelong follow-up service to reduce the risk of recurrence. In the long-term, the initial increase in demand may reduce as recurrence of wounds declines (**Figure 85**). It is hoped that there would be less demand for amputations and surgery, as a result of individuals receiving standardised evidence-based care and earlier diagnosis and treatment. Earlier access to treatment may provide further health impacts; research highlighted within the implementation case suggests that earlier access to 'at risk' foot clinics could significantly reduce the risk of amputation (NWCSP, 2020). As chronic lower limb wounds frequently cause pain and multiple appointments with health and care staff, implementation of the NWCSP recommendations may see wider benefits, such as a reduction in pain medication and reduction in the number of appointments required per wound.

In 2012/13, it was estimated that the cost to the NHS of managing 2.2 million wounds (including diabetic ulcers) and their comorbidities ranged between £4.5-5.1 billion (Guest et al., 2015). With prevalence of wounds increasing (Figure 85), these costs have likely increased further (NWCSP, 2020). Implementing the NWCSP recommendations may provide an annual reduction in wound care costs of 15% (NWCSP, 2020; Figure 88).

Figure 88: The potential reduction in cost of wound following implementation of the NWCSP recommendations (Figure obtained from: NWCSP, 2020)

As each of the screening questions have been answered as 'yes', it appears that conducting an HIA on the NWCSP is appropriate. The following sections shall explore the potential health impacts of the programme and provide recommendations where appropriate.

4. Stages 2 and 3

4.1. Identification of health impacts

This section lists the potential health impacts of the programme, categorised by whether the impact affects patients, the workforce, or the system. In some cases, the potential health impacts may be seen in more than one category, and additional health impacts may become apparent following programme implementation.

Potential impacts for patients

- Improved access to appropriate, standardised, evidence-based care

- Improved lower limb wound heal rate
- Reduction in recurrence of lower limb wounds
- Reduction in time spent with unpleasant side effects or wider impacts (Briggs & Flemming, 2007; Green et al., 2014; Phillips et al., 2017) including, but not limited to:
    - Physical impact, such as pain, malodour, leakage (exudate), impaired mobility, and sleep disturbance
    - Psychological impact, such as depression, anxiety, embarrassment, low self-esteem, and coping strategies
    - Social impact on relationships, social activities, social isolation, and clothing restrictions
- Promotion of self-care and management
- Reduction in lower limb amputation
- Potential impact of surgery, if chosen
- Reduced risk of infection
- Improved understanding of risk factors, treatment options, and management of wound care, through educational material
    - Equally, risk of low adherence if education materials are not in an appropriate format for all patients
- Impact of having to attend clinics on some patients
    - Travel implications
    - Time
    - Cost
- Inclusion within a local support group through localised community care (e.g. initiatives such as The Leg Club)
    - Social inclusion
    - Social support and group morale
- Earlier diagnosis and access to treatment
- Access to staff with wound care training
- Fewer appointments
- Potential improved adherence to treatment

Potential impacts on the workforce

- Opportunities for additional training and upskilling
- Potential job opportunities
- Reduction in travel time to patient's place of residence
- Reduction in appointment time, or more time available to focus on other health needs
- Requirement to collect further data
- Potential requirement to discuss educational material and resources with patients
- Impact of moving to evidence-based care, if not already provided
- Increase in job satisfaction
- Potential disruption on workload and temporary pressures from implementing new programme and pathways

Potential impacts on the system

- Financial impact, including costs incurred through implementing the changes, and potential cash releasing and non-cash releasing benefits
- Change of structural environment and referral pathways
- Adoption of a standardised approach delivering evidence-based care
- Improvements in data quality and availability through increased collection
- Re-allocation of resource, such as through reducing the number of lower limb amputations required and improving efficiencies
- Greater integration of services
- Wider implementation of social care models, such as The Leg Club

4.2. Prioritisation of health impacts

The implementation of the NWCSP guidelines will likely have a wide range of impacts on patients, the workforce, and the system. Reviewing the impacts across each category, the majority of the potential impacts identified would affect patients and their health outcomes and would therefore be considered the priority. Many of the health impacts identified across the cohorts address elements of the NHS Long Term Plan (2019): providing care at the right time in the optimal setting, capturing data to improve outcomes and support forward

planning, upskilling staff, and addressing unwarranted variation in care and subsequent health outcomes. As such, these may also be considered important health impacts of the programme.

The most important impact is that of patient health, with the need to avoid inequalities in access to care, improving patient outcomes in health and wellbeing, and avoiding risk of harm. Due to the prevalence of lower limb wounds increasing with age, the impact of the programme will primarily be on the older patient population. Patients living in areas with poorer access to evidence-based care may see greater impact on their health outcomes compared to those who currently have such access. Conversely, there is the potential for variation to widen. If access to enhanced care is through attending clinics, certain groups may require more support to access these, such as patients with disabilities, lack of social support, or those living in areas of higher deprivation. The same impact may also be seen regarding provision of education materials and encouragement of self-management; materials should be made accessible in both format and content to ensure that all patients and their caregivers can understand and engage with the information delivered, to provide equal opportunities in achieving good health outcomes.

With regards to the effects on the system, certain areas may require more resources than others to reduce the pre-existing unwarranted variation and prevent further contrast. These areas may require extra time to implement changes and reach certain targets, which would impact when the benefits are realised at a patient level.

Stage 4 of this assessment shall explore the potential impacts with important health outcomes in greater detail.

5. Stage 4: Analysis of potential health impacts

5.1. Patients

Research highlights the extensive physical, psychological, and social impact of chronic lower limb wounds on individuals (Briggs & Flemming, 2007; Green et al., 2014; Phillips et al., 2017). As the programme aims to improve the healing rate of such wounds, whilst reducing recurrence, there is potential for considerable patient benefits in the medium and long term, both physical, psychological, and social. Such improvements on health and wellbeing may enable patients to focus on other areas of their health, or explore activities previously avoided due to their wounds. The NWCSP (2020) report identified that the programme could generate an average of 0.034 quality-adjusted life years (QALYs) per patient for those already receiving evidence-based care. Further benefits around QALYs may be realised through further research.

Including a social care model of wound care provision may help reduce feelings of social isolation and negative mood through interaction with other local individuals with lower limb

wounds (White, 2016). Combined with educational materials and promotion of self-care, this may help to encourage adherence to treatment, and potentially impact on healing time and recurrence. With the COVID-19 pandemic, the extent of these health impacts is likely to be affected. Care provided within the community setting, such as through The Leg Club, may have to function in different ways, such as implementing appointments instead of drop-in sessions and reducing the size of social groups.

With a drive for providing standardised care within a clinic setting where possible, both positive and adverse health impacts may be realised. Such settings, staffed with clinicians with relevant training and experience of wound care, may provide greater access to standardised, evidence-based care and improve health outcomes. Previous research has noted that attending a clinic setting multiple times a week can be burdensome for some patients (Green et al., 2013). Some patient cohorts may struggle to access a clinical setting on a frequent basis, due to issues such as complex comorbidities, transport, cost, or mobility. Patients who are socio-economically disadvantaged are more likely to have chronic conditions, which often have a negative impact both socially and economically (Furler et al., 2011). Where possible, transport arranged through social care models may support equitable access to such care, whilst adopting the same treatment guidelines within home care provision would help support those unable to travel. Research suggests complex patients experience poorer outcomes than those without additional complexity, with wounds taking longer to heal (Anderson, 2017). Changes to pathways for referral to vascular services, podiatry, and dermatology may provide a clearer route for clinicians and staff in the wider system and encourage earlier patient referral to such services.

The implementation proposal highlights the unwarranted variation in care provided for chronic lower limb wounds. As such, areas with lower levels of evidence-based care provision and poorer outcomes may require a greater level of support to reduce such variation. This element of the programme may need to be closely monitored to ensure that the divide in care provision does not increase further. With the increased prevalence of lower limb wounds amongst older people (Darwin et al., 2019), there may be natural variation in the geographical demand for services. Lower limb ulcers are commonly associated with issues with blood return in the venous system, or due to complications from peripheral arterial disease (NWCSP, 2020). Risk factors behind such conditions include older age, smoking, lack of physical activity, stress, and unhealthy eating habits (Anderson, 2008; Ashrani et al., 2009; NHS, 2017). Where there are areas within England with higher proportions of older people, there may be a higher demand for services.

Though self-management is often considered necessary in supporting patients with chronic conditions, encouraging self-management of wound care has the potential to cause further divide in inequality of care. Prevalence of chronic wounds is higher amongst the older population (Darwin et al., 2019). Research suggests that older patients with multiple conditions are at an increased risk of impaired cognitive function, and subsequently may be less likely to successfully adopt a self-management approach (Coventry et al., 2014). Furthermore, patients' engagement with self-management are thought to be influenced by their capacity, responsibility, and motivation, with all three factors adversely impacted by socioeconomic deprivation (Coventry et al., 2014).

Though not a direct health impact of the NWCSP, COVID-19 is thought to have had a detrimental effect on some patients' experiences of wound care. Some patients have

struggled to get appointments within general practice or community nursing services, subsequently impacting their access to care, prescriptions, and dressings (Adderley, 2020). Such experiences may have exacerbated the problems faced by certain patients, further contributing to variation in care experience and placing increased demand on services. A drive in the uptake of technology has seen some wound care consultations occur remotely over telephone or video calls (Adderley, 2020). If these methods of consultation were continued through the NWCSP implementation, care should be taken to ensure that those who are not able to use these methods are not adversely impacted. If such methods are adopted and patient cohorts that are able and willing to engage remotely do so, this may enable those who require home visits to have greater or earlier access to such.

5.2. Workforce

Implementation of the recommendations proposed by the NWCSP would support the upskilling of staff and encourage them to adopt evidence-based care. Such factors may support the workforce to feel more motivated through higher levels of job satisfaction, and satisfaction with the quality of care provided. A move to more appointments within clinical settings may provide more time for focused wound care, allowing staff to concentrate on this concern.

Guest et al. (2017) found unhealed wounds to have ‘substantially greater’ resource usage compared to healed wounds, including 104% more community nurse visits, 40% more prescriptions, 20% more practice nurse visits, and 13% more GP visits. Though improving and standardising service provision, and increasing wound healing rates, implementing the NWCSP recommendations could reduce the burden on the workforce.

During initial implementation of the service changes, there may be a period of disruption and increased pressure. Such periods should be monitored to ensure that staff have a clear understanding of the changes being made and the perceived benefits of such. Incorporating staff feedback may support greater engagement and adherence to changes and identify further areas of improvement. Though additional data captured through the programme may support clinicians in their decision making and service forecasting it may, however, create greater administrative burden and negatively impact staff time and morale.

5.3. System

Compared to healed venous leg ulcers, the costs of managing unhealed venous leg ulcers have been found to be 4-5 times higher (Guest et al., 2018). Through increasing the proportion of wounds healed, and reducing recurrence rates, the NWCSP could reduce resource the impact of chronic lower limbs on the system. Significant implementation costs will be seen within the first three years, at an estimated sum of £225 million, however the break-even point has been estimated as achievable within 4 years of programme implementation. Overall, the NWCSP may see a net present value of £14.6bn and a benefit cost ratio of 9.8 over 30 years of implementation. Whilst providing benefits for the service area of wound care and management, the improvement in efficiency of the service will allow

resources to be better allocated across healthcare to enable a better quality of service and improved health outcomes for a wider patient population.

Implementing the programme may pose initial risk to the system through restructuring of pathways and changes to service provision. Care should be taken to avoid creating further health inequalities.

6. Stage 5: Recommendations to improve policy

The following recommendations are suggested to either further improve the potential positive impacts or minimise risk of adverse impacts.

- Identify an implementation approach which ensures that areas with poorer health outcomes around wound care do not fall further behind.
- Consider content and format of patient educational materials to ensure equal accessibility to information provided for patients with various health literacies, disabilities, or first languages. Different formats such as booklets or videos may support different cohorts and encourage engagement with material.
- There is limited research into the effect of self-management interventions in socio-economically disadvantaged patients with chronic conditions (Van Hecke et al., 2017). Implementing the NWCSP's recommendations provides an opportunity to explore how individuals from the most deprived areas, those with socio-economic disadvantage, or those with low health literacy, engage with the self-management aspect of the programme and how this may be developed to support greater equality.
- Where appropriate, provide patients with options as to the location of their consultation or care provided to ensure that factors such as travel, or cost, do not restrict patients' access to sufficient care. In certain areas, this may include provision of transport through social care models.
- In addition to providing education to care staff providing wound care in patient's own homes, the programme may seek to consider potential training or educational resources for care homes to support staff in understanding elements of wound care.
- Ensure additional data capture provides meaningful insights and does not induce a data burden on pressured staff and systems.

References

Adderley, U. (2020). National Wound Care Strategy Programme: Looking at the impact of COVID-19. *Wounds UK, 16*(2).

Anderson, I. (2008). Understanding chronic venous hypertension. *Wound Essentials*, *3*. https://www.woundsinternational.com/uploads/resources/content_9420.pdf

Anderson, I. (2017). Treating patients with venous leg ulcers in the acute setting: Part 1. *British Journal of Nursing*, *26*(12). https://www.magonlinelibrary.com/doi/pdf/10.12968/bjon.2017.26.12.S32

Ashrani, A. A., Silverstein, M. D., Lahr, B. D., Petterson, T. M., Bailey, K. R., Melton, L. J., & Heit, J. A. (2009). Risk Factors and Underlying Mechanisms for Venous Stasis Syndrome: A Population-Based Case-Control Study. *Vascular Medicine (London, England)*, *14*(4), 339–349. https://doi.org/10.1177/1358863X09104222

Briggs M, & Flemming K. (2007). Living with leg ulceration: a synthesis of qualitative research. *Journal of Advanced Nursing*. *59*(4):319-28. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/17608682/

Coventry, P. A., Fisher, L., Kenning, C., Bee, P., & Bower, P. (2014). Capacity, responsibility, and motivation: A critical qualitative evaluation of patient and practitioner views about barriers to self-management in people with multimorbidity. *BMC Health Services Research*, *14*(1), 536. https://doi.org/10.1186/s12913-014-0536-y

Darwin, E., Liu, G., Kirsner, R. S., & Lev-Tov, H. (2019). Examining risk factors and preventive treatments for first venous leg ulceration: A cohort study. *Journal of the American Academy of Dermatology*. https://doi.org/10.1016/j.jaad.2019.12.046

Davenport, C., Mathers, J., & Parry, J. (2006). Use of health impact assessment in incorporating health considerations in decision making. *Journal of Epidemiology and Community Health*, *60*(3), 196–201. https://doi.org/10.1136/jech.2005.040105

Department of Health. (2010). *Health Impact Assessment Tools*. https://www.gov.uk/government/publications/health-impact-assessment-tools

Furler, J., Harris, M., & Rogers, A. (2011). Equity and long-term condition self-management. *Chronic Illness*, *7*(1), 3–5. https://doi.org/10.1177/1742395310386978

GOV.UK. (2019). *English indices of deprivation 2019*. https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019

Gray, T. A., Wilson, P., Dumville, J. C., & Cullum, N. A. (2019). What factors influence community wound care in the UK? A focus group study using the Theoretical Domains Framework. *BMJ Open*, *9*(7). https://doi.org/10.1136/bmjopen-2018-024859

Green, J., Jester, R., McKinley, R., & Pooler, A. (2013). Patient perspectives of their leg ulcer journey. *Journal of Wound Care*, *22*(2). https://doi.org/10.12968/jowc.2013.22.2.58

Green, J., Jester, R., McKinley, R., & Pooler, A. (2014). The impact of chronic venous leg ulcers: A systematic review. *Journal of Wound Care, 23*(12), 601–612. https://doi.org/10.12968/jowc.2014.23.12.601

Guest, J. F., Ayoub, N., McIlwraith, T., Uchegbu, I., Gerrish, A., Weidlich, D., Vowden, K., & Vowden, P. (2015). Health economic burden that wounds impose on the National Health Service in the UK. *BMJ Open*, *5*(12). https://doi.org/10.1136/bmjopen-2015-009283

Guest, J. F., Ayoub, N., McIlwraith, T., Uchegbu, I., Gerrish, A., Weidlich, D., Vowden, K., & Vowden, P. (2017). Health economic burden that different wound types impose on

the UK's National Health Service. *International Wound Journal*, *14*(2), 322–330. https://doi.org/10.1111/iwj.12603

Guest, J. F., Fuller, G. W., & Vowden, P. (2018). Venous leg ulcer management in clinical practice in the UK: Costs and outcomes. *International Wound Journal*, *15*(1), 29–37. https://doi.org/10.1111/iwj.12814

McNichol, E. (2014). Involving patients with leg ulcers in developing innovations in treatment and management strategies. *British Journal of Community Nursing*, *19*(Sup9), S27–S32. https://doi.org/10.12968/bjcn.2014.19.Sup9.S27

Ministry of Housing, Communities & Local Government. (2019). *English indices of deprivation 2019*. https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019

National Wound Care Strategy Programme. (2020). Preventing and Improving Care of Chronic Lower Limb Wounds Implementation Case (Draft). [Unpublished]

NHS England. (2019). *The NHS Long Term Plan*. https://www.longtermplan.nhs.uk

NHS. (2017). *Peripheral arterial disease (PAD)*. https://www.nhs.uk/conditions/peripheral-arterial-disease-pad/

NICE. (2020). *Leg ulcer—Venous*. https://cks.nice.org.uk/topics/leg-ulcer-venous/

O'Meara, S., Al-Kurdi, D., Ologun, Y., Ovington, L. G., James, M. M.-S., & Richardson, R. (2014). Antibiotics and antiseptics for venous leg ulcers. *Cochrane Database of Systematic Reviews*, 1. https://doi.org/10.1002/14651858.CD003557.pub5

Office for National Statistics. (2020). *Population projections for local authorities: Table 2*. https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/datasets/localauthoritiesinenglandtable2

Phillips, P., Lumley, E., Duncan, R., Aber, A., Woods, H. B., Jones, G. L., & Michaels, J. (2018). A systematic review of qualitative research into people's experiences of living with venous leg ulcers. *Journal of Advanced Nursing, 74(*3), 550–563. https://doi.org/10.1111/jan.13465

Rowlands, G., Protheroe, J., Winkley, J., Richardson, M., Seed, P. T., & Rudd, R. (2015). A mismatch between population health literacy and the complexity of health information: An observational study. *British Journal of General Practice*, *65*(635), e379–e386. https://doi.org/10.3399/bjgp15X685285

Scottish Intercollegiate Guidelines Network. (2010). *Management of chronic venous leg ulcers: A national clinical guideline*. Scottish Intercollegiate Guidelines Network. https://www.sign.ac.uk/media/1058/sign120.pdf

Van Hecke, A., Heinen, M., Fernández-Ortega, P., Graue, M., Hendriks, J. M. L., Høy, B., Köpke, S., Lithner, M., & Van Gaal, B. G. I. (2017). Systematic literature review on effectiveness of self-management support interventions in patients with chronic conditions and low socio-economic status. *Journal of Advanced Nursing*, *73*(4), 775–793. https://doi.org/10.1111/jan.13159

White, R. (2016). Patient self-help in the management of chronic wounds. https://www.wounds-uk.com/download/resource/938

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