National Wound Care Strategy Programme

Lower Limb Wounds

Draft Foot Ulcer Recommendations

01.03.2023

Working in partnership with

The AHSN Network

NHS

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Glossary:

Acute Limb Ischaemia: Rapid decrease in blood flow to lower limb due to acute occlusion. Symptoms are sudden-onset, acute pain, pallor, pulseless, perishingly cold paraesthesia / acute sensory change, paralysis/ acute motor dysfunction.

ABPI: Ankle brachial pressure index (ABPI) is a non- invasive method of assessing peripheral arterial perfusion in the lower limb by measuring the ratio of systolic blood pressure at the ankle to that in the arm.

At risk foot: Describes a foot at risk of ulceration, amputation, and loss of tissue viability.

Charcot joint: a progressive, degenerative condition that affects one or more joints especially of the foot or ankle, is marked by bone fragmentation, swelling, erythema, pain, and joint deformity, and typically occurs following loss of nerve sensation associated with various diseases (such as diabetes, syphilis, and spina bifida).

Chronic Limb Threatening Ischaemia (CLTI): CLTI is a clinical syndrome defined by the presence of peripheral arterial disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration greater than 2 weeks in duration.

Chronic oedema: Is defined as swelling that lasts for more than 3 months.

Diabetic Foot Ulcer: Foot ulcer in person with diabetes mellitus.

Erythema: Inflammation of the skin, often referred to as 'redness' although it may present differently in a range of skin tones.

Foot Ulcer: a break in the skin of the foot that includes minimally the epidermis and part of the dermis that occurs below the ankle.

High Risk Foot: More than one risk factor presents e.g., a combination of loss of sensation, signs of peripheral arterial disease, significant callus, significant structural deformity.

Load: A generic term that covers all forces, including pressure and shear, applied to the skin and subcutaneous tissues. Also known as mechanical load.

Neuropathy: Damage to one or more nerves that typically results in numbness (sensory neuropathy), tingling, muscle weakness (motor neuropathy) and pain in the affected area. Autonomic neuropathy (damage to nerves that are part of the autonomic nervous system) can lead to symptoms such as dizziness, night sweats and constipation. Peripheral neuropathy (damage to peripheral nerves) increases the risk of ulceration through loss of protective sensation, foot deformities and its common association with dry skin, which can cause cracking, fissures, and calluses.

Peripheral Arterial Disease (PAD) PAD is a common condition where a build-up of fatty deposits in the arteries restricts blood supply to the limbs.

Offloading: the relief of mechanical stress (pressure) from a specific region of the foot.

Offloading device: any custom-made or prefabricated device designed with the intention of relieving mechanical stress (pressure) from a specific region of the foot (e.g., total contact cast (TCC), (non-removable walker, knee-high walker, ankle-high walker, ankle foot orthoses, healing sandal, cast shoe, forefoot offloading shoe, etc.). Note that this excludes footwear.

Offloading intervention: any intervention undertaken with the intention of relieving mechanical stress (pressure) from a specific region of the foot (includes surgical offloading techniques, offloading devices, footwear, and other offloading techniques).

Pressure: Results from the application of a force perpendicular (i.e., at right angles) to the surface of the skin. The pressure compresses the tissues and can distort or deform the skin, subcutaneous tissues, and muscle.

Shear: Causes layers of body tissues to move relative to each other and may occur superficially (e.g., as a result of a force applied parallel to the surface of the skin) or more deeply (as the result of deformation of skin and muscle when pressure is applied over a bony prominence.

Therapeutic footwear: Generic term for footwear designed to have a therapeutic effect that cannot be provided by or in a conventional shoe. Custom-made shoes or sandals, custom-made insoles, extra-depth shoes, and custom-made or prefabricated medical grade footwear are examples of therapeutic footwear.

Toe Pressure:

WIfI: The use of classification system like WIfI (wound, infection and ischaemia) can be used to predict the amputation risk in particular with people who have CLTI of any severity.

Introduction

The National Wound Care Strategy Programme (NWCSP) has been commissioned by NHS England to improve the care of pressure ulcers, lower limb wounds and surgical wounds. This document is focusing on foot ulcers, which are a common form of lower limb wound.

In England there is considerable variation in foot ulcer management and outcomes, which increases care costs and extends healing times. Foot ulcers are precursors of lower limb amputations both in people with and without diabetes. While the quality of care has steadily improved for people with foot ulceration and diabetes, care for those without diabetes lags behind. People with diabetes and foot ulceration can access expert multidisciplinary treatment far more easily than those without diabetes [1].

Those with foot ulceration, whether associated with diabetes or not, are at high risk of lower limb amputation associated with high mortality[2] . It is usually caused by combination of factors including, peripheral arterial disease, peripheral neuropathy, and infection.

Rapid assessment, diagnosis and treatment is crucial for all those with foot ulceration, especially when half of all major amputations are in those without diabetes[2]. The establishment of diabetic foot clinics has done much to address the needs of those with diabetic foot ulceration, but such clinics are not designed or resourced to meet the needs of people with foot ulcers without diabetes. The NWCSP recognises that whilst some healthcare services have adopted a 'high risk foot' approach to address this inequality, more is needed to ensure that all patients with foot ulcers can access appropriate care.

There is a strong argument that commissioning equitable and accessible services for leg ulceration would reduce unwarranted variation of care, increase the use of evidence-based care, and discourage the over-use of therapies for which there is insufficient evidence, resulting in higher healing rates and lower recurrence rates.

The process for developing and updating these recommendations

The original recommendations were developed using an evidence-informed approach, to include consideration of research evidence, health care resources, clinical settings, and patients' preferences[3]. The original recommendations were based on evidence retrieved using a systematic approach to searching (outlined in Appendix 1) and then sense-checked with academics, health practitioners and patients and carers, before a wider consultation with NWCSP stakeholder forums registrants. This update has followed the same process but following feedback from stakeholders, it has been decided to publish the foot ulcer recommendations and leg ulcer recommendations as separate documents, which together will form the suite of lower limb wound recommendations.

The purpose of these recommendations

The purpose of these recommendations is to provide clear advice to health and care professionals, service managers and commissioners about the fundamentals of evidence-informed care for people with foot ulcers. Implementing these recommendations will achieve better patient outcomes and more effective use of health care resources.

The recommendations outline a pathway of care that promotes early assessment and diagnosis, enabling fast access to evidence informed therapeutic interventions, with escalation of treatment or service provision for patients requiring more complex care.

The recommendations thus offer a framework for the development of local delivery plans that include consideration of:

- Relevant research evidence (where it exists) to inform care.
- Configuration of services, and deployment of workforce.
- Appropriate education for that workforce; and
- Relevant metrics to measure quality improvement.

These recommendations signpost to relevant clinical guidelines or outline evidence-informed care that will improve healing and optimise the use of healthcare resources. They do not replace existing evidence-informed clinical guidelines or replace clinical judgement and decision making in relation to the needs of the individual patient. They are intended for use in all clinical care settings and aim to support implementation of evidence-based clinical practice.

Recommendations

A. Identification and immediate and necessary care

Immediately escalate to the relevant clinical specialist, those with the following 'red flag' symptoms/ conditions:

- Acute infection *(e.g., increasing unilateral erythema, swelling, pain, pus, heat).*
- Deep foot ulcers where abscess is suspected, osteomyelitis or other deep or tracking[4]
- Symptoms of sepsis[5]
- Acute or chronic limb threatening ischaemia[6, 7], *(e.g., PAD with rest pain, gangrene, or a lower limb ulceration> 2 weeks in duration)*
- Suspected acute deep vein thrombosis (DVT)
- Suspected skin cancer.
- Charcot

1. Arrange for referral to multidisciplinary foot care team or foot protection service,
    - Diabetic foot ulcer – in hospital
      Refer within 24 hours of the initial examination of the person's feet[4]
    - Diabetic Foot ulcer: all other settings
      Refer within 1 working day of the initial examination of the person's feet[9]
    - Foot ulcer – no diabetes
      Refer within 1 working day of the initial examination of the person's feet.

    If there is also leg ulceration, refer to the NWCSP Recommendations for leg ulceration[9].

    For people in the last few weeks of life, seek input from their other clinicians to agree an appropriate care plan.

2. Treat any foot wound infection in line with NICE Guideline (NG19) Diabetic Foot Ulcer infection [5] or in line with locally developed guidance for managing foot ulcer infection.

3. Cleanse the wound bed, skin around the ulcer, consider debridement and apply emollient as required.

4. Record image of wound using digital imaging [6]

5. Apply simple, low adherent dressing with sufficient absorbency.

6. Implement offloading or pressure redistribution strategies to affected area.

7. Signpost to relevant, high-quality information and identify, discuss, and incorporate opportunities for supported self-management into treatment plan in line with the individual's capacity, capability and wishes.

B. Assessment, Diagnosis and Treatment

Assessment and diagnosis:

1. Undertake assessment,
    - Diabetic foot ulcer – in hospital within 24 hours of referral[9]
    - Diabetic Foot ulcer: all other settings within 2 days of referral[9i]
    - Foot ulcer – no diabetes within 7 days of referral [7]

2. Assess and identify causes and risk factors for non-healing by undertaking a comprehensive assessment that includes:
    - Full history including any previous history of foot ulceration and underlying cause.
    - Review of medication,
    - Pain and analgesia needs
    - Psychosocial needs
    - Possible infection
    - Nutrition
    - Screening for diabetes
    - Assess the ulcer in line with the wound minimum data set [8]
    - Record image of wound using digital imaging [9]
    - Undertake a lower limb assessment that includes:
        - Peripheral vascular assessment[7] (ABPI and/or TPI)
        - Assessment for sensation[9]
        - Biomechanical, and assessment of musculoskeletal function[4]
        - Use of a classification system such as WIfI[10] (wound ischemia and foot infection) to categorise these three major risk factors leading to amputation (See Appendix 2).

3. Diagnose causes of non-healing and formulate treatment plan.

Treatment:

4. Optimise management of contributing disease (e.g. Diabetes, CKD).

5. Use ANNT to cleanse the wound bed, skin around the ulcer.

6. Debride as required, *Sharp debridement should only be undertaken by healthcare professionals with the relevant training and skills, with consideration of the persons preference.*

7. Apply a low adherent dressing with sufficient absorbency.

8. Offer advice on skin care, footwear, exercise and mobility, rest, and limb elevation (to include both limbs) nutrition, smoking cessation, and weight loss.

9. Identify, discuss, and incorporate opportunities for supported self-management into treatment plan in line with the individual's and their carers' capacity, capability and wishes.

10. Provide the individual and their relevant health care providers responsible for supporting ongoing care, with verbal and written information about:

    - The diagnosis of the ulcer.
    - When to seek advice and specific information (including names and phone numbers) about who to contact from the previous clinical care provider.
    - If an image of the ulcer has been captured, this image should be shared with the individual (if they wish) and the health care provider responsible for ongoing care using NHS compliant digital technology[13].
    - Signs of infection.
    - Hygiene (including hand hygiene).
    - Advice on dressing changes and taking an image of their own ulcer to monitor healing.

For foot ulcers without diabetes

11. If there is evidence of peripheral arterial disease, then refer to vascular services for possible vascular intervention in line with NICE Guideline (CG147) Peripheral arterial disease: diagnosis and management [7] using the NWCSP PAD/CLTI referral form or equivalent [11].

12. If appropriate treat any foot wound infection in line with NICE Guideline (NG19) Diabetic Foot Ulcer infection [12] or in line with locally developed guidance for managing foot ulcer infection. Where appropriate
    - Send a soft tissue or bone sample from the base of the debrided wound for microbiological examination[9].
    - If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic treatment[9].
    - Consider an X-ray if you suspect osteomyelitis (probe to bone)[9].

13. Implement offloading and pressure redistributing strategies to affected area, which includes advising rest and elevation[7]. In line with the NICE guideline for pressure ulcers (CG179) [13],

use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing.

When choosing the most appropriate offloading and pressure redistributing device, consider the clinical assessment of the wound and the persons preference appropriate to the clinical circumstances[9].

For foot ulcers with diabetes

14. If there is evidence of peripheral arterial disease, then refer to vascular services for possible vascular intervention in line with NICE Guideline (CG147) Peripheral arterial disease: diagnosis and management [7] using the NWCSP PAD/CLTI referral form or equivalent [14].

15. If appropriate treat any foot wound infection in line with NICE Guideline (NG19) Diabetic Foot Ulcer infection [15] or in line with locally developed guidance for managing foot ulcer infection. Where appropriate
    - Send a soft tissue or bone sample from the base of the debrided wound for microbiological examination[9].
    - If this cannot be obtained, take a deep swab because it may provide useful information on the choice of antibiotic treatment[9].
    - Consider an X-ray if you suspect osteomyelitis (probe to bone)[9].

16. Implement offloading and pressure redistributing strategies to affected area, which includes advising rest and elevation[9]. In line with the NICE guideline for pressure ulcers (CG179) [16], use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing.

    When choosing the most appropriate offloading and pressure redistributing device, consider the clinical assessment of the wound and the persons preference appropriate to the clinical circumstances[9].

17. Refer to the NICE Guideline (NG 19) Diabetic foot problems: prevention and management which outlines recommended treatment for diabetic foot ulcers[9].

C. Ongoing care of foot ulceration

At each dressing change:

Immediately escalate to the relevant clinical specialist, those with the following 'red flag' symptoms/conditions:

- Acute infection *(e.g., increasing unilateral erythema, swelling, pain, pus, heat).*
- Deep foot ulcers where abscess is suspected, osteomyelitis or other deep or tracking[4]
- Symptoms of sepsis[5]
- Acute or chronic limb threatening ischaemia[6,7], *(e.g., PAD with rest pain, gangrene, or a lower limb ulceration> 2 weeks in duration)*
- Suspected acute deep vein thrombosis (DVT)
- Suspected skin cancer.
- Charcot

1. If appropriate treat any foot wound infection in line with NICE Guideline (NG19) Diabetic Foot Ulcer infection [17] or in line with locally developed guidance for managing foot ulcer infection.

2. Use ANNT to cleanse the wound bed, skin around the ulcer.

3. If appropriate, debride the wound bed, and remove devitalised tissue.

4. Apply a simple low-adherent dressing with sufficient absorbency.

5. If being treated with offloading or pressure redistributing device, review reduction in ulcer size and consider whether this should be adapted.

6. Review care and identify, discuss, and incorporate opportunities for supported self-management into treatment plan in line with the individual's and their carers' capacity, capability and wishes.

7. Review effectiveness of treatment plan and if there is deterioration, escalate in line with local pathways.

D. Review of healing

At 4 weekly intervals (or more frequently if concerned)

1. Monitor for healing by:
   - Completing ulcer assessment in line with the wound minimum data set[18]
   - Taking digital wound image and compare to previous images.
   - Measure the wound for reduction in size.

2. Review effectiveness of treatment plan.

   Foot ulcers that show no significant progress towards healing or are deteriorating should be escalated for advice in line with local care pathways e.g., multidisciplinary foot service, vascular service.

3. Review opportunities for supported self-management and discuss and incorporate into treatment plans as agreed with the individual. This may include remote monitoring techniques.

At 12 weeks:

1. Monitor for healing by:
   - Completing ulcer assessment in line with the wound minimum data set[18] including toe pressure.
   - Taking digital wound image and compare to previous images.
   - Measure the wound for reduction in size.

2. Review effectiveness of treatment plan

   Foot ulcers that remain unhealed should be escalated for advice in line with local care pathways e.g., multidisciplinary foot service, vascular service, orthopaedic service.

   For those where there is no progress to healing and other treatment is not possible, seek to agree an appropriate care plan which may include palliation of symptoms as an acceptable outcome.

E. Care following healing

For all types of foot ulcers, offer care as follows:

1. Advice should be given on how to reduce the risk of re-ulceration. This should be tailored to the individual patient but should consider, skin care, footwear, healthy eating, and exercise, (and if appropriate smoking cessation).

2. Verbal and written information should be provided and discussed about the diagnosis and ongoing treatment plan, and where to contact if there are any issues.

3. Opportunities for supported self-management should be identified, discussed, and incorporated into treatment plans as agreed with the individual.

For healed foot ulcers without diabetes

4. Review of individuals who are at high risk should be made on a case-by-case risk-assessed basis. Should regular reviews be required these would be carried out within a 2-month timeframe.

5. If a pressure redistributing/offloading device or therapeutic footwear has been issued an appropriate timeframe should be agreed to review and replace with advice to seek earlier review if any issues noted.

6. Advise that changes in lower limb symptoms should prompt the individual to seek earlier review which should include a comprehensive lower limb assessment that includes:
    - Peripheral vascular assessment[7] (ABPI and/or TPI)
    - Assessment for sensation[9]
    - Biomechanical, and assessment of musculoskeletal function[4]
    - Use of a classification system such as WIfI[18]

7. If there are no risk factors present, then discharge from the service with advice on how to access the service if there is recurrence of ulceration.

For healed foot ulcers with diabetes

8. Every individual who has diabetes and had a foot ulcer considered high risk. Regular reviews should be offered every 1 to 2 months if there are no immediate concerns in line with NICE Guideline (NG 19) Diabetic foot problems: prevention and management[4].

9. This review should be carried out in the foot protection service in line with NICE Guideline (NG 19) Diabetic foot problems[4] and should include:
    - Assessment of the feet.
    - Advice about, and provide, skin and nail care of the feet.
    - Assess the biomechanical status of the feet, including the need to provide specialist footwear and orthoses.
    - Assess the vascular status of the lower limbs.

Explanatory notes

Identification and immediate and necessary care

Prevention of injuries (which may be the start of lower limb ulceration) is outside the remit of the NWCSP, but early appropriate care can prevent foot wounds that are non-healing, or at risk of non-healing, becoming ulcers.

The treatment of foot ulcer infection should be in line with NICE Guideline (NG19) Diabetic Foot Ulcer infection or locally developed foot infection management guidance. In the absence of such guidance, healthcare professionals should be encouraged to develop local guidance in collaboration with microbiology.

There should be equal access to medicines and diagnostics such as X-Ray for all people who may present with foot ulceration and suspected osteomyelitis, regardless of underlying disease.

People presenting with CLTI are at an advanced stage of peripheral arterial disease and usually have significant other cardiovascular disease and comorbidities. There is clear evidence to support referral into vascular services for revascularisation to prevent limb loss supported by clear referral pathways.

The absence of foot pulses is not included as a ‘red flag’ symptom because pulse palpation has poor sensitivity and specificity as a diagnostic sign for inadequate arterial supply.

Charcot foot usually presents in a person with neuropathy, as an unexplained, erythematous, hot, swollen foot. In some cases, there can be early changes to the shape of the foot. If there is no ulceration it is highly unlikely to be cellulitis. Key to treatment is getting the weight off the foot, with treatment that usually involves a below knee boot or cast. Urgent referral should be made in line with local pathways.

Increased plantar pressure is a causative factor in the development of foot ulcers. Effective offloading treatment, includes advice on resting and elevation.

No robust evidence has been identified to support the superiority of any dressing type over another for standard care of leg wounds. Therefore, simple low-adherent dressings with sufficient absorbency are recommended as first line care but this recommendation does not replace clinical judgement and decision making in relation to the needs of the individual patient.

Some people in the last few weeks of life may benefit from some of the standard therapeutic interventions for lower limb ulceration to improve their quality of life. However, the complexity of the health needs of these people, means that a multi-disciplinary approach is particularly important in planning their health care to optimise outcomes and reduce the risk of harm.

Footcare services can refer to both acute and community-based teams. They are typically staffed by podiatrists, with integrated input from orthotists; diabetologists, microbiologists and general practice physicians; nursing; vascular, orthopaedic; and plastic surgeons; pharmacists and physiotherapists. The service structure is usually composed of a foot protection service (FPS), (which may be referred to as a community podiatry team) and an acute hospital-based service. The acute service has regular and additional multidisciplinary input and may be referred to as the MDFT (multidisciplinary footcare teams)[19]

Assessment, Diagnosis and Treatment

Assessment and Diagnosis

There are no published assessment times for foot ulcers without diabetes, however the underlying reason for non-healing is likely to be due to peripheral arterial disease (PAD) and therefore the PAD quality improvement framework times for assessment have been used to inform this recommendation.

A multi-disciplinary team (MDT) approach to care is essential. The multidisciplinary team for diagnosis and treatment may include clinicians from podiatry, nursing, medicine, tissue viability, vascular, lymphoedema and dermatology services with the capabilities / competencies identified for advanced practitioners.

Accurate wound assessment is essential for monitoring wound healing as wound size and wound bed status form the baseline against which all subsequent treatment effectiveness will be measured. Wound imaging should be incorporated into wound assessment and regarded as part of standard practice.

Structural foot deformities and abnormalities, such as flatfoot, hallux valgus, claw toes, Charcot neuroarthropathy and hammer foot, contribute to abnormal plantar pressures. Deformities to the foot alter the spatial location of the STJ axis and change the effect of external and internal forces on the structural components of the foot. Failure to address these biomechanical abnormalities result in ulceration.

Treatment

The SBAR tool (situation, background, assessment, recommendation) can be used when to support accurate communication of clinical information when discussing patients with vascular teams[20]

While there is a lack of robust evidence for first line dressings for promoting foot ulcer healing, there is some evidence to guide dressing selection for people with hard to heal foot ulcers. Dressing selection should therefore take account of current research evidence as well as patient preferences and cost.

Offloading and pressure redistribution: For the population with diabetes there is strong evidence to support the use of non-removable knee-high offloading devices as first choice offloading interventions for healing plantar neuropathic forefoot and midfoot ulcers with removable offloading devices, either knee high or ankle as second choice. The evidence base to support any other offloading intervention is weak.

Review of healing

Review and Escalation: If after 4 weeks of treatment, there is no evidence of progress towards healing, such people should be escalated for advice in line with local care pathways Similarly, those who are unhealed at 12 weeks should also be escalated for advice.

Care following healing

If it is possible to completely resolve the underlying cause of ulceration and remove the need for ongoing care, such patients can be discharged.

Appendix 1: Search strategy for research evidence

The search strategy was limited to pre-appraised sources of research evidence, using a 4S approach[1] to structure a search strategy as shown.

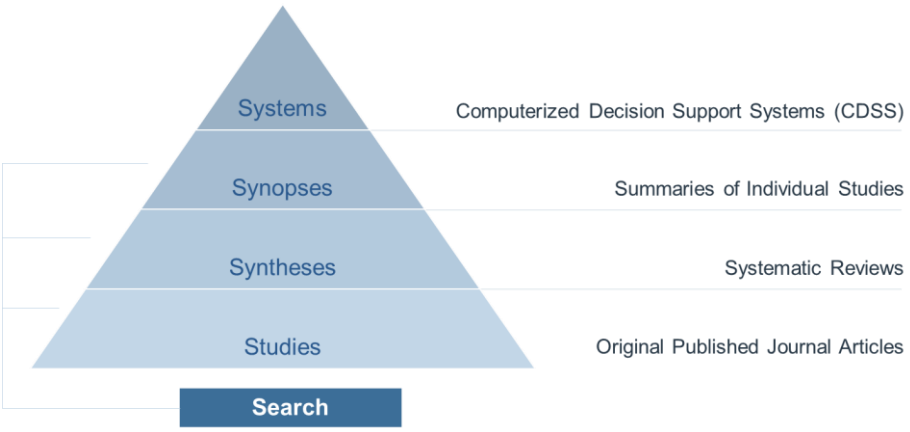
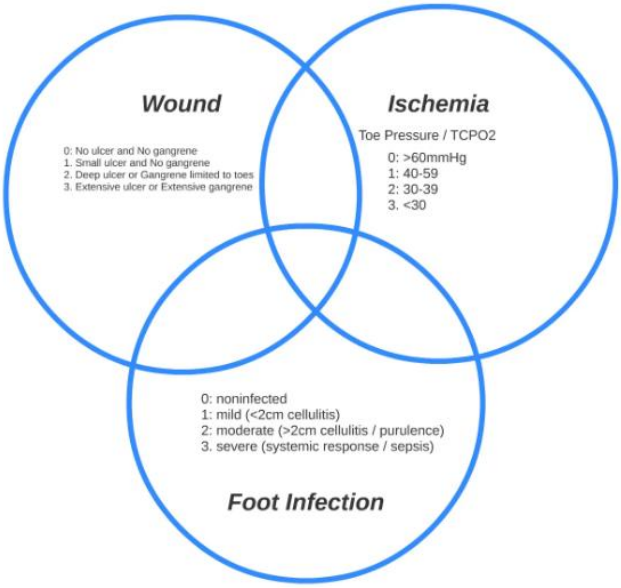


Figure 1 4S search strategy approach

- *Systems*: searched UK computerised decision support systems for chronic lower limb wounds.
- *Synopses*: searched for summaries of the current state of knowledge about the prevention and treatment of chronic lower limb wounds.
- *Syntheses*: searched the Cochrane Library of Systematic Reviews to identify reviews for chronic lower limb wounds leg ulcer treatment.
- *Studies*: searched the NIHR library for NIHR funded studies completed after publication of the relevant Cochrane systematic reviews for venous leg ulceration.

[1] 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.

Appendix 2: WIfI



Component	Score	Description		
W (Wound)	0	No ulcer (ischaemic rest pain)		
	1	Small, shallow ulcer on distal leg or foot without gangrene		
	2	Deeper ulcer with exposed bone, joint or tendon ± gangrenous changes limited to toes		
	3	Extensive deep ulcer, full thickness heel ulcer + calcaneal involvement ± extensive gangrene		
I (Ischaemia)		ABI	Ankle pressure (mmHg)	Toe pressure or $TcPO_2$
	0	≥0.80	>100	≥60
	1	0.60-0.79	70-100	40-59
	2	0.40-0.59	50-70	30-39
	3	<0.40	<50	<30
fI (foot Infection)	0	No symptoms/signs of infection		
	1	Local infection involving only skin and subcutaneous tissue		
	2	Local infection involving deeper than skin/subcutaneous tissue		
	3	Systemic inflammatory response syndrome		

Example: A 65-year-old male diabetic patient with gangrene of the big toe and a <2 cm rim of cellulitis at the base of the toe, without any clinical/biological sign of general infection/inflammation, whose toe pressure is at 30 mmHg would be classified as Wound 2, Ischaemia 2, foot Infection I (WIFI 2-2-1). The clinical stage would be 4 (high risk of amputation). The benefit of revascularisation (if feasible) is high, also depending on infection control.

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