clinical practice GUIDELINES

The management of patients with venous leg ulcers

Technical Report

Part1
Guideline objectives and methods of guideline development

Part 2
Recommendations for assessment, compression therapy, cleansing, debridement, dressing, contact sensitivity, training/education and quality assurance

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clinical practice

GUIDELINES

The management of patients with venous leg ulcers

Technical Report: Part 1

Guideline objectives and methods of guideline development

Contents

people with venous ulcers should have a significant impact on healing rates and save time spent by community nurses. Despite the promotion in the UK of 4-layer bandaging, there is little reliable evidence for its superiority over other high compression techniques.

- High compression bandage systems and their components vary in their availability in the community. Orthopaedic wool padding, a component of most high compression systems, is not available on prescription, and purchasers and providers should consider how this can be made readily available to community nurses.

- Whichever high compression approach is employed, it is important that it is used correctly so that sufficient (but not excessive) pressure is applied. Community nurses and other practitioners should be better trained and monitored in leg ulcer management, including patient assessment, and bandage application.

- Use of compression stockings should be encouraged for the prevention of recurrence. However, there is little evidence to support the use of drug therapy using stanozolol or oxerutins.

- Systems should be put in place to monitor standards of care as measured by *structure* (e.g. the proportion of appropriately trained staff); *process* (e.g. the proportion of patients whose arterial status has been determined by ABPI measurement, and the proportion with uncomplicated venous ulcers receiving high compression therapy); and *outcome* (e.g. the prevalence of active ulceration, proportion of patients healed, rates of healing and adverse outcomes due to incorrectly treated arterial disease or excessive compression).[56]

- The issues raised in this bulletin should be discussed with providers of primary care and district nurse services and relevant hospital specialists so as to co-ordinate services, ensure nurse training and supervision and establish systems to monitor standards of care.

- Further RCTs of sufficient size and follow-up are necessary. In particular there is a need to determine the most cost-effective high compression systems, whether surgery for certain groups of patients confers any added benefit, and the additional importance (if any) of the organisation of care once proper compression systems are in place.

- The Royal College of Nursing is leading the development of a clinical guideline on leg ulcer assessment and management, based on this *Effective Health Care* bulletin. It is expected that the guideline will be available in mid-1998.

Appendix: Methods used to review the research

A systematic review of research with no restriction on date or language was carried out using 18 electronic databases including MEDLINE, CINAHL and EMBASE. Relevant journals and conference proceedings were handsearched and experts consulted. Published and unpublished RCTs which measured ulcer healing were included because in RCTs statistically significant differences in outcomes can be more confidently attributed to a particular treatment. Studies which compared healing rates using a new treatment with historical controls were excluded as this design is more susceptible to bias. The methodological quality of each study was assessed using a checklist, by two reviewers working independently.

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Table 10 RCTs of pharmacological interventions for the prevention of recurrence of venous ulceration

Study	Patients and interventions	Initial ulcer size & duration	Results
Lagatolla et al 1995[45] UK	136 patients with healed venous ulcers attending outpatients clinic I1: Stanozolol 5mg bd for 12 months plus compression stockings I2: surgery – ligation of calf, perforating veins plus compression stockings Follow up: 5 yrs	Not stated	I1: 10/42 recurrences (24%) I2: 13/41 recurrences (32%) Life table analysis: increased ulcer-free survival in surgery group (NS) Attrition: I1: 9; I2: 13
McMullin et al 1991[42] UK	48 limbs with healed venous ulcers out of a total of 85 limbs in 60 patients being treated for lipodermatosclerosis I1: Stanozolol 5 mg bd + below knee class II graduated compression stocking (Venosan, Switz) I2: placebo tablet + stockings as in I1 Follow up: not stated how much beyond 6 mths treatment	Not stated	Recurrence of ulceration: I1: 7/25 limbs (20%) I2: 4/23 limbs (17%) [p>0.6] Attrition: I1: 6/30; I2: 3/30
Stacey et al. 1990[44] UK	68 limbs of 54 patients with healed venous ulcer I1: Stanozolol 5 mg bd for 9 months + below knee graduated stockings (Sigvaris) I2: Ligation of the incompetent communicating veins and eradication of all visible varicose superficial veins + stockings as I1 (stockings worn continuously and replaced every 6 mths) Follow up: 12 mths	Number of limbs with normal deep veins I1: 9/49; I2: 13/49 Number of limbs with post-thrombotic changes: I1: 15/49; I2: 12/49	Limbs in which ulcers recurred within 12 mths I1: 6/24 limbs (5/17 pts) I2: 1/25 limbs (1/20 pts) Attrition: I1: 8; I2: 9
Wright et al 1991[43] UK	138 patients with recently healed venous ulcer recruited at first follow up appointment I1: Oxerutins (Paroven, Zyma, UK) 500 mg bd + below knee class II graduated elastic stockings I2: identical placebo + stockings as in I1 Stockings replaced where necessary at 3-monthly intervals, equal numbers in each group randomised to surgery Follow up: 18 mths	Mean duration (mths) I1: 8.9; I2: 8.8 Additional illnesses No significant differences between groups	Cumulative recurrence at 18 mths I1: 34%; I2: 32% [p = 0.93 log rank test] Attrition: not stated

Table 11 RCTs of compression from trained nurses and/or specialised clinics versus usual district nurse treatment

Study	Patients and interventions	Initial ulcer size & duration	Results
Morrell et al[35] UK	233 ambulant patients from 8 clinics who had suspected venous ulcers I1: 4-layer bandaging delivered by project nurses in clinic I2: 'usual care' from district nurses at home Follow up: 1 yr	Mean ulcer area (cm^2) I1: 16.2 ; I2: 16.9 Mean duration (mths) I1: 27.5; I2: 29.7	Complete healing at 12 mths I1: 65%; I2: 55% Difference in percentage healed = 11; 95% CI: -0.02 – 0.24. Overall there is a statistically significant difference in healing rate $p = 0.03$ log rank test Attrition: I1: 16; I2: 13
Taylor et al[17]	See Table 1		

Large variability in the way bandages are applied and the pressures achieved have also been observed. More experienced or well trained bandagers obtained better and more consistent pressure results.[54] Training of nurses can result in improved bandaging technique,[55] but there is some evidence that maintenance of good practice requires monitoring, feedback and supervision.[52,55]

F. Implications

- Diagnosis of arterial status (to determine eligibility for compression therapy) is more accurate when based upon the ABPI measurement than manual palpation of foot pulses alone. However, unless operators are well trained, ABPI measurements can be unreliable.
- The most effective intervention for the treatment of venous leg ulcers is high compression provided by 4- or 3-layer (multilayer) or short stretch bandages, Unna's boot or compression stockings, possibly with the addition of intermittent pneumatic compression. Routine application of one of these high compression techniques in

Table 8 Quality of RCTs of interventions to prevent recurrence of venous ulcers

Study	Clear inclusion and exclusion criteria reported	Sample size [arms]	A priori sample size calculation?	Method of randomisation	Baseline comparability or treatment groups	Blinded outcome assessment	Withdrawals reported by group with reasons	Analysed by intention to treat/life table method
Franks et al 1995[10]	✓	166 [2]	✓	not stated	✓	not stated	none stated	✓
Harper et al 1995[41]	×	300 [2]	not stated	concealed	not stated	×	×	✓
McMullin et al 1991[42]	✓	48 limbs [2]	not stated	not stated but double blind so assume allocation concealment	not stated for previously ulcerated limbs	✓	✓ but no individual details for previously ulcerated limbs	unclear
Lagatolla et al 1995[45]	brief	105 [2]	not stated	not stated	not stated	not stated	X (reasons given for 22 withdrawals but a further 19 people are missing from the data)	✓
Stacey et al 1988[61]	✓	30 (41 limbs) [2]	not stated	not stated	only for venous status	not stated	not stated	unclear
Stacey et al 1990[44]	brief	55 (68 limbs) [2]	not stated	not stated	✓	not stated	✓	×
Wright et al 1991[43]	brief	138 [2]	✓	concealed randomisation code	✓	✓	not stated	✓

Table 9 RCTs of prevention of recurrence of venous ulceration using compression stockings and venous surgery

Study	Patients and interventions	Initial ulcer size & duration	Results
Franks et al 1995[10] UK	166 patients from community leg ulcer clinics with newly healed ulcers, mean age 72 yrs I1: class 2 below knee stockings (Medi, UK) I2: class 2 below knee stockings (Scholl) New stockings prescribed every 3 months Follow up: 18 mths	Median ulcer (cm^2) I1: 3.3; I2: 3.5 Median ulcer duration: (mths) I1: 5.7; I2: 2.0 Mobility (chairbound; walk+aid; walk freely I1: 4(4%): 27(29%); 61(67%) I2: 1(1%): 23(31%); 50(68%)	Recurrence rate at 18 mths I1: 24% I2: 32% Adjusted RR = 1.16; 95% CI 0.65–2.04] Attrition: none stated Overall 83% all day wear (no difference)
Harper et al 1995[41] UK	300 patients with newly healed venous leg ulcers I1: Class 2 stockings I2: Class 3 stockings Refitting and supply of new stockings every 4 months Follow up: 5 yrs	Not stated	recurrence within 36–60 mths I1: 32%; I2: 21% [p=0.034]
Stacey et al 1988[58] UK	30 patients with 41 previously ulcerated limbs attending surgical outpatients I1: surgery – ligation of incompetent communicating veins and ablation of incompetent superficial veins plus permanent below-knee elastic stockings (Sigvaris) I2: stockings – below-knee stockings (Sigvaris) NB. Limbs rather than patients were randomised Follow up: 1 yr	I1: 8 had evidence of past DVT I2:10 had evidence of past DVT	Ulcer recurrence: I1: 1 (5% limbs); I2: 5 (24% limbs) Attrition: not stated

Table 6 RCTs of compression stockings *versus* compression bandaging

Study	Patients and interventions	Initial ulcer size & duration	Results
Hendricks & Swallow 1985[36] USA	21 patients attending outpatients clinic I1: Unna's boot + Kerlix roll + elastic bandage I2: open toe, below knee graduated compression stockings Follow up: 18 mths	Median ulcer area (cm^2) 2.55 Median duration 4.5 yrs	Complete healing I1: 7/10 (70%); I2: 10/14 (71%) but 3 of these were transferred from I1 Patients cross between arms depending on progress. No intention to treat analysis carried out.
Horakova & Partsch 1994[37] Austria	59 patients attending a dermatology clinic I1: Short stretch bandage (Rosidal K) I2: Thrombo stocking + compression stocking (Sigvaris– removed at night) Follow up: 3 mths	Mean ulcer area (cm^2) I1: 3.2; I2: 6.0 Mean duration (mths) I1: 2; I2: 5 [$p<0.05$]	Complete healing I1: 13/25-(52%); I2: 21/25 (84%) [$p < 0.05$] Attrition: I1:6; I2:3

Table 7 RCTs of intermittent pneumatic compression treatment

Study	Patients and interventions	Initial ulcer size & duration	Results
Coleridge Smith et al 1990[38] UK	45 patients (48 ulcers) attending venous ulcer outpatient clinic I1: graduated compression stockings I2: I1 + intermittent sequential gradient pneumatic compression used daily in the home Follow up: 3 mths	Median ulcer area (cm^2) I1: 17.3; I2: 49.8 Median duration (yrs) I1: 3.5; I2: 3.9	Completely healed I1: 1/24 (4%) patients; I2: 10/21 (48%) patients [$p = 0.009$] I1 contained patients with 2 ulcers Attrition: none
McCulloch et al 1994[39] USA	22 patients attending vascular surgery clinic I1: Unna's boot only I2: I1 + intermittent one cell pneumatic compression applied for one hour, twice a week after cleansing Follow up: 6 mths	Mean ulcer area (cm^2) I1: 0.4 - 59.4 I2: 0.4 - 45.0	Completely healed I1: 8/10 (80%); I2: 12/12 (100%) Attrition: none

Arterial disease of the leg is most commonly detected by a combination of general clinical examination and either manual palpation of foot pulses or by measuring the ratio of the systolic blood pressure at the ankle to that in the arm (the ankle:brachial pressure index ABPI).[47] The ABPI ratio is measured using a hand-held Doppler ultrasound together with a sphygmomanometer. An ABPI ratio of less than 1.0 is viewed as indicative of some arterial impairment. The cut-off point below which compression is generally not applied in clinical practice is often quoted as 0.8[47] however, many trials use the higher cut-off of 0.9.

There is generally poor agreement between manual palpation of foot pulses and ABPI. Two large studies have shown that 67% and 37% of limbs respectively with an ABPI <0.9 had palpable foot pulses, with the consequent risk of applying compression to people with arterial disease.[47,48] Even though ABPI measurement appears to be better than manual palpation for excluding arterial disease, ABPI measurement has been shown to be unreliable when carried out by inexperienced operators.[49] Reliability can however, be significantly improved if people are highly trained.[50,51]

E. Organisation of care

A recent trial in Sheffield (Table 11) showed that care delivered in leg ulcer clinics, by trained nurses, following a treatment protocol which included use of 'Charing Cross' 4-layer bandaging resulted in better healing at 1 year (65%) than in patients who continued their usual treatment at home provided by their district nurse, who did not routinely have access to the 4-layer bandage (55%).[35] The clinic was also more cost-effective. Improved healing associated with specialist clinics using 4-layer bandaging was also shown in a second small trial.[17] These 2 trials do not however, provide information on the relative impact of, or interactions between, the various elements of setting, nurse training, compression bandaging, and protocols for treatment and referral. It is possible for example, that similar improvements in healing could be achieved without the use of clinics or by using other high compression therapies.

A survey in Leeds found that district nurses' knowledge of the assessment and management of leg ulcers was often inadequate.[52] Another survey reported that 50% of nurses made a diagnosis of the cause of the ulcer based on visual assessment alone.[53]

Table 4 RCTs of elastic high compression bandaging *versus* inelastic compression

Study	Patients and interventions	Initial ulcer size & duration	Results
Duby 1993[25]	See Table 2		
London and Scriven[26] UK	30 ambulant patients I1: 4-layer bandage (orthopaedic wool, crepe, Elset, Coban) I2: short stretch (orthopaedic wool, short stretch, Coban) Follow up: 1 yr	Median ulcer area (cm^2) I1: 12.4; I2: 8.16 Median duration (mths) I1: 18; I2: 24	Healing rate I1: 60%; I2: 60% Attrition: I1: 4
Colgan et al[27] Ireland	30 patients at routine venous ulcer out-patient clinic I1: modified Unna's boot (paste bandage + Elastocrepe + Elastoplast + class II compression sock) I2: 4-layer bandage (Profore) (4LB) I3: Lyofoam dressing + Setopress compression bandage Follow up: 3 mths	Median ulcer area (cm^2) I1: 7; I2: 9; I3: 20 Median duration (mths) I1: 24; I2: 10; I3: 12	Complete healing: I1: 6/10 (60%) I2: 7/10 (70%) I3: 2/10 (20%) Mean bandage costs in IR£ I1: £82.54 I2: £66.24 I3: £58.33
Knight & McCulloch 1996[28] USA	10 patients randomly chosen from patients at a wound care centre I1: 4-layer bandage (Profore) I2: Unna's boot Follow up: 6 wks	Not stated	Average rate of ulcer healing (cm^2/ wk) I1: 1.14 ; I2: 0.34 Attrition: not stated
Inelastic compression versus single layer bandage			
Cordts et al 1992[24] USA	43 patients, >18 yrs, male and female, outpatient clinic I1: Hydrocolloid dressing (Duoderm) + graduated compression (Coban wrap) I2: Unna's boot Follow up: 3 mths	Median ulcer area (cm^2) I1: 9.1 I2: 6.0 Mean duration (wks) I1: 95 I2: 96	Complete healing I1: 8/16 (50%); I2: 6/14 (43%) [$p = 0.18$] Attrition: I1: 7; I2: 6

Table 5 RCTs of multilayer high compression systems versus single-layer bandage systems

Study	Patients and interventions	Initial ulcer size & duration	Results
Nelson et al 1995[31] UK	200 patients referred by GPs and community nurses, age > 18 years, attending leg ulcer clinic I1: 4-layer bandage (orthopaedic wool + crepe + Elset + Coban) I2: single layer bandage (Granuflex adhesive compression bandage) [Primary dressing randomised to knitted viscose dressing or hydrocolloid dressing. Patients were also randomised to oxpentifylline or placebo] Follow up: not stated	Mean ulcer area (cm^2) I1: 7.8; I2: 12.4 Mean duration (mths) I1: 15.5; I2: 11	Complete healing I1: 69%; I2: 49% Odds ratio = 2.4; 95% CI: 1.3–4.3 Attrition: greater in I1 than I2
Kralj & Kosicek[32] Slovenia	40 in- and outpatients I1: 4-layer bandage (Profore) I2: single layer bandage (Porelast) + hydrocolloid dressing (Tegasorb) Follow up: 6 mths	Mean ulcer area (cm^2) I1: 18.6; I2: 17.2 Mean duration (mths) I1: 7.9; I2: 6.9	Complete healing I1: 7/20 (44%); I2: 8/20 (44%) Attrition: I1: 4; I2: 2
Travers et al 1992[33] UK	27 patients attending leg ulcer clinic I1: self adhesive 1-layer bandage (Panelast Acryl) I2: 3-layer bandage (Calaband + Tensopress + Tensogrip) Follow up: 6 mths	Mean ulcer area (cm^2) I1: 31 I2: 23 Mean duration (mths) I1: 23 I2: 35	Reduction in ulcer area I1: 86%; I2: 83% [no sig. diff.] Bandage costs equivalent Attrition: none

Table 2 RCTs of elastic high compression bandaging *versus* low compression

Study	Patients and interventions	Initial ulcer size & duration	Results
Callam et al 1992[22] UK	132 patients from leg ulcer clinics (multicentre) Male and female I1: elastic compression: Soffban+ Tensopress+ Tensoshape I2: non-elastic compression: Soffban + Elastocrepe + Tensoplusforte Follow up: 3 mths	Mean ulcer area (cm^2) I1: 8.2 I2: 11.0 Mean duration (mths) I1: 11.3 I2: 11.5	Complete healing I1: 35/65 (54%); I2: 19/67 (28%). [$p = 0.01$] However, patients were only followed up for 12 wks and at this point a large number of I2 patients were almost healed. Attrition: I1:8; I2: 20
Northeast et al 1990[23] UK	106 patients presenting to outpatient clinic I1: 3-layer bandage (Calaband + Elastocrepe + Tensogrip) I2: 3-layer bandage (Calaband + Tensopress + Tensogrip) Follow up: 3 mths	Not stated	Complete healing I1: 51%; I2: 64% [$p = 0.01$] Attrition: 3
Gould et al[24] UK	39 ambulatory patients (46 ulcers) from general practices attending outpatient clinic I1: elastic compression (Setopress) + medicated paste bandage + elasticated viscose stockinette I2: inelastic bandage (Elastocrepe) + medicated paste bandage + elasticated viscose stockinette 1 wk prior to treatment patients wore Setopress bandage Follow up: 16 wks	Mean ulcer area (cm^2) 7.44 Median duration (mths) 10	Healed or progressed I1: 11 (58%); I2: 7 (35%) [$p>0.05$] Attrition: 7 patients (10 ulcers)
Duby et al 1993[25] UK	67 patients (76 legs) I1: orthopaedic wool + short stretch bandage (Comprilan) + Tricofix net covering I2: 4-layer bandage (orthopaedic wool + crepe bandage + Elset + Coban) I3: paste bandage (Icthopaste) + support bandage (Elastocrepe and Tubigrip) Follow up: 3 mths	Mean ulcer area (cm^2) I1: 13.1 I2: 11.9 I3: 12.3 Mean duration (mths) I1: 26.7 I2: 20.5 I3: 34.5	Complete healing (ulcers) I1: 40%; I2: 44%; I3: 23% Attrition: none

Table 3 Comparing between different multilayer high compression systems

Study	Patients and interventions	Initial ulcer size & duration	Results
McCollum et al[29] UK	232 patients from community leg ulcer services I1: 'original' Charing Cross 4-layer I2: new proprietary 4-layer (Profore system) Follow up: 6 mths	Percentage <10cm^2 I1: 82%; I2: 84% Median duration: (wks) I1: 8; I2: 7	Complete healing I1: 82%; I2: 84% (p>0.05) Attrition: I1: 16%; I2: 15%
Wilkinson et al 1997[30] UK	35 legs in 29 patients recruited through district and practice nurses I1: Charing Cross 4-layer bandage I2: "Trial bandage": Tubifast + separate strips of lint applied horizontally + Setopress + Tubifast (to secure bandage) [Patients were stratified by ulcer size] Follow up: 3 mths	Mean ulcer area (cm^2) I1: 11.2; I2: 8.6	Complete healing I1: 8/17 (47%); I2: 8/18 (44%) Odds Ratio = 1.1; 95% CI: 0.2–5.2 Attrition: I1: 4; I2: 2

D. Diagnosis

The high rates of co-morbidity in patients with leg ulceration mean that careful assessment of all patients is important. This is particularly the case as considerable damage can be caused by inappropriately applying high compression in patients with arterial and small vessel disease.[46] There is debate about how arterial status should be assessed and whether this assessment should be undertaken routinely by nurses. Research into the precision and accuracy of the nursing assessment of leg ulcer patients is lacking.

Table 1 RCTs of compression versus no compression (alone/usual treatment) I = Intervention

Study	Patients and interventions	Initial ulcer size & duration	Results
Charles 1991[18] UK	53 community-based patients from inner London I1: short stretch bandage applied by project nurse (Rosidal K) I2: 'usual treatment' applied by district nurse Follow up: 3 mths	Mean ulcer area (cm^2) I1: 12; I2: 15 Mean duration (mths) I1: 32; I2: 25	Complete healing I1: 71%; I2: 25% Ulcers increased in size I1: 0%; I2: 21% Attrition: I1:3; I2: 3
Eriksson 1984[16] Sweden	44 patients, setting unclear I1: Skintec porcine skin dressing (no compression) I2: Metallina aluminium foil dressing (no compression) I3: double layer bandage (ACO paste bandage + Tensoplast) Follow up: 2 mths	Not stated	No statistical analysis reported. Decrease in ulcer area and volume I1: 60%, 67%; I2: 10%, 0%; I3: 80%, 90% Attrition: I2:6 In the 'middle' of the trial, patients in the porcine skin group were crossed over to double layer bandage
Kikta et al 1988[19] USA	84 patients from vascular surgery clinics with 87 ulcers I1: Unna's boot I2: Duoderm hydrocolloid dressing Follow up: 6 mths	Mean ulcer area (cm^2) I1: 9 I2: 8.6 Mean duration (wks) I1: 45 I2: 51	N.B. 69 ulcers in 66 patients; I2 group contained 3 patients with 2 ulcers Completely healed at 6 mths I1: 21/30 (70%); I2: 15/39 (38%) Life table analysis - ulcers healed at 15 wks I1: 64%; I2: 35% [p=0.01] Complication rate I1: 0%; I2: 26% Attrition: I1: 12; I2: 16
Rubin et al 1990[20] USA	36 consecutive ambulatory patients I1: Unna's boot I2: polyurethane foam dressing (Synthaderm) Follow up: unclear possibly 1 yr	Mean ulcer area (cm^2) I1: 76; I2: 32.2 Mean duration: not stated	Completely healed I1: 18/19 (94.7%); I2: 7/17 (41.2%) [p = 0.005] Attrition: I2: 9
Sikes 1985[21] USA	13 male patients (42 ulcers), a convenience sample from outpatient vascular surgery clinic I1: Unna's boot I2: polyurethane moisture vapour permeable, transparent film dressings (OpSite) Follow up: 1 yr	Mean ulcer area not stated but I1 had a mean of 3 ulcers and I2 had a mean of 3.5 ulcers. Mean duration I1: 3.5 yrs; I2: 6.9 yrs	Completely healed I1: 17/21 (81%); I2: 15/21 (71%) [p>0.05] Attrition: none
Taylor et al[17] UK	30 patients referred to the clinic by GPs Community setting I1: 4 layer bandage I2: conventional treatment (FP10 non-compression) Follow-up: 3 mths	Mean ulcer area (cm^2) I1: 5.4; I2: 4.2 Mean duration I1: 7 ulcers <6 mths; 9 ulcers >6 mths I2: 9 ulcers <6 mths; 5 ulcers >6 mths	Complete healing I1: 12 (75%); I2: 3 (21%) [p = 0.003] Median time to healing (days) I1: 55; I2: >84 [p = 0.003] Total average wkly treatment costs and cost of district nursing time were less in I1 [p = 0.04]

stockings however, were better tolerated by patients (Table 9).[41]

C.2 Pharmacological and surgical interventions: Two drugs have been investigated for their effects on leg ulcer recurrence: stanozolol, an anabolic steroid which increases fibrinolysis; and rutoside (Paroven) an oxerutin which is said to decrease capillary permeability. These drugs have been compared with placebo in 2 RCTs in which all patients also received class 2 compression stockings.[42,43] Both trials found that neither drug reduced recurrence.

Surgery in which incompetent communicating veins are ligated and varicose veins are eradicated has been compared in 2 small trials with the drug stanozolol (both combined with compression stockings) (Table 10). These gave conflicting results; one showing a lower recurrence rate with surgery within 1 year[44] and the other showing reduced recurrence with drug therapy at 5 years.[45]

One trial appeared to show a moderately reduced rate of recurrence when surgery was carried out in addition to the use of elastic stockings, however the study was small and poorly reported (see Table 9).[58]

Box Examples of compression bandages commonly used in the management of venous leg ulcers. Adapted from Morison[57]

Type of Compression	Examples	Performance Characteristics
High elastic compression	Tensopress* (Smith & Nephew) Setopress* (Seton) Surepress* (Convatec)	Sustained compression; can be worn continuously for up to 1 week; can be washed and reused
Light compression/ light support	Elastocrepe* (Smith & Nephew)	Low pressures obtained; used alone it only gives light support; a single wash reduces pressures obtained by about 20%
Light support only	crepe* (many manufacturers)	For holding dressings in place, as a layer within a multilayer bandage, for light support of minor strains and sprains; pressures from crepe alone are too low to be effective in management of venous ulcers; 40-60% of pressure lost in first 20 minutes after application
Cohesive bandages	Co-Plus* (Smith & Nephew) Tensoplus* (Smith & Nephew) Coban* (3M)	Self-adherent so preventing slippage; useful over non-adhesive bandages such as Elastocrepe and paste bandages; compression well sustained
Multilayer high compression	'Charing Cross' 4 layer bandage comprising: orthopaedic padding; crepe; Elset; Coban. Other multilayer systems are in use e.g. orthopaedic padding; Tensopress; shaped tubular bandage.	Designed to apply 40 mmHg pressure at the ankle, graduating to 17 mmHg at the knee, sustainable for a week.
Inelastic compression	Short-stretch bandage e.g. Comprilan (Beiersdorf) Unna's boot	Principal bandage in mainland Europe. Reusable with slight stretch giving low resting pressure but high pressure during activity. Non compliant, plaster-type dressing used in USA.
Compression stockings	Class 1 - light support Class 2 - medium support Class 3 - strong support	Used to treat varicose veins Used to treat more severe varicosity and to prevent venous ulcers in patients with thin legs For treatment of severe chronic venous hypertension and severe varicose veins and to prevent ulcers in patients with large-diameter legs

*often used as component of multi-layer system

Elastocrepe) (Table 2).[22–24] More patients were healed at 12–15 weeks with high compression (Odds Ratio = 2.26; 95% CI: 1.4, 3.65). The advantage of higher compression was confirmed in another RCT in which patients with either 4-layer or short stretch bandaging healed faster than those receiving a paste bandage with outer support.[25]

B.3 Different types of high compression: Several types of high compression systems are available, some of which have been compared directly in RCTs. The original 'Charing Cross' 4-layer bandage (see Box) has been compared with both a kit that provides all the constituents to make up a 4-layer bandage,[29] and a regimen adapted to achieve similar levels of compression using materials available on prescription.[30] No statistically significant difference in outcome was found in either study, although the latter trial was very small (Table 3).

Four-layer bandaging has also been compared with short stretch[25,26] and with Unna's boot[27,28] in 4 RCTs. No differences were found in the healing rates. However, because these studies were small in size, we cannot be confident that there are not clinically important differences in effectiveness (Table 4).

The advantage of multilayer high compression systems over single layer systems is shown by 1 large and 2 small trials which found more ulcers healed at 24 weeks using 4-layer bandaging than were healed using a single layer, adhesive compression bandage (Table 5).[31–33]

Even though 3-layer, 2-layer and other compression bandages have been shown to be effective, they appear not to have been directly compared with 4-layer bandaging in RCTs. A trial comparing 4-layer with 3-layer bandaging is however, being carried out at St. Thomas's Hospital, London.

Compression stockings have also been used to treat current ulcers.[40] A combination of 2 compression stockings has been shown to increase the rate of healing compared to a short stretch bandage (Odds Ratio = 4.9, 95%CI: 1.3, 18.3) (Table 6).[37]

B.4 Intermittent pneumatic compression treatment: Two small studies showed that more ulcers healed when intermittent pneumatic compression was used in addition to compression stockings or Unna's boot (pooled OR = 10.0; 95% CI: 2.96, 33.8) (Table 7).[38,39]

C. Prevention of recurrence

Seven RCTs comparing interventions to prevent recurrence were identified; their quality is summarised in Table 8.

C.1 Compression stockings: No RCT was found which compared recurrence rates achieved with and without compression stockings in people with healed ulcers. One trial however, showed that 3–5 year recurrence rates were lower in patients using strong support from class 3 compression stockings (21%) than in those randomised to receive medium support from class 2 compression stockings (32%) (p=0.034); class 2

A. Background

A.1 The importance of leg ulceration: Leg ulcers are areas of *"loss of skin below the knee on the leg or foot which take more than 6 weeks to heal".*[1] Leg ulceration is a common chronic recurring condition and a major cause of morbidity and suffering (Fig. 1).[2,3] Annual costs to the NHS of leg ulceration have been estimated to be as high as £230–400 million (1991 prices) of which nursing time is a major element.[4]

Fig. 1 A venous ulcer

About 1.5–3.0 per 1,000 population have active leg ulcers and prevalence increases with age up to around 20 per 1,000 in people over 80 years.[5–7] Leg ulceration is strongly associated with venous disease (e.g. varicose veins and a history of deep vein thrombosis).[8] Arterial disease is present (alone or with venous problems) in approximately 20% of cases of leg ulceration.

Leg ulcer disease is typically chronic and patients with active ulceration for more than 60 years have been documented.[9] There is wide variation in reported recurrence with re-ulceration rates of 26%[10] to as high as 69% at one year being reported.[11] People at higher risk of recurrence include those with a previous ulcer size greater than 10cm^2, a history of deep vein thrombosis and those unable to wear compression stockings.[10]

A.2 The management of venous leg ulceration: Most people with leg ulcers are managed by GPs and community nurses but a significant number are managed in hospital settings.[5,6] Audits have shown wide variation in the clinical management of leg ulcers.[3,12] Numerous types of wound dressings, bandages and stockings are used in the treatment of venous leg ulcers and the prevention of recurrence. A survey of 301 patients with leg ulcers in the Wirral found 26 different primary dressings in use and 42 different preparations being applied to the surrounding skin. A similar audit in Stockport identified 31 different dressings, 28 bandages and 59 topical preparations in use.[13]

This issue of *Effective Health Care* summarises the results of research on the effectiveness and cost-effectiveness of different forms of compression in the treatment of venous ulceration;[14] on interventions to prevent recurrence; and on methods of diagnosing venous ulceration. The methods used in this systematic review[15] are outlined in the appendix and given in more detail in the *Cochrane Library.* The bulletin does not consider the effectiveness of dressings, debridement or skin grafts which are the subject of future review work.

B. Compression therapy

Below-knee compression graduated from toe (highest) to knee (lowest), in the form of bandaging or stockings, is viewed as a key component of treatment when venous leg ulceration occurs in the absence of significant arterial disease (Fig 2). A range of compression systems are used (see Box), which apply varying levels of compression, using different materials with varying degrees of elasticity. There is considerable uncertainty however, as to the most effective method. The preferred treatment for leg ulcers in the USA is Unna's boot; in other parts of Europe short stretch bandaging is more popular, whilst 4-layer bandaging is increasingly advocated in the UK. Twenty randomised controlled trials (RCTs) evaluated different forms of compression bandaging on venous ulcer healing in a wide range of age groups.[16–35] Two of these incorporated economic evaluations,[17,35] 2 compared compression stockings with compression bandages,[36,37] and 2 evaluated intermittent pneumatic compression.[38,39] Overall, the quality of trials is poor; a summary is available elsewhere.[14]

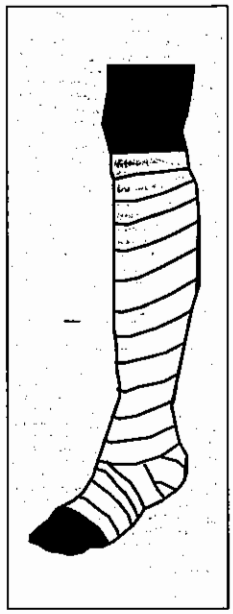

Fig. 2 Compression bandaging from toe to knee

B.1 Compression versus no compression: Six RCTs assessed whether compression therapy was better than no compression (Table 1).[16–21] These show that compression provided either by Unna's boot,[19,20] 2-layer,[16] 4-layer[17] or short stretch bandages[18] improve healing rates compared to treatments using no compression. One study showed that compression therapy was more cost-effective because the faster healing rates saved nursing time.[17]

B.2 High compression versus low compression: Three RCTs compared elastic high compression 3-layer bandaging (two using Tensopress and one Setopress as a component) with low compression (using

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Effective Health Care

Bulletin on the effectiveness of health service interventions for decision makers

NHS Centre for Reviews and Dissemination, University of York

Compression therapy for venous leg ulcers

- Venous leg ulcers are a major cause of morbidity, especially in older people. There is wide variation in practice, and evidence of unnecessary suffering and costs due to inadequate management of venous leg ulcers in the community.
- Routine application of high compression therapy using one of a number of systems such as 3-, or 4-layer or short stretch bandages, Unna's boot or compression stockings, possibly with the addition of intermittent pneumatic compression, can significantly improve healing rates.
- Use of compression stockings should be encouraged to prevent the recurrence of venous leg ulcers. However, there is little evidence to support the use of drug therapy using stanozolol or oxerutins.
- Patients with arterial disease are not suitable for high compression therapy. Arterial disease can be diagnosed more accurately if highly trained operators measure the ratio of ankle to brachial systolic pressure (ABPI) rather than feel for foot pulses alone.
- Community nurses should be adequately trained in leg ulcer management, including patient assessment and bandage application.
- The issues raised in this bulletin should be discussed with providers of primary care and community nursing services and relevant hospital specialists so as to co-ordinate services, ensure adequate nurse education and establish systems to monitor standards of care.

The contents of this bulletin are likely to be valid for around one year, by which time significant new research evidence may have become available.

Appendix 2
Effective Health Care Bulletin
(Compression therapy for venous leg ulcers, 1997)

Table of excluded studies (following second sift)

Staff training and education

Author	Objective	Design	Comments on quality
Charles H 1996	To set up a programme to educate nurses in assessment and management of leg ulcers	Unsure. 'Survey population was randomly divided into two groups'	Very little information on methods and design No information on sampling frame or strategy No response rates Insufficient information on characteristics of patients, randomization procedure, follow-up period ('minimum of 3 months') Conclusions cannot be substantiated because of design of study No detail on content, duration etc. of staff training module
Jones et al 1997	To identify community nurses' training needs and to develop an internal training programme in response to those needs	Before-after design	No discussion of possible confounding Experience/educational background of nurses not stated Was additional training from other sources undertaken? Some 'before' results not reported Cannot agree with conclusions in view of design
Moffatt & Kam 1994	To identify education needs of nurses related to leg ulcer management and to devise an educational strategy	No information	No information on methods

Table of excluded studies (following second sift)

Patient assessment

Author	Objective	Design	Comments on quality
Briggs 1996	To evaluate different methods of wound management documentation	Comparative	Information on controls and recruitment lacking Patient outcomes not examined Control group small (15) relative to cases (136)
Davies 1996	To evaluate a standardized protocol for the assessment and treatment of leg ulcers in the community	Before-after	Confounding not controlled for which may explain fall in prevalence and improvements in patient morbidity rather than the protocol
Hayes 1995	To examine the microbiology and immunology in patients with leg ulcers	Cross-sectional	Cohort study needed to see if bacteriology etc. relates to impaired healing etc.
Sterling 1996	To investigate whether relevant parameters of wound assessment are documented more frequently if a wound assessment chart is used.	Non-experimental, comparative independent groups design	Convenience sampling Nil adjustment for possible confounders such as skill-mix of nurses from different clinical settings Not community nurses

Psychological/quality of life

Author	Objective	Design	Comments on quality
Franks et al 1994	To investigate changes in the quality of life of patients with leg ulcers being treated in community leg ulcer clinics	Before-after	Lack of control group weakens conclusions Nil information on sampling Outcome assessment not blind No baseline control for co-morbidity
Hyland et al 1994	To develop a disease-specific QOL questionnaire for patients with leg ulcers	3 phases: qualitative information; development of questionnaire; quantitative analysis	Report of work in progress - quantitative 'phase' gives no information on sampling, exclusion/inclusion criteria, or case definition
O'Hare 1994	To evaluate a nurse-led venous leg ulcer clinic	Before-after	Cannot claim improvements in quality of life of patients and Nottingham Health Profile scores are attributable to organization of care because no control group. Patients who experience healing will probably report improvement regardless of organization of care Details of arterial/venous status measurement not objective Initial mean size of ulcers not reported Small sample size
Ruane-Morris et al 1995	To educate patients so they will have the knowledge and understanding necessary to make lifestyle changes	Unsure	Lack of control group makes conclusions unsupportable Small sample size Recruitment strategies not specified

Evidence table: staff training and education

Study	Design	Results	Comments	Conclusions
Nelson & Jones 1997 To evaluate the impact of a training pack on the knowledge and reported practice of nurses in the management of leg ulcers UK	Non-randomized groups (experimental and control) were assessed pre- and post-training for knowledge and reported practice	After exposure to the training pack, changes in scores for experimental groups were highly significant for assessment, treatment and general knowledge. However, there were certain areas where poor results were found both pre- and post-test	Uneven group sizes No baseline information on groups (skill-mix, data completed training etc) Non-randomized, but appears to be no adjustment for confounding in analysis.	The clinical information pack and the video proved to be a valuable adjunct to the study days
Roe et al 1994 To investigate the nursing management of patients with chronic leg ulcers UK	Descriptive survey by group questionnaire in 3 trusts within Mersey area of 146 district nurses Sampling: not specified	64% respondents reported they would apply compression bandaging to venous ulcers only Only 6 described the recommended technique for compression bandaging	Sampling method not specified	Nurses require further information and knowledge about the normal physiology of the leg and aetiology of leg ulcers to reduce variation in practice
Stockport et al 1997 To compare levels of compression achieved in the application of both multi-layer compression bandage systems and single-layer bandages by both inexperienced and experienced practitioners UK	Evaluation of bandaging technique of 25 nurses and 12 doctors both experienced and inexperienced in the application of compression bandaging systems on a healthy volunteer Sub-bandage pressure was measured using an Oxford Pressure Monitor II	In general, differences were greater for the 2 single-layer bandages than for the 2 multi-layer systems tested	Would be valuable to see if technique improved over time	Multi-layer bandage systems are easier to apply and more consistent pressures are achieved than with single-layer compression bandaging with both experienced and inexperienced practitioners Specialist training in the application of high compression bandaging is required

Evidence table: staff training and education

Study	Design	Results	Comments	Conclusions
Bell 1994 To examine nurses' knowledge of the physiology of wound healing Eire	Pilot descriptive structured interview of 18 RGNs from 2 Dublin hospitals Inclusion criteria: 2 years post-graduate; work in a hospital outpatient department with leg ulcer clinics; care for at least 1 patient/week with leg ulcer Sampling: non-probability convenience	4 identified a good blood supply; 14 identified adequate nutrition; 1 identified walking/exercise; 11 identified absence of infection; and 12 identified rest as factors that enhance wound healing in venous leg ulcers	Nil response rate Small, non-probability sample	An educational programme for qualified nurses should be set up to improve their knowledge of the physiology of wound healing
Dealey 1998 To evaluate changes in nursing knowledge and practice with respect to leg ulcers UK	Pre- and post-training test to evaluate changes in nursing knowledge	There was significant improvement in level of nursing knowledge (94% able to use Doppler at end of programme compared with 27%; numbers of nurses aware that they should use compression bandages for venous ulcers increased from 27% to 98%)	Scant information sampling, method of education, skill-mix of nurses prior to study; time span of pre- post-testing.	Nursing knowledge improved with introduction of training
Logan et al 1992 To compare sub-bandage pressures produced by experienced and inexperienced bandagers UK	Cross-sectional 10 patients 10 bandagers (5 experienced nurses and 5 inexperienced in leg bandaging) Sampling: patients-volunteers; bandagers-unspecified Setting: not specified	Pressures produce by inexperienced bandagers were much more variable than those of experienced bandagers	Small sample size	Lack of experience or training was an important factor in the observed inconsistency of results and in achieving target pressures
Luker & Kenrick 1995 To evaluate the impact of a leg ulcer information pack on reported practice UK	Pre-post test 2 group experimental design 171 community nurses in 5 health authorities Sampling: not specified Follow-up: 6 weeks	Experimental group's knowledge scores significantly improved (p=<0.0001; 95%CI 5.1-7.5)	Sampling strategy not specified Uneven group sizes Non-randomized groups and no information on comparability of nurses in experimental and control sites pre- and post-test respondents, therefore difficult to substantiate conclusions that leg ulcer pack was effective No adjusting for potential confounders (years of experience, skill-mix etc)	
Nelson et al 1995a To examine the effect of a bandage tension indicator and pressure monitor on bandaging skill To examine the bandaging skills of nurses and to what extent improvements in bandaging technique are sustained UK	18 nurses who had attended leg ulcer study days (mix district and hospital) applied bandage to volunteer's leg using normal technique and then used a marked bandage to indicate recommended extension Feedback given on actual pressures and continuous feedback given from monitor while each nurse practised bandaging Follow-up: 2 weeks Sampling: self-selected Setting: not reported	Difference in bandage proficiency score between the baseline and post-training readings was <0.01 and maintained after 2 weeks <0.01	11/18 returned for repeat testing Small sample size (though non-parametric tests used) Self-selected group Single-layer bandage used (though authors state future studies will include multi-layer bandages) Additional follow-up periods would be useful Examination of patient outcomes (eg., improved healing rates) would be useful	Improvements effected by training sustained at 2 weeks Tension guides are not sufficient to produce an acceptable bandage pressure profile Bandage position and overlap are also important Training, consisting of feedback from a pressure monitor and advice from an experienced bandager, important factors in improving sub-bandage pressure profile

Evidence table: psychological issues and compliance

Compliance

Study	Design	Results	Comments	Conclusions
Ericksson et al 1995 To evaluate a treatment programme for venous ulceration USA	71 patients (99 venous ulcers) analysed by a retrospective review of clinic records Sampling: unsure Follow-up: 1-156 months Setting: nurse managed/physician supervised ambulatory clinic in academic medical centre	Patients who strictly complied had significantly faster healing (P=0.02) and fewer recurrences (p=0.004)	Unsure of reliability of measurement of compliance Information needed on whether the compliant group differed from the non-compliant group on prognostic/Socio-demographic factors Other methodological problems outlined by Scriven JM & London NJM in letter *Journal of Vascular Surgery* 1995; 24(5):905	
Mayberry et al 1991 To document the healing percentage and long-term recurrence rate of venous ulcers in compliant and non-compliant patients USA	Retrospective medical record review of 119 patients with severe chronic venous insufficiency treated for venous stasis ulcer Sampling: all patients 1974-1989 Setting: hospital vascular clinic	Non-compliance with elastic stockings (p<0.0001) and a pretreatment ulcer duration of > 9 months (p=0.02) significantly decreased initial ulcer healing	Possibility of surveillance bias, selection bias, inaccuracies in medical records	
Samson & Showalter 1996 To analyse patient compliance and to evaluate cost of compression stocking therapy USA	Cohort 56 patients with documented deep venous insufficiency and ulceration Sampling: convenience Follow-up = 'more than' 6 months Setting: 2-person private practice	Stocking use was good in 47%, poor in 23% and negligible in 30%. Reasons for not wearing stockings included expense 78%; forgot instructions 25%; difficult to don 21%; and too hot 4% Recurrence rates in noncompliant patients were 96% compared with 4% in patients who wore stockings appropriately	Did not specify who classified compliance and report the reliability of the compliance measure	
Taylor 1992 (unpublished) To examine the problems and perceptions patients experience in complying with venous leg ulcer management UK	Semi-structured interview technique Sampling: convenience Setting: patients presenting to leg ulcer clinics	No patient fully complied with their care plan	Small sample size (n=12) Inclusion/exclusion criteria not applied? (case definition of leg ulcer; cognitive status of patients etc.)	Patients require education to see the benefit and rationale for compression bandaging

Evidence table: psychological issues and compliance

Healing and quality of life

Study	Design	Results	Comments	Conclusions
Johnson 1995(a) To identify the physiological, therapeutic and psychosocial determinants of leg ulcer healing Australia	Longitudinal, using Edema Index; Wound Status Index, Pain in Mobility Index; Self-Efficacy scale; Medical Outcomes Study Social Support scale Sampling: partly random selection and partly convenience Follow-up: 1 month Community-residing older people from home-nursing lists with venous and venous-arterial disease (n=156)	Increased pain on mobility (p=0.002), with other variables, explained 24% of the variance in healing rate	Not clear if age or duration of ulcer adjusted for in analysis – this may explain why physiological factors explain major variance in healing rates Short follow-up period	Physiological determinants including pain on mobility were associated with poorer healing rates in the venous sample rather than measures of self-efficacy and social support
Johnson 1995(b) To examine the effects of patient characteristics and environmental factors on the healing of leg ulcers Australia	Descriptive comparative study Follow up: 1 month Sampling: convenience Setting: Patients ≥ 60 years using home nursing services in two Australian cities	Healers and non-healers differed significantly only on socio-economic status as measured by occupational status (p=0.03) with poor healers more likely to be from lower occupational status	Uncertain if occupational status measured by asking subjects previous occupation. As older age group many may not have been employed Unclear if self-rated health measured using a validated instrument Short follow-up period	Practitioners must consider that poor healers may have less access to appropriate dressings and medical care
Moffatt et al 1991 To examine the effect of successful ulcer healing on psychological factors UK	Longitudinal Sampling: convenience Follow-up: 12 weeks Setting: Charing Cross Hospital/Riverside Health Authority	Symptom Rating Test scores and pain scores improved over 12 weeks. Anxiety, depression, hostility and cognition scores were all significantly improved at 12 weeks	Uncontrolled study therefore reduced depression and hostility may have directly or indirectly been the cause of the healing rather than a result of it	Difficult to ascertain in absence of control group

Measurement of quality of life

Study	Design	Results	Comments	Conclusions
Franks et al 1992 To examine the impact of venous disease on quality of life UK	Self-administered symptom rating test to cases and matched controls. Dimensions examined by the scale include anxiety, depression, hostility, cognition and somatic Sampling: patients were drawn from a larger investigation of prevalence of venous disease Setting: 3 general practices	There was no significant difference in psychiatric morbidity between cases and controls	Not sure if psychiatric morbidity necessarily measures quality of life Low response rate of controls may bias results Results aggregated (venous ulcer grouped in 'venous disease') More information of reliability required	The impact of venous disease on psychiatric well-being may be small However, the result may be biased due to low response rate of controls
Price & Harding 1996 To examine the usefulness of the SF-36 in patients with chronic leg wounds USA	63 patients with a variety of conditions producing chronic wounds on the leg (minimum duration of 3 months) compared with normative data based on British samples Sampling: not stated Setting: wound healing clinic attached to university teaching hospital	Patients rated themselves significantly lower on 7 of the 8 subscales, experiencing more pain, less vitality, more restriction in physical and social functioning, poorer general health and limitations in physical and emotional roles	Mixed aetiology Small sample size	Patients with chronic leg ulceration rate themselves as functioning well below age-matched groups, with mean differences in excess of 20 points for 5 subscales Duration of the ulcer for >24 months was related to healthier perceptions in terms of pain and general health, possibly because patients have reduced expectations of recovery over time Further research is needed to investigate the sensitivity of the SF-36 to changes over time for this group and to compare the performance of this tool with a form of outcome measure specifically designed for patients with leg ulcers

Evidence table: psychological issues and compliance

Quality of life continued

Study	Design	Results	Comments	Conclusions
Lindholm et al 1993 To describe leg ulcer patients' subjective perception of health related to quality of life Sweden	Comparative analysis between 125 patients with leg ulcers of venous, arterial and mixed venous-arterial aetiology with sex- and age-adjusted normal score values, using the first section of the NHP Sampling: consecutive Setting: department of dermatology	Pain scores were elevated in all categories of patients The global NHP score for leg ulcer patients was 173% that of normal score values	Did not control for aetiology which may have explained some of the results Analysis of NHP scores difficult to interpret Non-random sample	The presence of a leg ulcer has a marked impact on patients' perceived health
Phillips et al 1994 To assess the financial, social and psychological implications of leg ulcers USA	Cross-sectional 73 patients with chronic leg ulcers presenting to vascular surgery or dermatology services at university medical centre interviewed using standardized personal interview schedule Sampling: not specified Setting: as above	65% had severe pain 81% stated their mobility was adversely affected 76% said that their financial situation was adversely affected by the ulcer 68% reported that the ulcer had a negative emotional impact, including feelings of fear, social isolation, anger, depression and negative self-image	No breakdown by aetiology Inadequate reporting of multivariate results No control group or population norm comparisons Nil reports of reliability and validity of instrument used	Morbidity from leg ulcers can substantially reduce many aspects of a patient's quality of life
Walshe 1995 To describe the experience of living with a venous leg ulcer UK	Qualitative: phenomenological Unstructured interviews conducted with 13 informants in their homes Sampling: purposeful random sample Setting: one health district	Pain and impaired mobility were the major restrictions described	Small sample size No information on how patients recruited Poor response rate (13/26)	

Socio-economic factors

Study	Design	Results	Comments	Conclusions
Callam et al 1988 To report the relative incidence of chronic leg ulceration in the different socio-economic classes and assess the effect of leg ulceration on employment, leisure activities and mobility UK	Survey of 600 patients receiving treatment for chronic leg ulceration in any branch of the health services at the time of the survey Sampling: convenience Setting: Lothian and Forth Valley	No increased incidence of chronic leg ulceration in the more disadvantaged socio-economic groups but patients with a semi-skilled or unskilled background had a higher percentage of ulcers of more than 5 years duration than other social classes 21% had moderate or severe limitation of work representing prolonged periods of work or inability to continue with their occupation 42% experienced moderate or severe limitation of their leisure activities	No significance testing Unsure of method used to measure effect of leg ulcer on employment Possibility for recall bias	Chronic leg ulceration does not seem in this study to be more common in the lower socio-economic classes but the prognosis appears to be less favourable when it occurs Leg ulceration can result in considerable restriction of activities which in 5% of cases leads to loss of employment

Evidence table: psychological issues and compliance

Quality of life

Study	Design	Results	Comments	Conclusions
Charles 1995 To examine the quality of life experienced by people who have lived with leg ulceration for many years UK	Phenomenology 4 patients selected Sampling strategy or setting not specified	Patients experienced pain, lack of effective help and a reduced quality of life	Sample size very small Aetiology unknown Control group needed to see if results differ from population norms	Nurses should acknowledge the physical, psychological and social suffering that patients with leg ulcers experience
Chase et al 1997 To examine the lived experience of healing a venous ulcer for patients treated in an ambulatory surgical clinic USA	Phenomenological participant observation of 37 patients Sampling: convenience Follow-up: 1 year Setting: ambulatory surgical clinic population in an urban teaching hospital	Four major themes emerged: 'a forever healing process', 'limits and accommodation', 'powerlessness' and 'who cares '		Patients experience pain, powerlessness and disability Limitations to mobility, activity and socializing were also experienced
Cullum & Roe 1995 To investigate patients' perceptions of their leg ulcers and the impact of having a leg ulcer on well-being and lifestyle UK	Survey using semi-structured interview and established health measures such as NHP, Life Satisfaction Index, Hospital Anxiety and Depression Scale, short form McGill Pain Questionnaire, Health Locus of Control Sampling: random sample of 88 patients ≥ 65 years matched with health- and age-matched controls Setting: Wirral Health Authority	Patients with leg ulcers had significantly lower scores for life satisfaction than the control group ($p<0.05$) but there was no difference in anxiety levels. However, there were more depressed patients with leg ulcers than without. Patients with malodorous ulcers had higher anxiety and depression scores, lower life satisfaction and less social contact ($p<0.05$)	Unsure if sample restricted to venous ulcers or other aetiologies No information on response rates	Appropriate assessment and treatment (compression for venous ulcers) will facilitate quicker healing and many of those factors which diminish quality of life would disappear with the ulcer
Flett et al 1994 To compare the perceived health and psychological well-being of a group of patients with chronic lower leg ulceration with a matched group of controls NZ	Survey of convenience sample of 14 leg ulcer patients matched with controls using the General disability spectrum, medical problems score and a 9-item measure of common psychosomatic symptoms, health and pain ratings Sampling: convenience through district nurses Setting: Dunedin	Leg ulcer patients reported more pain ($p<0.01$) and health worries and concerns ($p<0.05$), lower self-esteem ($p<0.01$) and more negative affect ($p<0.05$) than the controls	Matching procedure not described Aetiology not specified Convenience sample Data collection procedures different for cases and controls Small sample size without a power calculation No comparative baseline table Conclusions restricted in view of lack of comparative baseline data More information on reliability and validity of some instruments	Ulcer patients reported significantly greater problems than matched controls, although did not report significantly greater feelings of loneliness or dissatisfaction that the controls

Evidence table: wound evaluation and measurement

Study	Design	Results	Comments	Conclusions
Liskay et al 1993 To compare the reliability, validity and feasibility of grid measurements to a tape measure USA	Cross-sectional Patients from a dermatology clinic of a teaching hospital with a well-defined leg ulcer were eligible (60 leg ulcers) 2 registered nurses independently measured each ulcer and kept the results separate from each other Setting: dermatology clinic Sampling: convenience	Inter-rater: no significant differences were noted between the two raters for either technique Intra-rater: no significant differences occurred for either raters in the 3 tape measurements (p=0.91) or for 3 grid measurements (p=0.51) Good correlations were obtained between tape and grid measurements by both raters Wound size was significantly overestimated by the tape compared with the grid Validity Compared with computer-generated tracings, both raters, measurements were significantly greater Tape accuracy decreased with larger size ulcers; grid accuracy varied with the shape of the ulcer	Intra-class correlation not used No information on prior training and experience of the nurses	Use of the plastic grid is a reliable and valid method to determine wound size The greater accuracy of the grid is good for medium to large wounds and those whose shapes are irregular The grid takes no more time than use of a paper tape measure
Majeske 1992 To establish intra-rater and inter-rater reliability of 4 methods of measuring wound surface from transparency film tracings USA	Cross-sectional 3 physical therapists without training or practice sessions prior to data collection made 2 tracings of each wound to estimate wound area by a) a ruler; b) placing the transparency on graph paper and counting the squares; c) hand-held planimeter; d) a digitizer Sampling: peripheral vascular clinic Setting: unclear	Inter-rater reliability for each method of determining wound area was high (intra-class correlation=0.97-0.99) Inter-tester reliability was also high (intra-class correlation=0.99)	Physiotherapists rather than district nurses may restrict generalizability	The ruler method was less accurate. Although the planimeter can be used to calculate wound areas more quickly than using a grid, most community nurses would not have this rather expensive equipment Consistent use by the same examiner and technique may be more important Evaluating wound depth requires different methods

Evidence table: wound evaluation and measurement

Study	Design	Results	Comments	Conclusions
Ahroni et al 1992 To establish the reproducibility of wound area calculations using a computerized method USA	Cross-sectional 50 diabetic foot ulcers were traced onto transparent film 3 times each within a single clinic visit then scanned into a computer to calculate wound surface area Sampling: consenting volunteers Experienced family nurse practitioner Setting: Veterans Affairs Medical Centre	For all 50 sets of tracings the mean coefficient of variation was 0.026; Cronbach's alpha was 0.99	Intra-rater reliability not examined	Placing the current tracing over a previous tracing is helpful in determining healing progress
Buntinx et al 1996 To study the inter-observer variation in wound evaluation in a group of physicians and nurses Netherlands	Cross-sectional 20 patients with 21 pressure sores, 2 arterial and 3 venous ulcers 3 physicians and 3 nurses Sampling: convenience Setting: geriatric department of university hospital	Average inter-observer agreement was 75% for inflammation; 76% for local heat; 85% for pus; the respective group kappa values and 95% CIs were 47% (19-85); 29% (0-58) and 55% (21-89) Average observer agreement for 6 possible scores was 76% and group Kappa was 59% (95% CI 41-77)	Accuracy of measurement or intra-observer agreement not measured Small samples of both patients and observers Only small number of leg ulcers in patient sample Intra-class correlation not used	Classification by colour was moderate to good Moderate agreement was found in assessment of signs of infection Inter-observer agreement was very good for assessment of size and area of wounds
Etris et al 1994 To evaluate the predictability and accuracy of the photo and tracing method for wound size measurement USA	Cross-sectional 65 patients with an ulcer diagnosed secondary to either venous insufficiency or diabetes mellitus 1-100 cm^2 present for a minimum of 4 weeks Sampling: subjects from RCT Setting: not reported	Correlation coefficient between the 2 methods was 0.97 Inter-site variability accounted for only 54% of total variability in these observations	Study conduct details lacking 60 patients but 450 observations P-value of correlation coefficient not specified Intra-class correlation not used Unclear who did the assessments	Both the photo and tracing methods were accurate and reproducible
Johnson & Miller 1996 To compare the reliability and validity of 4 methods of measuring leg ulcer healing Australia	Cross-sectional Leg ulcers were measured with stereophotogrammetry as the standard and concurrent validity testing of planimetry, the Kundin Wound Gauge and the Johnson and Healing scales was performed at weekly intervals until the ulcer healed or for a maximum of 7 intervals Sampling (patients): convenience Setting: metropolitan rehabilitation hospital and community nursing setting	Comparisons using digital planimetry and the Kundin Wound Gauge supported the use of these methods for monitoring healing in any setting (r= 0.99; r= 0.98 respectively). The Healing and Johnson scales did not show concurrent validity when compared with stereophotogrammetric methods and had limited reliability	Analysis did not correct for chance	Subjective methods (Healing and Johnson scales) should not be considered as suitable methods for measuring healing Stereophotogrammetry, digital planimetry and the Kundin Wound Gauge are suitable methods for measuring healing, although stereophotogrammetry is time-consuming and requires specialist skills

Evidence table: patient assessment

Other ulcers

Study	Design	Results	Comments	Conclusions
Ackroyd & Young 1983 To report on 3 case studies of malignant leg ulcers UK	3 case studies	Illustration of the different ways in which the diagnosis of malignant leg ulcers may be delayed	Case study - small sample	
Baldursson et al 1995 To obtain an estimate of the relative risk of squamous cell carcinoma in venous ulcers Sweden	Record audit of 10913 patients with venous leg ulcer matched with Swedish Cancer Registry registrations of SCC in lower limbs Sampling population	0.21% of patients in this study developed a SCC in their ulcer Risk for patients with venous leg ulcers of developing SCC in their ulcers, relative to the risk for the normal population of developing non-melanoma skin-cancer on the lower limb was 5.80 (95% CI 3.08-9.29)	Study findings dependent on the accuracy of medical records (possibility of recorder error, misclassification, selection and surveillance bias)	–
Nelzen et al 1993 To estimate the point prevalence of active leg ulcers among diabetic patients Sweden	Cross-sectional 414 leg ulcer patients from a Swedish survey using a structured history and objective assessment to assess disease Sampling: random selection from 827 patients with leg ulcers Setting: Skarabourg county	Point prevalence of active leg ulcers in diabetic patients was 3.5% (95% CI 2.8-4.2); the prevalence of isolated foot ulcers was 1.8% (95% CI 1.3-2.3)	Unsure of validity of case ascertainment Inter-observer reliability not assessed	Arterial impairment is present in a majority of ulcerated legs of diabetic patients
Yang et al 1996 To evaluate the frequency of malignant ulcers in patients presenting with leg ulcers Australia	Descriptive study from data collected 1988-1995 981 patients (2448) ulcers Sampling: consecutive Setting: specialized leg ulcer clinic at a tertiary teaching hospital	The frequency of malignant ulcers was 4.4 per 100 leg ulcer patients, or 2.2 per 100 leg ulcer; 75% were basal cell carcinoma and 25% were squamous cell carcinoma	Results may not be generalizable as Australia has high skin cancer rates and a higher proportion of malignant ulcers were found in this study compared with other reported frequencies	A biopsy should be taken from all suspicious ulcers or ulcers that do not respond to treatment

Bacteriology

Study	Design	Results	Comments	Conclusions
Skene et al 1992 To evaluate the prognostic factors in uncomplicated venous leg ulcer healing (chosen for information on bacterial growth) UK	Randomized parallel group controlled trial Assessment of a hospital vascular unit with community based treatment 200 patients with clinical and objective evidence of uncomplicated venous leg ulceration and an initial ulcer diameter of >2cm Sampling: unsure Follow-up: 4 months Setting: hospital vascular unit	Bacteria present at initial assessment was entered into a proportional hazards model as a possible covariate but did not enter the final model	4 months may be insufficient follow-up Unsure of how bacterial growth ascertained (swabs?) Unsure if outcome assessment blinded	The presence of bacterial contamination seems to be of little relevance to venous ulcer healing
Trengove et al 1996 To investigate the bacterial profile of patients with leg ulcers Australia	52 patients with venous or venous and arterial disease participating in RCT Sampling: unspecified Follow-up: ? 6 months Setting: Fremantle hospital leg ulcer clinic	Of the 26 ulcers in which 4 or more bacterial groups were present, a significantly greater number failed to heal (42%; p<0.01)	Nil report of losses to follow-up Nil adjustment for prognostic factors (aetiology, co-morbidity) No definition of failure of progression of healing Unsure if documentation each visit made by same observer	The number of types of bacteria present rather than the specific type of bacteria appears to affect healing rate Wound swabs are not necessary in the routine treatment of these wounds

Evidence table: patient assessment

Pain assessment

Study	Design	Results	Comments	Conclusions
Chase et al 1997 To examine the lived experience of healing a venous ulcer for patients treated in an ambulatory surgical clinic USA	Phenomenological participant observation of 37 patients Sampling: convenience Follow-up: 1 year Setting: ambulatory surgical clinic population in an urban teaching hospital	Pain was rated as one of the major problems related to leg ulcer disease		Further research needs to be conducted to determine whether the kind of pain venous ulcer patients experience necessitates unique approaches to management
Cullum & Roe 1995 To investigate patients' perceptions of their leg ulcers and the impact of having a leg ulcer on well-being and lifestyle UK	Survey using semi-structured interview and established health measures such as NHP, Life Satisfaction Index, Hospital Anxiety and Depression Scale, short form McGill Pain Questionnaire, Health Locus of Control Sampling: random sample of 88 patients ≥ 65 years matched with health- and age-matched controls Setting: Wirral Health Authority	Using the McGill Pain Questionnaire, the majority of leg ulcer patients (70%) described their pain as 'aching' while at the time of the interview, 31% experienced pain from their leg ulcer The intensity of pain was inversely proportional to the ABPI, supporting the notion that ulcers with an arterial component are more painful ($p<0.05$)	Unsure if sample restricted to venous ulcers or other aetiologies No information on response rates	
Dunn et al 1997 To evaluate graduated compression bandaging (selected because includes descriptive statistics on pain assessment) UK	Longitudinal audit study on 30 patients Sampling: convenience Follow-up: 12 weeks Setting: NHS Trust	72% suffered with moderate pain and 14% had severe pain	No stratification analysis (eg., relating to pre-treatment duration of ulcer) Not a random sample No information on how pain measured	
Hamer et al 1994 To evaluate the perceptions patients have of their leg ulcers and the impact leg ulcers have on lifestyle	Survey Leg ulcer patients, 65 years and over Sampling: random Setting: Wirral Health Authority	Preliminary results show that pain (38%) and restriction of mobility (31%) were the worst things about having an ulcer 53% did not want more information about their leg ulcer	Control group analysis not available Baseline characteristics of respondents not reported No breakdown by aetiology	
Hofman 1997 To assess the prevalence, severity and diagnostic utility of pain in patients with venous leg ulcers Sweden/UK	Prospective Interviews of 140 patients Sampling: consecutive Follow-up: unsure/? 6 months Setting: leg ulcer clinics at Malmo and Oxford over a period of 6 months using a validated verbal pain rating scale	69% said pain was the worst thing about leg ulcer; 64% reported the pain was 'horrible' or 'excruciating' - of these 27% were prescribed no analgesia	No information on refusal/ follow-up rates Sampling strategy not specified	Patients in the study did not all get relief by leg elevation and this should not be used as a diagnostic criterion Assessment of pain is an important but neglected part of the management of venous ulceration

Evidence table: patient assessment

Progression of arterial disease

Study	Design	Results	Comments	Conclusions
Scriven et al 1997 To report the results of a single-visit ulcer clinic UK	Cross-sectional results reported (although says patients studied prospectively) Sampling: convenience (n=88) Arterial status measured with ABPI, Duplex scanning Setting: leg ulcer clinic	14% limbs ABPI < 0.9; 79% ulcers were classified as venous, 2% as arterial and 13% as mixed aetiology; 4 were secondary to lymphoedema, 1 as a BCC and 2 of uncertain aetiology Clinical history with respect to previous DVT was unreliable as an indicator of deep venous function	Unsure regarding timing of assessments	Stresses the importance of correctly identifying aetiology before commencement of therapy
Simon et al 1994 To investigate the progression of arterial disease in a group of patients with healed leg ulcers UK	Cohort Follow-up = 'at least 1 year' 55 patients (79 recently ulcerated legs) with ABPI > 0.8 Sampling: consecutive Setting: not specified	'Significant' reductions in ABPI over 12 months were recorded in 23 out of 79 (29%) limbs	Details on study lacking, eg: how/where recruited (risk of referral bias) Representativeness of sample or attrition rates Unclear whether length of time ulcers healed taken into account Diagnostic criteria not stated clearly Appears to have used only 1 criterion (ABPI) to define arterial disease (ABPI does not constitute a diagnosis but is indicator of underlying arterial disease) Multiple counting of individuals Use of word 'significant' without results Unclear whether adjustment for important prognostic factors	Makes important point that when patients present with recurrence of ulceration nurses may apply compression bandaging without repeating ABPI measurement

Evidence table: patient assessment

Doppler studies

Study	Design	Results	Comments	Conclusions
Fisher et al 1996 To determine the variation of ABPI measurements in routine clinical practice Australia	Before-after Examination of pre-operative and post-operative ABPIs in 130 limbs in 123 patients by vascular technicians Mean time between tests: 51 days Sampling: consecutive Setting: hospital department of vascular surgery	Overall time between tests was a median of 51 days (10-103) Rate of change in observed ABPIs after surgery was from -0.33 to +0.25 No net change occurred in the ABPI between tests	Vascular technicians rather than nurses were used	Differences arose solely as a result of variations in measurement Repeat ABPIs to assess the results of intervention or progression of disease should be compared with a mean ABPI determined from multiple measurements, so that a smaller change in ABPI will be recognized as significant The size of the difference in repeat ABPIs required to demonstrate significant change should be broadened to 0.21 when the ABPI has not been determined from multiple observations
Ray et al 1994 To examine the accuracy of ABPI measurements as performed by junior medical staff UK	Cross-sectional 37 patients 2 newly qualified doctors paired with vascular technicians 2 different newly qualified doctors who had undertaken a formal initial 40 min training session paired with one of the same 2 vascular technicians Sampling: unspecified Setting: unspecified	The majority of the 76 ABPIs measured by doctors without formal Doppler training were lower than those recorded by the technician The differences in 46 ABPIs taken by the doctors with training and technicians were distributed more normally	More details about the skill mix of the newly trained doctors would be useful - it is possible the ones in experiment 2 may have had more experience in vascular studies during training	Junior doctors should not perform ABPI measurements until they have received formal training Measurements that reveal a significant fall in ABPI should be repeated by a more experienced person

Clinical predictors

Study	Design	Results	Comments	Conclusions
Nelzen et al 1994 To report data on the clinical history and appearance of ulcers and analyse the diagnostic value of classic clinical predictors of venous leg ulcers Sweden	Cross-sectional All patients with current chronic leg ulcers (827) were identified and a random sample of 382 studied in detail Sampling: random Setting: Skarabourg	The predictive value did not exceed 0.74 for any single predictor Combinations of predictors did not substantially raise the predictive value	No information on who did clinical assessments and whether or not assessor blinded to case status	The most useful clinical predictor of venous ulcer was the presence of varicose veins. This finding highlights the importance of performing non-invasive haemodynamic investigations to make a proper aetiological diagnosis - in this study 26% of legs with venous ulcer also had detectable arterial insufficiency

Evidence table: patient assessment

Pulse palaption

Study	Design	Results	Comments	Conclusions
Brearley et al 1992 To assess the accuracy with which different observers can detect peripheral pulses UK	Cross-sectional 4 patients with peripheral vascular disease and one asymptomatic 50 observers (medical) Sampling: unspecified Setting: unspecified	Over 10% of assessments diagnosed PVD in asymptomatic limbs and pulses were reported in over 10% of limbs where these were absent Vascular surgeons agreed over the palpability of 48/50 pulses Surgical trainees and non-vascular surgeons failed to detect 23% of palpable popliteal pulses and 40% of posterior tibial pulses	Doctors only	Implications for staff training: assessment of peripheral pulses by inexperienced observers is unreliable. Pulse assessments should be used only in combination with blood pressure measurements or other objective criteria
Callam et al 1987a & b To ascertain how frequently arterial impairment could be detected by simple non-invasive means UK	Survey All patients receiving treatment for chronic leg ulceration (limit set at 600) were examined and interviewed by senior surgical registrar Sampling: convenience Setting: Lothian and Forth Valley Health Boards	65% of those with low Doppler pressures had palpable pulses; 5% of those with normal Doppler pressures had impalpable pulses 21% had an APBI of 0.9 or less and 10% had an index of 0.7 or less		Implications for staff training and for recommending use of objective criteria such as Doppler measurements of ABPI
Magee et al 1992 To investigate observer variation in assessment of pedal vessels by pulse palpation and Doppler auscultation UK	Claudicant group of 33 patients (66 limbs) and control group of 5 patients (10 limbs) examined during same period by 4 observers (consultant, registrar, senior house officer and vascular clinic nurse) with no knowledge of patient's history Sampling: unspecified for patients or staff Setting: unspecified	Overall agreement for dorsalis pulse was 67%, while the overall level of agreement for posterior tibial was 53% The consultant performed best in palpating pulses in both DP and PT arteries with pressure indices >0.9; the consultant was significantly better than the nurse ($p<0.01$) In the claudicant group, indices measured by the 4 observers varied by more than -/+0.15 in only 8 limbs (12%)	Small sample - only one nurse Previous training of staff not mentioned Small number of controls relative to 'test' patients Results not corrected for chance	The poor results of the trainees and the nurse in palpating pulses in claudicants with normal ankle pressures suggest that acquired skill is required A careful history and palpation of the important proximal pulses at femoral and popliteal level, supplemented by Doppler studies, is recommended
Moffatt et al 1994 To investigate the ability of district nurses to detect lower limb arterial disease by palpation of ankle pulses UK	Ankle pulses palpation of patients presenting with ulcerated limbs compared with ABPI Sampling: sequential patients Setting: community ulcer clinics	Sensitivity for lack of pulses as a predictor of arterial disease (ABPI ≤0.9) was 63% with a specificity of 75% and positive predictive value of 35% Using only the absence of palpable pulses would lead to 37% of patients with arterial disease being treated inappropriately	Nil inclusion/exclusion criteria Nil studies of reproducibility of methods Study period not specified Unsure whether blinded interpretation of the reference standard and pedal pulse palpation	Palpation of pedal pulses by community nurses is a poor predictor of arterial disease and must by used in combination with ABPI Only when arterial disease is excluded should compression be applied

Evidence table: patient assessment

Current assessment practice

Study	Design	Results	Comments	Conclusions
Cornwall et al 1986 To identify all active leg ulcers in a defined population UK	Cross-sectional study of all patients with leg ulcers known to GPs and district nurses Sampling: all eligible patients Setting: regional health district	Prevalence of leg ulceration = 0.18% 62% of patients with leg ulcers had never attended any hospital despite having an open infected wound	No information on response rates of epidemiological survey	Lack of clinical assessment of patients with limb ulceration in the community has led to long periods of ineffective and often inappropriate treatment A national initiative is required to improve management of leg ulcers
Elliott et al 1996 To assess the prevalence of leg ulcer disease, identify current practices used in leg ulcer treatment and evaluate treatment regimens UK	Cross-sectional 30 district nurses and 10 community hospital nurses surveyed by audit questionnaire within a trust Sampling: not specified Setting: Highland Communities Trust	53% response rate 50% of respondents used visual assessment alone 30% used Doppler ultrasound, leg assessment form and visual assessment 15% used Doppler and visual assessment 5% used assessment form and visual assessment	Small sample size No information on sampling method Percentage of those trained in Doppler or skill mix of sample not mentioned Study included because of implications for patient outcomes and training	Required standards for leg ulcer assessment are not being met
Lees & Lambert 1992 To assess the prevalence of lower limb ulceration within the community health district and evaluate current patterns of treatment UK	Cross-sectional survey of 70 district nurses using a questionnaire Sampling: convenience Setting: Newcastle community health district	85% of patients with lower limb ulceration had been seen by a doctor during the history of their ulcer; 42% were seen by their GP only if requested by the district nurse 35% had been examined in hospital for their ulceration by a specialist (7% by a vascular surgeon) Only 14% of patients with ulceration had been treated by compression	Use of computerized prospective data may decrease accuracy - verification of patient hospital appointments with medical records would have improved reliability More information on who does initial assessment and when would have been useful No details on questionnaire used	
Roe et al 1993 To describe the current management of leg ulcers by community nurses UK	Cross-sectional 146 district nurses in 3 district health authorities/community trusts Sampling: unspecified Setting: Mersey region	79% check for foot pulses with or without Doppler 55% assess patient's experience of pain 71% measure the ulcer 63% refer a non-healing ulcer for a medical opinion 28% would give advice on analgesia and 7 nurses would recommend the patient for referral to a consultant 6 would refer patients with rheumatoid or diabetic ulcers for specialist advice	Sampling strategy not specified Comparability of findings in other regions would be of interest	The importance of referral and pain assessment need emphasizing Community nurses would benefit from further information on the aetiology and clinical management of leg ulcers Community nurses who qualified before 1981 could benefit most from further education Educational initiatives designed to disseminate research evidence for good practice in the management of leg ulcers are needed
Stevens et al 1997 To examine the effect of a multidisciplinary community and hospital leg ulcer service on patient outcomes and quality of life UK	Before-after audit Interviews with 79 patients identified from district nursing caseloads currently being treated for ulceration, using a questionnaire based on the Nottingham Health Profile (NHP) compared to population norms Sampling: unspecified Setting: community mental health trust	Audit demonstrated that 81% of patients had not been assessed to determine the aetiology of their ulcer prior to treatment Pain and immobility levels were substantially higher than population norms ($p<0.05$)	No breakdown by aetiology Report rather than research format Research material relating to practice used (rather than material addressing main hypothesis because study design inappropriate)	Adequate training in the appropriate techniques of assessment and treatment are required

Appendix 1
Evidence tables

Contents

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4.0 Education/training in leg ulcer care

4.1 Health care professionals with recognized training in leg ulcer care should cascade their knowledge and skills to local health care teams. This should include providing education on the following:

- pathophysiology of leg ulceration
- leg ulcer assessment
- use of Doppler ultrasound to measure ABPI
- normal and abnormal wound healing
- compression therapy – theory, management, application
- dressing selection
- skin care and management
- health education
- preventing recurrence
- criteria for referral for specialized assessment

Rationale

To reduce variation in practice, research-based information and knowledge about aetiology, assessment and management are required (Morrell et al 1998; Simon et al 1998). Research using non-randomized comparison groups or pre- and post-test designs has shown that community nurses' knowledge of leg ulcer management is often inadequate, but that knowledge can be improved by provision of training (Dealey, in press; Luker & Kenrick 1995). There is also some evidence to suggest that information packs and videos are a valuable adjunct to study days (Nelson & Jones 1997). However, there is little research on the impact of different training programmes on patient outcomes and the long-term impact on nursing knowledge. Hence, a specific training approach is not recommended.

Strength of evidence (III)

Most existing research in this area is presented within the context of a poorly reported audit study, utilizing one-sample, before-after designs and often failing to describe in adequate detail the education programme or baseline skill mix of the participants. However, there is some evidence from pre- and post-test analysis of non-randomized comparison groups that knowledge of leg ulcer care is improved by training (2 studies). There is a need for well-designed, prospective studies which evaluate the impact of well-described educational interventions on nursing practice and patient outcomes. In the absence of such research, this recommendation is based on consensus opinion.

5.0 Quality assurance

5.1 Systems should be put in place to monitor standards of leg ulcer care as measured by structure, process and outcome

Rationale

Measurement by strueture (for example, the proportion of patients treated by appropriately trained staff); process (for example, the proportion of patients whose arterial status has been determined by ABPI measurement, and the proportion with uncomplicated venous ulcers receiving high compression therapy) and outcome (for example, the prevalence of active ulceration, proportion of patients healed, rates of healing and adverse outcomes due to incorrectly treated arterial disease or excessive compression) ensures that appropriate performance indicators are monitored (from the EHCB Compression therapy for venous leg ulcers, NHS CRD 1997).

Concern was expressed by a consensus group member that for audit to be of benefit in leg ulcer care, a large number of variables (eg., healing rates, recurrence rates, time to complete healing, patient health status, patient-centred outcomes (such as an ulcer-free leg), ulcer size etc. adjusted for case-mix, setting etc.) would need to be collected to assess whether meaningful change has taken place. Another comment was that many audits have revealed that patient outcomes were much poorer than staff expected; consequently, standards require continual monitoring.

Strength of evidence (III)

Much of the published audit-related research has used weak designs that have not sufficiently examined the impact of monitoring systems on patient outcomes. The recommendation is consensus-based.

3.0 Cleansing, debridement, dressings, contact sensitivity

Table 1: Common allergens and their importance in the care of venous ulcers

Name of allergen	Type	Potential sources
wool alcohols, amerchol l-101, eucerin	lanolin	bath additives, creams, emollients, barriers and some baby products
neomycin, framycetin, bacitracin	antibiotic	medicaments, tulle dressings, antibiotic creams and ointments
parabens (hydroxybenzoates)	preservative	medicaments, creams and paste bandages
cetyl alcohol, stearyl alcohol, cetylstearyl alcohol, cetostearyl alcohol	vehicle	most creams, including corticosteriod creams, aqueous cream, emulsifying ointment and some paste bandages
colophony/ester of rosin	adhesive	adhesive-backed bandages and dressings
mercapto/carba/thiuram mix	rubber	elastic bandages and supports, elastic stockings, latex gloves worn by carer
chlorocresol	biocide	corticosteroid creams and some moisturizers
quinoline mix	biocide	antiseptic and antifungal creams and ointments
chlorhexidene	biocide	antiseptics, tulle dressing
tixocortal pivalate	steriod	steroid preparations, eg. hydrocortisone
fragrance mix/balsam of Peru	perfume	bath oils, over-the-counter preparations such as moisturizers and baby products

3.0 Cleansing, debridement, dressings, contact sensitivity

Dressings

3.3 Dressings must be simple, low adherent, low cost and acceptable to the patient

Rationale

A recent systematic review (Bradley et al, in press) has concluded that there is no evidence that any particular dressing or dressing type is more effective in healing venous leg ulcers. The most important aspect of treatment for uncomplicated venous ulcers is the application of high compression using a stocking or bandage. In the absence of evidence, dressings should be low cost and low or non-adherent to avoid any damage to the ulcer bed. For this reason, wet to dry gauze is not recommended.

Strength of the evidence (I)

A recently completed systematic review (Bradley et al, in press) identified 42 randomized trials of dressings and topical agents in patients with venous ulcers and concluded there was insufficient evidence to promote the use of any particular dressing.

3.4 Health professionals should be aware that patients can become sensitized to elements of their treatment at any time.

Rationale

Patients can develop allergies after using a product over time. Cameron (1998) found that more than 20% of patients previously patch tested had developed at least one new allergy at retesting 2 and 8 years later.

Strength of evidence (II)

One cohort study (Cameron 1998).

Contact sensitivity

3.5 Products which commonly cause skin sensitivity, such as those containing lanolin and topical antibiotics, should not be used on any patient

Rationale

Patients with venous leg ulcers have high rates of sensitivity to these products. Preparations commonly used as part of leg ulcer treatment reported to cause contact sensitivity in certain individuals are listed in Table 1. Frequency of contact sensitivity and the commonest sensitizers in leg ulcer patients have been examined in a number of studies (Blondeel et al 1978; Cameron 1990; Cameron et al 1991; Dooms-Goossens et al 1979b; Fraki et al 1979; Kulozik et al 1988; Malten et al 1973; Malten & Kuiper 1985; Paramsothy et al 1988). Given that skin condition can be improved using products without lanolin, that there is no evidence that topical antibiotics aid healing and that patients may develop a sensitivity after using the product for a while, the safest course is to avoid these products wherever possible.

Strength of the evidence (III)

The evidence for the recommendation is based on observation and clinical experience.

3.6 Patients with suspected sensitivity reactions should be referred to a dermatologist for patch testing. Following patch testing, identified allergens must be avoided and medical advice on treatment should be sought

Rationale

A large proportion of patients with venous leg ulcers are allergic to a number of commonly used products (Dooms-Goossens et al 1979a; McLelland & Shuster 1990). It is important that these are identified so that they may be avoided in future. Treatment will vary and may consist of elevation of the affected limb and application of steroid ointment.

Strength of evidence (III)

The evidence supporting this recommendation is based on observation and clinical experience.

3.0 Cleansing, debridement, dressings, contact sensitivity

Cleansing

3.1 Cleansing of the ulcer should be kept simple:
- irrigation of the ulcer, where necessary with warmed tap water or saline is usually sufficient
- dressing technique should be clean and aimed at preventing cross-infection: strict asepsis is unnecessary

Rationale

There is no evidence that use of antiseptics confers any benefit and some evidence from studies of animal models and cell culture that it might be harmful. Cleansing traumatic wounds with tap water was associated with a lower rate of clinical infection when compared with sterile isotonic saline (Angeras et al 1992).

Wounds and skin are colonized with bacteria and these do not appear to impede healing. The purpose of the dressing technique is not to remove bacteria but rather to avoid cross-infection with sources of contamination, eg. other sites of the patient or other patients. A trial of clean versus aseptic technique in the cleansing of tracheotomy wounds failed to demonstrate any difference in infection rates between the 2 methods (Sachine-Kardase et al 1992). There are no trials comparing aseptic technique with clean technique in chronic wounds, including leg ulcers.

Strength of evidence (III)

There are no trials comparing aseptic technique with clean technique in chronic wounds, including leg ulcers.

Debridement

3.2 Removal of necrotic and devitalized tissue can be achieved through mechanical, autolytic, chemical or enzymatic debridement

Rationale

A systematic review (Bradley et al, in press) concluded that there have been no trials which measure the impact of debridement on the time wounds take to heal. It is acknowledged, however, that clinicians may wish to remove sloughy or necrotic tissue from the ulcer bed and this should be accomplished in a manner unlikely to delay healing. Sharp debridement is a relatively swift and inexpensive method of debridement but must be undertaken by someone with specific training in this skill as it is essential that underlying structures are not damaged.

The chemical agents 1% providone iodine, 0.25% acetic acid, 3% hydrogen peroxide and 0.5% hypochlorite have been shown to damage cells in vitro (Lineaweaver et al 1985); however, there are no trials of these solutions in leg ulcers. Nevertheless, the consensus view is that they should not be used.

The second generation chemical debriding agents dextranomer and cadexomer iodine have been compared with a variety of standard treatments, usually involving saline or antiseptic-soaked gauze, and may facilitate healing compared with these alternatives.

The use of maggots as biological debriding agents is enjoying a resurgence in the UK. However, there have been no randomized controlled trials of their use and current evidence does not support their use; patients' perceptions of this therapy have not been researched.

Autolytic debridement, the breakdown and removal of dead tissues by the body's own cells and enzymes, can be facilitated through the maintenance of a moist wound environment. In patients wearing compression bandages, it is possible to maintain a moist wound environment under simple non-adherent dressings as moisture is retained beneath the bandage.

Strength of the evidence (III)

Moist wound environment aids debridement– no trial evidence could be found.

Chemical debridement is harmful to cells– in vitro studies for example, Lineaweaver et al (1985).

2.0 The management of venous leg ulcers

2.5 Other strategies for the prevention of recurrence may also include the following, depending on the needs of the patient:

Clinical

- venous investigation and surgery
- lifetime compression therapy (see 2.4)
- regular follow-up to monitor skin condition for recurrence
- regular follow-up to monitor ABPI

Patient education

- compliance with compression hosiery
- skin care
- discourage self-treatment with over-the-counter preparations
- avoidance of accidents or trauma to legs
- early self-referral at signs of possible skin breakdown
- encouragement of mobility and exercise
- elevation of the affected limb when immobile

Rationale

A variety of strategies have been proposed, largely based on expert opinion, which range from medical investigation to health education. The recommended approach will depend on the particular patient and likely compliance with suggested strategies.

Strength of evidence (III)

There is little evidence evaluating the effectiveness of each of these strategies - much of the published research is based on what is judged to be current best practice and clinical common-sense. There is some evidence for the importance of early self-referral from a trial (Moffatt & Dorman 1995), which showed that the more quickly someone re-attends to receive 4-layer compression bandaging after recurrence, the shorter the time to rehealing.

Pain assessment and relief

2.3 Health professionals should regularly monitor whether patients experience pain associated with venous leg ulcers and formulate an individual management plan, which may consist of compression therapy, exercise, leg elevation and analgesia, to meet the needs of the patient.

Rationale

A significant proportion of patients with venous ulcers report moderate to severe pain (Cullum & Roe 1995; Dunn 1997; Hamer et al 1994; Hofman et al 1997; Stevens et al 1997; Walshe 1995). Yet, one survey found that 55% of district nurses did not assess patients' pain (Roe et al 1993). Increased pain on mobility may be associated with poorer healing rates (Johnson 1995) and may also be a sign of some underlying pathology such as arterial disease or infection (indicating that the patient requires referral for specialized assessment - refer to recommendation 1.13).

Leg elevation is important since it can aid venous return and reduce pain and swelling in some patients. However, leg elevation may make the pain worse in others (Hofman et al 1997). Compression counteracts the harmful effects of venous hypertension and may relieve pain (Franks et al 1995). Exercise maintains the venous calf pump function.

Fifty per cent of patients with purely venous aetiology reporting severe pain were taking either mild analgesia or none at all (Hofman et al 1997). Analgesics containing opioids may be necessary in some patients.

Strength of evidence (II)

Although the research is quite heterogeneous, the results consistently report that patients with venous leg ulcers can experience considerable pain (one prospective, one matched and 2 cross-sectional studies). There is also some evidence that pain relief occurs with compression and healing (Franks et al 1995). No research could be identified that examined the use of a pain assessment method specifically designed for patients with venous leg ulcers or compared different methods of relief. There is very little conclusive research on other pain relief strategies such as exercise and leg elevation.

Prevention of recurrence of ulceration

2.4 Use of compression stockings reduces venous ulcer recurrence rates.

Rationale

The EHCB compression therapy for venous leg ulcers (NHS CRD1997) found no RCT which compared recurrence rates achieved with and without compression stockings in people with healed ulcers. One RCT however, showed that 3–5 year recurrence rates were lower in patients using strong support from class III compression stockings (21%) than in those randomized to receive medium support from class II compression stockings (32%) (p=0.034); class II stockings, however, were better tolerated by patients (Harper et al 1995).

Drug tariff recommendations for compression hosiery

Class I 14–17mmHg at the ankle for light support

Class II 18–24mmHg at the ankle for medium support

Class III 25–35mmHg at the ankle for strong support

Strength of evidence (II)

Although no RCTs were found, there is fairly strong evidence in support of the recommendation from one controlled trial.

2.0 The management of venous leg ulcers

Four-layer vs. other types of compression bandaging

Rationale

Even though 3-layer, 2-layer and other compression bandages have been shown to be effective, they appear not to have been directly compared with 4-layer bandaging in RCTs. Four-layer bandaging has been compared with short-stretch and with Unna's boots in 4 RCTs (Colgan et al unpublished; Duby et al 1993; Knight & McCulloch 1996; Scriven et al 1998). No differences were found in healing rates. However, because these studies were small in size, there cannot be confidence that there are not clinically important differences in effectiveness. A trial comparing 4-layer with 3-layer bandaging is being carried out at St. Thomas's Hospital, London. When clinics have specifically promoted the delivery of 4-layer high compression treatment, their healing rates have improved compared with results for the usual care given by community nurses (Morrell et al 1998; Taylor et al 1998). However, the 2 available trials do not provide information on the relative impact of, or interactions between, the various elements of setting, nurse training, compression bandaging and protocols for treatment and referral (Morrell et al 1998; Taylor et al 1998), and a trial comparing 4-layer with short stretch is under way co-ordinated by the CEBN.

Strength of evidence II

Currently, there is little reliable evidence which directly compares 4-layer with other types of compression bandaging in RCTs.

2.2 The compression system should be applied by a trained practitioner

Rationale

Whichever high compression approach is employed, it is important that it is used correctly so that sufficient (but not excessive) pressure is applied. Incorrectly applied compression bandages may be harmful or useless and may predispose the patient to cellulitis or skin breakdown. In the presence of diabetes or any other condition that compromises arterial circulation, compression must be applied with extreme caution. The consensus group was able to give several examples where staff are not trained in applying compression bandaging.

Inexperienced nurses or those without additional training in compression bandaging apply bandages at inappropriate and widely varying pressures (Logan et al 1992, Nelson et al 1995a, Stockport et al 1997). More experienced or well trained bandagers obtain better and more consistent pressure results (Logan et al 1992; Nelson et al 1995a). One study found that multi-layer compression bandage systems were easier to apply correctly than single-layer bandages (Stockport et al 1997). It is difficult to ascertain from existing studies if these results are maintained over time. Whether nurses who consistently find it difficult to apply a compression bandage should be given additional training, or whether it is more appropriate to promote the use of a core team of nurses skilled in bandaging to provide a compression therapy service, requires formal evaluation.

Strength of evidence (II)

There is fairly reliable research evidence supporting the recommendation (a one-sample follow-up study, one cross-sectional study). However, more research is needed to see what training strategies improve compression bandage techniques and if the effects of training are maintained over time. The consensus group view was that it is essential that only properly trained staff apply compression bandages.

2.0 The management of venous leg ulcers

Compression therapy

This guideline does not address compression bandaging in patients with mixed aetiology ulcers. Patients with this condition usually require some form of reduced compression, which requires expertise in application and close monitoring.

2.1 Graduated multi-layer high compression systems (including short-stretch regimens), with adequate padding, capable of sustaining compression for at least a week,* should be the first line of treatment for uncomplicated venous leg ulcers (ABPI must be ≥ 0.8)

* if wound large and heavily exuding, more frequent dressing changes will be required

Patient suitability for compression bandaging

Rationale

Patients with arterial disease are not suitable for high compression therapy as it can decrease perfusion and worsen ischaemia. People with venous ulcers usually have an ABPI equal to or greater than 0.8. Arterial involvement is suggested by an ABPI of less than 0.8 (the presence of the latter readings do not necessarily diagnose an ulcer as arterial); mixed venous/arterial ulcers may have an ABPI of 0.6–0.8. Although the cut-off point below which compression is not recommended is often quoted as 0.8, vascular surgeons may use a lower cut-off point, for example 0.6/0.7 (Moffatt et al 1995), and in one study reduced compression was used in patients with an ABPI of 0.5 (Moffatt et al 1995). However, the use of compression on patients with a reduced ABPI requires assessment and supervision by an experienced and trained leg ulcer care expert. Again, the importance of adequate assessment, correct interpretation of that assessment, prescription of appropriate compression systems and their meticulous application cannot be over-stressed (Cullum 1994).

Strength of evidence (III)

This recommendation is based mainly on the logic and principles of pathophysiology, consensus group views and 2 studies (Callam et al 1987b; Moffatt et al 1992).

Compression vs. no compression

Rationale

Randomized controlled trials (RCTs) have shown that compression provided either by Unna's boot (Rubin et al 1990; Sikes 1985), 2-layer (Eriksson et al 1984), 4-layer (Taylor et al 1998) or short-stretch bandages (Charles 1991) improved healing rates compared with treatments using no compression. Furthermore, compression therapy is more cost-effective because the faster healing rates saved nursing time (Taylor et al 1998).

Strength of evidence (I)

This recommendation is based on 6 RCTs.

High compression vs. low compression

Rationale

Three RCTs compared elastic high compression 3-layer bandaging (2 using Tensopress and one Setopress as a component) with low compression (using Elastocrepe) (Callam et al 1992; Gould et al, unpublished; Northeast et al 1990). More patients were healed at 12-15 weeks with high compression. The advantage of higher compression was confirmed in another RCT in which patients with either 4-layer or short-stretch bandaging healed faster than those receiving a paste bandage with outer support (Duby et al 1993).

Strength of evidence (I)

There is reliable evidence that high compression achieves better healing rates than low compression (4 RCTs).

Multi-layer vs. single-layer

Rationale

The advantage of multi-layer high compression systems over single-layer systems is shown by one large and 2 small trials which found more ulcers healed at 24 weeks using 4-layer bandaging than were healed using a single-layer, adhesive compression bandage (Kralj et al unpublished; Nelson et al 1995b; Travers et al 1992).

Strength of evidence (I)

This recommendation is based on one large and 2 small trials

1.0 The assessment of patients with leg ulcers

Referral criteria

1.13 Specialist medical referral may be appropriate for:

- treatment of underlying medical problems
- ulcers of non-venous aetiology (rheumatoid, diabetic, arterial, mixed-aetiology)
- suspected malignancy
- diagnostic uncertainty
- reduced ABPI (for example, <0.8 – routine vascular referral; <0.5 – urgent vascular referral)*
- increased ABPI (for example, >1.0)*
- rapid deterioration of ulcers
- newly diagnosed diabetes mellitus
- signs of contact dermatitis (spreading eczema, increased itch)
- cellulitis
- healed ulcers with a view to venous surgery
- ulcers which have received adequate treatment, and have not improved after 3 months
- recurring ulceration
- ischaemic foot
- infected foot
- pain management

* may vary according to local protocols

Rationale

There is some research which shows that patients may not be referred appropriately for specialist assessment. One study of district nurse records indicated that only 35% of leg ulcer patients were referred at any stage for a specialist assessment and 7% had been examined by a vascular surgeon (Lees & Lambert 1992). However, most of the nurses felt that further investigation of the patients was necessary. Another study found that only 6 out of 146 nurses would refer patients with rheumatoid or diabetic ulcers for specialist advice (Roe et al 1993).

Local protocols will dictate if the patient is to be referred to a vascular surgeon, dermatologist, rheumatologist, diabetologist or other medical specialist.

Strength of evidence (III)

Principal criteria for referral are widely agreed by experts although no studies examining the outcomes of patients with leg ulcers referred from primary to secondary care or between health professionals within primary care were found. Trials are being established to evaluate the effectiveness of early surgery before ulcer healing.

1.0 The assessment of patients with leg ulcers

1.11 Doppler ultrasound to measure ABPI should also be conducted when:

- an ulcer is deteriorating
- an ulcer is not fully healed by 12 weeks
- patients present with ulcer recurrence
- compression therapy is to be recommenced
- patient is wearing compression hosiery as a preventive measure
- there is a sudden increase in size of ulcer
- there is a sudden increase in pain
- foot colour and/or temperature change
- and, as part of ongoing assessment (3-monthly)

Rationale

Arterial disease may develop in patients with venous disease (Callam 1987c; Scriven et al 1997; Sindrup et al 1987) and significant reductions in ABPI can occur over relatively short periods of time (3–12 months) (Simon et al 1994). Estimates of between 13% and 29% of legs with venous ulcers also having detectable arterial insufficiency have been reported (Nelzen et al 1994; Scriven et al 1997; Simon et al 1994). ABPI will also fall with age. The regularity with which Doppler studies are repeated as part of ongoing assessment may be determined by local protocols.

Strength of evidence (II)

One cohort and 2 cross-sectional studies.

Ulcer size/measurement

1.12 A formal record of ulcer size should be taken at first presentation, and at least at monthly intervals thereafter

Rationale

The literature demonstrates a variety of methods used to measure wounds which mainly focus on wound area rather than depth (Ahroni et al 1992; Buntinx et al 1996; Etris et al 1994; Liskay et al 1993; Majeske 1992). Many of the described measurement techniques (Johnson & Miller 1996) may be too cumbersome and invasive for everyday use in the clinical setting where rapid assessment is required and where monitoring of progress rather than accurate measurement is the priority. Therefore, the choice of a measurement method should be based primarily on the local expertise available to perform and interpret the measurement and on the availability of equipment. Monitoring progress can be done cheaply and easily using serial tracings: placing a current tracing over a previous tracing, ideally by the same practitioner each time. However, the practitioner should be mindful that wound state should also be regularly monitored (refer to recommendation 1.7).

Strength of evidence (III)

Design, setting, personnel and statistical differences in the 6 cross-sectional studies prevent adequate comparison of the reliability of measurements obtained with the various wound measurement procedures. There was consensus agreement that sophisticated measuring devices are unnecessary in everyday clinical practice.

Doppler measurement of ankle/brachial pressure index (ABPI)

1.10 All patients presenting with an ulcer should be screened for arterial disease by Doppler measurement of ABPI, by staff who are trained to undertake this measure

The importance of assessing the blood supply to the leg

Rationale

All patients should be given the benefit of Doppler ultrasound measurement of ABPI to ensure detection of arterial insufficiency which could result in the commencement of inappropriate and even dangerous therapy. Absent or very weak foot pulses indicate poor peripheral blood supply and are regarded as signs of arterial disease. However, there is a body of research which suggests that diagnosis should not be solely based on the absence or presence of pedal pulses because there is generally poor agreement between manual palpation and ABPI (Brearley et al 1992; Callam et al 1987b; Magee et al 1992; Moffatt et al 1994). Two large studies have shown respectively that 67% and 37% of limbs with an ABPI of <0.9 had palpable foot pulses, with the consequent risk of applying compression to people with arterial disease (Callam et al 1987b; Moffatt & O'Hare 1995). One survey of surgeons found that 32% reported at least one instance of necrosis induced or aggravated by compression bandages or stockings (Callam et al 1987c).

The importance of making an objective aetiological diagnosis by measuring ABPI, *in addition* to visual inspection of the ulcer, pedal pulse palpation and a thorough clinical history and physical assessment, is highlighted by a number of studies (Moffatt et al 1994; Nelzen et al 1994; Simon et al 1994). Furthermore, venous and arterial disease can and often do, coexist in the same individual (Callam 1987c; Scriven et al 1997; Sindrup et al 1987) and Doppler ultrasound can aid diagnosis in such cases.

Strength of evidence (I)

The evidence for this recommendation is mainly from a number of cross-sectional studies, one controlled study and one cohort study.

ABPI training

Rationale

Unless operators have undergone formal training in Doppler ultrasound technique, ABPI measurements can be unreliable (Brearly et al 1992; Callam et al 1987b; Cornwall et al 1986; Magee et al 1992; Ray et al 1994). Reliability of Doppler measurements can be considerably improved if operators are highly trained (Fisher et al 1996; Fowkes et al 1988).

Training should also emphasize that ABPI measurements in patients with diabetes or atherosclerosis may not be reliable. Patients with these conditions may have deceptively high pressure readings (Callam et al 1987b; Corson et al 1986; Dealey 1995) and such patients should be referred for specialist assessment (refer to recommendation 1.4).

Strength of evidence (II)

One before-after, four cross-sectional and one controlled study.

1.0 The assessment of patients with leg ulcers

1.7 The presence of oedema, eczema, hyperkeratotic skin, maceration, cellulitis, degree of granulation tissue, signs of epithelization, unusual wound edges (e.g. rolled), signs of irritation and scratching, purulence, necrosis, slough, granulation and odour should be recorded at first presentation and as part of routine monitoring thereafter

Rationale

The condition of the ulcer and surrounding skin will influence skin care and will provide baseline information for evaluating treatment outcomes. For example, if eczema with itching is present, a topical steroid may be required; if there is no eczema the surrounding intact skin can be moisturized. If the ulcer is odorous and sloughy, frequent dressing changes may be considered. Also, fragile, oedematous skin will need careful application of compression bandages (although not necessarily decreased compression).

Strength of evidence (III)

Although the exact role that a systematic and comprehensive skin inspection plays in improving care has not been empirically tested, there is general expert agreement that skin inspection is a fundamental part of assessment.

Clinical investigations

1.8 Blood pressure measurement, weight, urinalysis and Doppler measurement of ABPI should be recorded on first presentation

Rationale

Blood pressure is taken to monitor arterial disease, weight is taken at baseline to monitor weight loss if the patient is obese and urinalysis is taken to screen for undiagnosed diabetes mellitus. The need for additional blood and biochemical investigations will depend on the patient's clinical history and on local protocols. Measurement of ABPI is essential to rule out arterial disease (refer to recommendations 1.10; 1.11).

Strength of evidence (III)

This recommendation is supported by consensus opinion.

1.9 Routine bacteriological swabbing is unnecessary unless there is evidence of clinical infection such as:

- inflammation/redness/cellulitis
- increased pain
- purulent exudate
- rapid deterioration of the ulcer
- pyrexia

Rationale

Chronic leg ulcers are usually colonized by micro-organisms, but how this affects healing is debatable (Skene et al 1992; Trengove et al 1996). The influence of bacteria on ulcer healing has been examined in a number of studies (Ericksson 1984; Ericksson et al 1984; Skene et al 1992; Trengove et al 1996) and most have found that ulcer healing is not influenced by the presence of bacteria.

Strength of evidence (I)

One RCT and one prospective study.

1.0 The assessment of patients with leg ulcers

1.5 Information relating to ulcer history should be recorded in a structured format and may include:

- year first ulcer occurred
- site of ulcer and of any previous ulcers
- number of previous episodes of ulceration
- time to healing in previous episodes
- time free of ulcers
- past treatment methods (both successful and unsuccessful)
- previous operations on venous system
- previous and current use of compression hosiery

Rationale

Collection of this data in a structured format will enable consideration of clinical factors that may impact on treatment and healing progress, as well as provide baseline information on ulcer history. However, diagnosis of ulcer type should not be made solely on this information.

Strength of evidence (III)

This statement is consensus-based as no research was identified which examined whether a structured approach for recording ulcer history results in improved management and patient outcomes.

1.6 Examine both legs and record the presence/absence of the following to aid assessment of type of ulcer:

Venous disease

- usually shallow ulcers (situated on the gaiter area of the leg)
- oedema
- eczema
- ankle flare
- lipodermatosclerosis
- varicose veins
- hyperpigmentation
- atrophie blanche

Arterial disease

- ulcers with a 'punched out' appearance
- base of wound poorly perfused and pale
- cold legs/feet (in a warm environment)
- shiny, taut skin
- dependent rubor
- pale or blue feet
- gangrenous toes

Mixed venous/arterial

These will have the features of a venous ulcer in combination with signs of arterial impairment

Rationale

All of the above are well-recognized signs respectively of chronic venous insufficiency and arterial disease (as indicated). However, these signs do not construct a diagnosis per se (refer to recommendations 1.10; 1.11)

Strength of evidence (III)

Consensus statements and literature reviews concur on well known features of these conditions (Alexander House Group 1992; Browse et al 1988).

1.0 The assessment of patients with leg ulcers

Strength of evidence (III)

Although the methods employed and population structures examined are not comparable, there is relative concordance of data on aetiological factors and the medical criteria used to define venous, non-venous and mixed aetiology ulcers are well-defined (Alexander House Group 1992). Well-designed, prospective, epidemiological studies are needed to determine risk factors for venous disease and venous ulceration so that prevention strategies can be developed (Cullum & Roe 1995).

1.4 The person conducting the assessment should be aware that ulcers may be arterial, diabetic, rheumatoid or malignant, should record any unusual appearance and if present refer the patient for specialist medical assessment*

* if there is any doubt about aetiology the patient should be referred to the appropriate specialist

Rationale

Arterial ulcers

Arterial leg ulcers are caused by an insufficient arterial blood supply to the lower limb, resulting in ischaemia and necrosis (Belcaro et al 1983; Carter 1973). A vascular assessment is required in order to establish the location and extent of the occlusion and the presence of small vessel disease (Cullum 1994). The specialised assessment will determine whether the patient is suitable for angioplasty or major vascular surgery.

Rheumatoid ulcers

These are commonly described as deep, well-demarcated and punched-out in appearance. They are usually situated on the dorsum of the foot or calf (Lambert & McGuire 1989) and are often slow to heal. Patients with rheumatoid arthritis might also develop ulcers associated with venous disease.

Diabetic ulcers

These are usually found on the foot, often over bony prominences such as the bunion area or under the metatarsal heads and usually have a sloughy or necrotic appearance (Cullum & Roe 1995).

An ulcer in a diabetic patient may have neuropathic, arterial and/or venous components (Browse et al 1988; Nelzen et al 1993). It is essential to identify underlying aetiology. **Consequently, all diabetic patients with leg ulcers should be referred to a diabetologist or diabetic clinic, particularly if diabetes is poorly controlled.** Specialist assessment is essential as Doppler measurement of ABPI may be unreliable in this group of patients.

Malignant ulcers

Malignancy is a rare cause of ulceration and, more rarely, a consequence of chronic ulceration (Ackroyd & Young 1983; Baldursson et al 1995; Yang et al 1996). Malignant ulcers can be confused with venous ulcers and long-standing venous ulcers may become malignant (Ackroyd & Young 1983; Yang et al 1996). Ulcers with atypical site and appearance such as rolled edges, or non-healing ulcers with a raised ulcer bed should be referred for biopsy and medical attention (Ackroyd & Young 1983; Baldursson et al 1995; Yang et al 1996).

Strength of evidence (III)

This recommendation is based on expert opinion although, as referenced above, there are a number of studies (mainly prevalence surveys and case studies) which have examined the prevalence and/or clinical features of these types of ulcers.

1.0 The assessment of patients with leg ulcers

Clinical history and inspection of the ulcer

1.2 A full clinical history and physical examination should be conducted for a patient presenting with either their first or a recurrent leg ulcer and should be ongoing thereafter

Rationale

Lack of appropriate clinical assessment of patients with limb ulceration in the community has often led to long periods of ineffective and often inappropriate treatment (Cornwall et al 1986; Elliott et al 1996; Roe et al 1993; Stevens et al 1997). There is evidence that danger occurs if arterial ulcers are not properly diagnosed and receive compression (Callam et al 1987b). It is therefore advisable that diagnosis of ulcers should be based on a thorough clinical history and physical examination, as well as appropriate laboratory tests and haemodynamic assessment. This will assist identification of both the underlying cause and any associated diseases and will influence decisions about prognosis, referral, investigation and management. If the practitioner is unable to conduct a physical examination, they must refer the patient to an appropriately trained professional.

Strength of evidence (III)

This recommendation is consensus-based as there are no studies which examine patient outcomes comparing patients given or not given the benefit of a full clinical history and physical examination.

1.3 Record the following which may be indicative of venous disease:

- family history
- varicose veins (record whether or not treated)
- proven deep vein thrombosis in the affected leg
- phlebitis in the affected leg
- suspected deep vein thrombosis (for example, a swollen leg after surgery, pregnancy, trauma or a period of enforced bed rest)
- surgery/fractures to the leg
- episodes of chest pain, haemoptysis, or history of a pulmonary embolus

Record the following which may be indicative of non-venous aetiology:

- family history of non-venous aetiology
- heart disease, stroke, transient ischaemic attack
- diabetes mellitus
- peripheral vascular disease/intermittent claudication
- cigarette smoking
- rheumatoid arthritis
- ischaemic rest pain

In mixed venous/arterial ulcers patients may present with a combination of the features described above.

Rationale

Patients with venous and non-venous leg ulcers often have a readily recognized clinical syndrome comprising some of the above features, and staff should be trained to recognize these. This will assist the accurate identification of aetiology, which has major implications for treatment choice. However, observation alone is insufficient to determine the aetiology (refer to recommendations 1.10; 1.11).

1.0 The assessment of patients with leg ulcers

Who should assess the patient?

1.1 Assessment and clinical investigations should be undertaken by a health care professional trained in leg ulcer management

Rationale

Surveys of reported practice of leg ulcer care by nurses have demonstrated that knowledge often falls far short of that which is ideal (Bell 1994; Roe et al 1994) and that there is wide variation in the nursing management, including assessment of leg ulcers, in areas of the UK (Elliott et al 1996; Roe et al 1993). One audit found that over 80% of patients known to the district nursing services had not been assessed using Doppler ultrasound to determine ulcer aetiology prior to treatment (Stevens et al1997) and another study (Elliott et al 1996) found that 50% of district nurses used visual assessment alone to diagnose a leg ulcer. There is also debate about whether leg ulcer assessment should be undertaken routinely by nurses (Cullum et al 1997). Insufficient training, as well as lack of equipment and referral criteria (Griffey 1992; Stevens et al 1997) may also contribute to variation in assessment practices by nurses. The UKCC gives little guidance on the matter of what constitutes adequate training levels for nurses involved in leg ulcer care. Consequently, this recommendation states 'health care professional': referring to a nurse or a practitioner other than a nurse. The essential point is that the person conducting the assessment (and who is responsible for the care and treatment of the patient and the application of these recommendations) must be trained and experienced in leg ulcer care. The consensus group view is that there needs to be a commitment to make training in the assessment and management of patients with leg ulcers a mandatory part of general practitioner, district nurse and practice nurse training courses.

Strength of the evidence (III)

The recommendation is consensus rather than evidence-based. No trials were found which assess and compare the reliability and accuracy of nursing assessment or which compare the cost-effectiveness of general practitioner (or other health professional) with nurse assessment of patients with leg ulcers or compare other models of assessment. Surveys of knowledge and reported practice were of variable quality (four cross-sectional and one before-after design) but gave fairly consistent results.

Summary of recommendations

Assessment of leg ulcers	Strength of evidence
Assessment and clinical investigations should be undertaken by a health care professional trained in leg ulcer management	III
A full clinical history and physical examination should be conducted for a patient presenting with either their first or a recurrent leg ulcer and should be ongoing thereafter	III
Record the following, which may be indicative of venous disease: family history of venous disease, varicose veins; proven deep vein thrombosis in the affected leg; phlebitis in the affected leg; suspected deep vein thrombosis; surgery/fractures to leg; episodes of chest pain, haemoptysis or history of a pulmonary embolus	III
Record the following, which may be indicative of non-venous aetiology: family history of non-venous aetiology; heart disease; stroke; transient ischaemic attack; diabetes mellitus; peripheral vascular disease/intermittent claudication; cigarette smoking; rheumatoid arthritis; ischaemic rest pain	III
In mixed venous/arterial ulcers, patients may present with a combination of the features described above	
The person conducting the assessment should be aware that ulcers may be arterial, diabetic, rheumatoid or malignant, should record any unusual appearance and if present refer the patient for specialist medical assessment	III
Information relating to ulcer history should be recorded in a structured format and may include: year first ulcer occurred; site of ulcer and of any previous ulcers; number of previous episodes of ulceration; time to healing in previous episodes; time free of ulcers; past treatment methods; previous operations on venous system; previous and current use of compression hosiery	III
Examine both legs and record the presence/absence of the following to aid assessment of ulcer type:	III
venous disease: ulcer is usually shallow (usually on gaiter area of leg); oedema; eczema; ankle flare; lipodermatosclerosis; varicose veins; hyperpigmentation; atrophie blanche	
arterial disease: 'punched out' ulcer appearance; base of wound poorly perfused and pale; cold legs/feet; shiny, taut skin; dependent rubor; pale or blue feet; gangrenous toes	
mixed venous/arterial: features of venous ulcer in combination with signs of arterial impairment	
The presence of oedema, eczema, hyperkeratotic skin, maceration, cellulitis, degree of granulation tissue, signs of epithelization, unusual wound edges (eg. rolled), signs of irritation and scratching, purulence, necrosis, slough, granulation and odour should be recorded at first presentation and as part of routine monitoring thereafter	III
Blood pressure measurement, weight, urinalysis and Doppler measurement of ankle-brachial pressure index (ABPI) should be recorded on first presentation	III
Routine bacteriological swabbing is unnecessary unless there is evidence of clinical infection such as: inflammation /redness/evidence of cellulitis; increased pain; purulent exudate; rapid deterioration of the ulcer; pyrexia	I
All patients presenting with an ulcer should be screened for arterial disease by Doppler measurement of ABPI	I
Doppler measurement of ABPI should be done by staff who are trained to undertake this measure	II
Doppler ultrasound to measure ABPI should also be conducted when: an ulcer is deteriorating; an ulcer is not fully healed by 12 weeks; patients present with ulcer recurrence; before recommencing compression therapy; patient is wearing compression hosiery as a preventive measure; there is a sudden increase in size of ulcer; there is a sudden increase in pain; foot colour and/or temperature change; and, as part of ongoing assessment (3 monthly)	II

Assessment of leg ulcers *continued*	Strength of evidence
A formal record of ulcer size should be taken at first presentation, and at least at monthly intervals thereafter	III
Specialist medical referral may be appropriate for: treatment of underlying medical problems; ulcers of non-venous aetiology; suspected malignancy; diagnostic uncertainty; reduced ABPI; increased ABPI; rapid deterioration of ulcers; newly diagnosed diabetes mellitus; signs of contact dermatitis; cellulitis; healed ulcers with a view to venous surgery; ulcers which have received adequate treatment and have not improved after 3 months; recurring ulceration; ischaemic foot; infected foot; pain management	III
Management of venous leg ulcers	
Graduated multi-layer high compression systems (including short-stretch regimens), with adequate padding, capable of sustaining compression for at least a week, should be the first line of treatment for uncomplicated venous leg ulcers (ABPI must be ≥ 0.8)	I
The compression system should be applied by a trained practitioner	II
Health professionals should regularly monitor whether patients experience pain associated with venous leg ulcers and formulate an individual management plan, which may consist of compression therapy, exercise, leg elevation and analgesia to meet the needs of the patient	II
Use of compression stockings reduces venous ulcer recurrence rates	II
Other strategies for the prevention of recurrence may also include the following, depending on the needs of the patient:	III
Clinical: venous investigation and surgery; lifetime compression therapy; regular follow-up to monitor skin condition for recurrence; regular follow-up to monitor ABPI	
Patient education: compliance with compression hosiery; skin care; discourage self-treatment with over-the-counter preparations; avoidance of accidents or trauma to legs; early self-referral at signs of possible skin breakdown; encouragement of mobility and exercise; elevation of the affected limb when immobile	
Cleansing, debridement, dressing, contact sensitivity	
Cleansing of the ulcer should be kept simple: irrigation of the ulcer, where necessary, with warmed tap water or saline is usually sufficient. Dressing technique should be clean and aimed at preventing cross-infection - strict asepsis is unnecessary	III
Removal of necrotic and devitalized tissue can be achieved through mechanical, autolytic, chemical or enzymatic debridement	III
Dressings must be simple, low adherent, low cost and acceptable to the patient	I
Health professionals should be aware that patients can become sensitized to elements of their treatment at any time	II
Products which commonly cause skin sensitivity, such as those containing lanolin and topical antibiotics, should not be used on any patient	III
Patients with suspected sensitivity reactions should be referred to a dermatologist for patch testing. Following patch testing, identified allergens must be avoided and medical advice on treatment should be sought	III
Education/training	
Health care professionals with recognized training in leg ulcer care should cascade their knowledge and skills to local health care teams	III
Quality assurance	
Systems should be put in place to monitor standards of leg ulcer care as measured by structure, process and outcome	III

Notes for users of the guideline

Evidence base

The evidence base for these recommendations came from the Effective Health Care Bulletin, Compression Therapy for Venous Leg Ulcers, NHS CRD and updated sections of an original systematic review (Cullum 1994). Recommendations without a strong evidence base were informed by expert opinion and are thought to reflect current good clinical practice.

This document contains recommendation statements which were graded as follows:

I Generally consistent finding in a majority of multiple acceptable studies;

II Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies;

III Limited scientific evidence which does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes published or unpublished expert opinion.

(adapted from Waddell et al 1996)

The evidence grade alerts the reader to the type of evidence supporting each statement. However, this grading should not be interpreted as indicative of the strength of recommendation. All of the recommendations are equally strongly endorsed and are not regarded as optional, whatever the strength of evidence grade accorded to them.

Updating of the guideline

The guideline was completed in mid-1998. Resources permitting, it is envisaged that the guideline will be updated 2-yearly.

Audit

Audit criteria based on this guideline are being piloted in 1999 and will be available in 2000. This work is being undertaken as part of a national sentinel audit project funded by the NHS Executive, in partnership with the Royal College of Nursing, Centre for Evidence Based Nursing, Eli Lilly National Clinical Audit Centre, the Royal College of Physicians, the Royal College of General Practitioners and the Tissue Viability Society.

Disclaimer

Guideline users should be mindful that, as with any clinical guideline, recommendations may not be appropriate for use in all circumstances. Clearly, a limitation of any guideline is that it simplifies clinical decision-making processes and recommendations (Shiffer 1997). Decisions to adopt any particular recommendation must be made by the practitioner in the light of available resources, local services, policies and protocols, the particular patient's circumstances and wishes, available personnel and equipment, the clinical experience of the practitioner and knowledge of more recent research findings.

The reader is referred to the document: *Clinical practice guidelines. The management of patients with venous leg ulcers. Technical report: guideline objectives and methods of guideline development* for further information on the methods used to develop the guideline and its evidence base. Evidence tables and the Effective Health Care Bulletin on Compression Therapy for Venous Leg Ulcers which summarise the evidence base of the guidelines are appended to this document. The Technical Report can be obtained from RCN Publishing, Nursing Standard House, 17–19 Peterborough Road, Harrow HA1 2AX.

Contents

clinical practice GUIDELINES

The management of patients with venous leg ulcers

–

Technical Report: Part 2

Recommendations for assessment, compression therapy, cleansing, debridement, dressings, contact sensitivity, training/education and quality assurance

Qualitative research data extraction form users' guide

* fatal flaw ** less serious methodological error

Research question

Qualitative research is best suited to addressing questions about what, why and how events are occurring and may be relevant to: research, theory building, practice

Design of the study appropriate to the objective?

(If no reject)

Ask if :

Selected method appropriate to research the problem?

Understanding of the method and its theory demonstrated?

Appropriate references cited?

Sample

Ask if:

Sample constitutes the full range of likely respondents?

Strategy specified for access to settings and participants?

Data collection

Ask if:

Data coding method specified (if relevant)?

Time-scale of the observation that made up the study specified?

Method for development of trust and rapport with participants specified?

Data collection methods appropriate for gaining the information required?

Data validation methods appropriate?

Standardized research protocols piloted?

Data processing and analysis

Characteristics of responders and non-responders tabled?

Analysis involves interpretation as well as frequency of events/categories?

*Respondent validation by feeding back data/researcher's interpretation to them? (REJECT IF NOT)

*Analysis and interpretation procedures demonstrated? (REJECT IF NOT)

Conflicts between researchers and participants discussed

*Interpretations and theorizations grounded/supported by data? (REJECT IF NOT)

Clinical judgement

Ask if:

Findings transferable to guideline population?

Does the evidence support the claims the researchers are making?

Results of clinical importance?

Emergent relationships plausible?

Limitations of methodology and biases discussed?

Subjective rating

- low risk of bias
- nil serious errors or fatal flaws
- moderate risk of bias
- one or more serious but non-fatal flaws
- high risk of bias
- one or more fatal flaws

Qualitative data extraction/validity checklist

Data analysis

Describe how data analysed

how were concepts, themes or categories developed and interpreted?

indicate if:

- *conceptualized in terms of themes or typologies*
- *presented as a loose collection of descriptive material, with little analysis**
- *responses to individual questions categorized and the range of categories reported*
- *coded using coding categories developed post hoc and reported numerically*

Response rate?**

Describe results

Analysis and interpretation procedures discussed?*

☐ yes ☐ no*

Evidence that supporting material is representative?

sources should be given

☐ yes ☐ no*

Evidence of efforts to establish validity?

evidence that accounts of the phenomenon reflect it accurately

☐ yes ☐ no*

Evidence of efforts to establish reliability?

evidence that accounts of the phenomenon are consistent over time or between researchers

☐ yes ☐ no*

Respondent validation by feeding back data/researcher's interpretation ?*

☐ yes ☐ no*

Interpretations and theorizations grounded/supported by data?*

excerpts from original data, summaries of examples or numerical data presented as evidence for interpretation made; use of extracts of data alone to support theory avoided

☐ yes ☐ no*

Evaluation

findings transferable to guideline population?

☐ yes ☐ no

evidence supports researcher's claims?

☐ yes ☐ no**

results of clinical importance?

☐ yes ☐ no

emergent relationships plausible?

☐ yes ☐ no**

limitations of methodology and biases discussed?

☐ yes ☐ no**

risk of bias?

☐ low ☐ moderate ☐ high

Author's conclusions

Do you agree with the author's conclusions?

☐ yes ☐ no

List specific reservations

Is the paper to be included?

☐ yes ☐ no**

Qualitative data extraction/validity checklist

Study aim?

Qualitative method used?

Design of study appropriate for answering study question?*

☐ yes ☐ no*

Sample and generalizability

Are the criteria for selecting the sample clearly described?

inclusion and exclusion criteria must be specified

☐ yes ☐ no*

Describe the setting in which the study takes place

Method of recruitment

Is an account given of where, whom and how those potentially included in sample were contacted?

Method of sampling

☐ random ☐ purposeful/therotical

☐ convenience ☐ census

☐ quota ☐ not stated

Describe the sample characteristics

age, gender, ethnicity, social class and other relevant demographic characteristics

Is the final sample adequate and appropriate?

☐ yes ☐ no*

Methods of data collection

Is the fieldwork adequately described?

Is there an account of where data were collected, by whom, and in what context?

☐ yes ☐ no*

describe

Are methods of data collection adequately described?

How were data elicited/type and range of questions

describe

indicate:

- *unstructured interviews*
- *semi-structured interviews*
- *focus groups*
- *participant observation*
- *non-participant observation (video/audio recordings)*
- *existing documents*
- *free written text or drawings*

Data collected systematically?

evidence of consistent use of interview guide/study protocol

☐ yes ☐ no*

Analytic cohort/one sample longitudinal data extraction validity checklist form

Analysis *continued*

results

End point/outcome	*Result (p-value; effect size; confidence interval)*

negative study without a power calculation?

☐ yes** ☐ no

confounding satisfactorily dealt with?

☐ yes ☐ no**

comments

Reviewer's judgement

findings generalizable to guideline population?

☐ yes ☐ no

clinically important differences in outcome?

☐ yes ☐ no

outcomes true or substitute?

☐ true ☐ substitute

benefits outweigh harms risk?

☐ yes ☐ no

results biologically plausible?

☐ yes ☐ no

subjective rating of risk of study bias?

☐ low ☐ moderate ☐ high

Author's conclusions

Do you agree with the author's conclusions?

☐ yes ☐ no

List specific reservations

Is the paper to be included?

☐ yes ☐ no**

Analytic cohort/one sample longitudinal data extraction validity checklist form

Outcome

what was measured and how often?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

was tool(s) validated?

1 ☐ yes ☐ no ☐ not stated
2 ☐ yes ☐ no ☐ not stated
3 ☐ yes ☐ no ☐ not stated
4 ☐ yes ☐ no ☐ not stated

data collectors blinded to exposure status of subjects?

1 ☐ yes ☐ no ☐ not stated
2 ☐ yes ☐ no ☐ not stated
3 ☐ yes ☐ no ☐ not stated
4 ☐ yes ☐ no ☐ not stated

length of follow-up?

time frame for ascertainment of outcome appropriate?

☐ yes ☐ no* ☐ not stated**

Analysis

table of demographic and clinical baseline characteristics of participants (please state key socio-demographic and prognostic variables, including proportions, mean, standard deviation, range as relevant)

Variable	*Exposed (if relevant)*	*Comparison group*

80% of those followed-up included in analysis?

☐ yes ☐ no* ☐ not stated**

(if alternative sources of data used to complete dataset these should be specified)

losses to follow-up differ from those contacted?

☐ yes** ☐ no ☐ not stated**

attrition rate (by comparison group if appropriate)?

Specify numerator/denominator

statistical analysis adequate and appropriate?

☐ yes ☐ no**

unit of analysis?

method of analysis?

Analytic cohort/one sample longitudinal data extraction validity checklist form

* fatal flaw/reject ** less serious flaw requiring consideration in summing up study

Objective

aim

hypothesis clearly defined?

☐ yes ☐ no*

design appropriate to the objective?

☐ yes ☐ no*

If no explain why and reject

Sample

diagnostic criteria stated clearly?

☐ yes ☐ no* ☐ not stated*

diagnostic criteria adequate?

☐ yes ☐ no**

if 'no', why?

exposed group?

inclusion criteria (please state)

exclusion criteria (please state)

how were exposed recruited?

indicate if controls used?

☐ historical** ☐ concurrent ☐ none (one sample study)

non-exposed group?

inclusion criteria (please state)

exclusion criteria (please state)

Sample *continued*

non-exposed cohort selected from same population as exposed?

☐ yes ☐ no* ☐ not stated**

how were non-exposed recruited?

If study of prognosis

exposed identified at an early and uniform point in the course of their disease/exposure?

☐ yes ☐ no* ☐ not stated ☐ irrelevant

power calculations included?

☐ yes ☐ no ☐ not stated

numbers required?

actual numbers recruited?

Exposure

what was measured?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

was tool(s) validated?

1 ☐ yes ☐ no ☐ not stated

2 ☐ yes ☐ no ☐ not stated

3 ☐ yes ☐ no ☐ not stated

4 ☐ yes ☐ no ☐ not stated

Checking validity of assessment/diagnostic evaluations

(This form is for formal analysis studies where assessment/diagnosis method is compared with a gold standard. It does not apply to case reports or reproducibility studies)

Paramount questions

1. Diseased and non-diseased patients included?

☐ yes ☐ no

2. Test appropriately performed?

Diagnostic test being evaluated performed in a standardized manner

☐ yes ☐ no

3. Appropriate reference standard?

Was an appropriate 'gold' standard used?

☐ yes ☐ no

Test purpose questions

4. Proposed use/purpose of the test described?

☐ yes ☐ no

Study population questions

5. Appropriate population studied?

Study population appropriate for evaluating the diagnostic test?

☐ yes ☐ no

6. Inclusion/exclusion criteria described?

☐ yes ☐ no

7. Wide spectrum of diseased patients included?

☐ yes ☐ no

8. Control (non-diseased) patients with comorbid diseases included?

☐ yes ☐ no

9. Patient characteristics described?

Demographic and clinical characteristics should be described.

☐ yes ☐ no

10. Cases (diseased) patients with comorbid diseases included?

☐ yes ☐ no

11. Population sources described?

☐ yes ☐ no

Diagnostic test questions

12. Normal/abnormal defined?

Was a normal/abnormal test value adequately defined?

☐ yes ☐ no

13. Test precision described?

Reproducibility described?

☐ yes ☐ no

Reference standard questions

14. Interpretations of reference standard and test blinded?*

Interpretation of the reference ('gold') standard and diagnostic test applied independently (blindly)?

☐ yes ☐ no

15. Reference standard appropriately performed?

Reference ('gold') standard performed in a standardized manner in all patients?

☐ yes ☐ no

16. Normal/abnormal defined?

Was a normal/abnormal reference ('gold') standard adequately defined?

☐ yes ☐ no

Analysis

17. Data presented in enough detail to calculate appropriate test characteristics?*

☐ yes ☐ no*

REJECT if data not presented in enough detail to calculate test characteristics

Sensitivity:
Number of diseased individuals with a positive test result divided by total number of diseased individuals

Specificity:
Number of non-diseased individuals with a negative test result divided by the total number of non-diseased individuals

(These are basic concepts of test validity and data should be clearly presented in a 2 x 2 table from which calculations of sensitivity and specificity can be verified)

Positive predictive values:
Given a patient with a positive test result, what is the likelihood that the target disease is present

Negative predictive value:
Given a patient with a negative test result, what is the likelihood that the target disease is absent?

(These values are critical in the assessment of clinical utility - a relatively high sensitivity and specificity do not suffice to establish clinical significance)

14. Design flaws affecting internal validity?

1. 3.
2. 4.

15. Design flaws affecting external validity?

Study population

Investigator/care given

Care setting

Cross-sectional/survey/prevalence data extraction/validity checklist form

Author's conclusions

List specific reservations

Do you agree with the author's conclusions?

☐ yes ☐ no

Is the paper to be included?

☐ yes ☐ no**

Cross-sectional/survey/prevalence data extraction/validity checklist form

Outcome(s) of interest *continued*

was it validated?

1

2

3

4

Analysis

Characteristics of participants (state key socio-demographic and prognostic variables, with relevant statistics)

Variable	Baseline measurements

if face to face interview/procedure > 80% approached participated?

☐ yes ☐ no** ☐ not stated

if telephone interview > 60% approached participated?

☐ yes ☐ no** ☐ not stated

if postal survey > 50% approached participated?

☐ yes ☐ no** ☐ not stated

response rate including numerator and denominator?

statistical analysis appropriate and adequate?

☐ yes ☐ no** ☐ not stated

statistical techniques used?

unit of analysis?

results (specify p-values, effect size and confidence intervals for each outcome)?

End point/outcome	*Result (p-value; effect size; confidence interval)*

confounding dealt with?

☐ yes ☐ no**

comments

Reviewer's judgement

findings generalizable to guideline population?

☐ yes ☐ no

clinically important differences in outcome?

☐ yes ☐ no

benefits outweigh harms/risk?

☐ yes ☐ no

results biologically plausible?

☐ yes ☐ no

subjective rating of risk of bias in study?

☐ low ☐ moderate ☐ high

Cross-sectional/survey/prevalence data extraction/validity checklist form

* fatal flaw/reject ** less serious flaw requiring consideration in summing up study

Objective

Aim

design appropriate to the objective?

☐ yes ☐ no*

If no explain why and reject

Study population

study setting?

target population?

eligibility criteria stated clearly?

☐ yes ☐ no* ☐ not stated

inclusion criteria (please state)

exclusion criteria (please state)

sampling method (please state)

☐ random ☐ stratified random

☐ quota ☐ convenience**

☐ cluster sample ☐ no detail**

sample representative of study population?

☐ yes ☐ no* ☐ not stated**

power calculations included?

☐ yes ☐ no** ☐ not stated

numbers needed

actual sample size

when was the study conducted?

Exposure

what was measured?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

was it validated?

1

2

3

4

Outcome(s) of interest (if relevant)

what was measured?

1

2

3

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

Case-control data extraction/validity checklist form

Author's conclusions

List specific reservations

Do you agree with the author's conclusions?

☐ yes ☐ no

Is the paper to be included?

☐ yes ☐ no**

Case-control data extraction/validity checklist form

Exposure

what was measured?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

was tool(s) validated?

1 ☐ yes ☐ no ☐ not stated

2 ☐ yes ☐ no ☐ not stated

3 ☐ yes ☐ no ☐ not stated

4 ☐ yes ☐ no ☐ not stated

subjects blinded to study hypothesis?

☐ yes ☐ no** ☐ not stated

data collectors blinded to exposure status of subjects?

☐ yes ☐ no** ☐ not stated

Analysis

attrition rate (specify numerator/denominator)?

cases

controls

>80% complete data set at study completion?

☐ yes ☐ no** ☐ not stated

If alternative sources of data used to complete dataset, these should be clearly specified:

Analysis *continued*

statistical analysis appropriate and adequate?

☐ yes ☐ no**

unit of analysis

method of analysis

results

End point/outcome	*Result (p-value; effect size; confidence interval)*

negative study without a power calculation?

☐ yes** ☐ no

confounding satisfactorily dealt with?

☐ yes ☐ no**

comments if 'no'

Reviewer's judgement

findings generalizable to guideline population?

☐ yes ☐ no

clinically important differences in outcome?

☐ yes ☐ no

outcomes true or substitute?

☐ true ☐ substitute

benefits outweigh harms risk?

☐ yes ☐ no

results biologically plausible?

☐ yes ☐ no

subjective rating of risk of study bias?

☐ low ☐ moderate ☐ high

Case-control data extraction/validity checklist form

* fatal flaw/reject ** less serious flaw requiring consideration in summing up study

Objective

aim

hypothesis clearly defined?

☐ yes ☐ no

design appropriate to objective?

☐ yes ☐ no*

If 'no' explain why and reject

Sample

diagnostic criteria for case definition stated clearly?

☐ yes ☐ no*

inclusion criteria (please state)

exclusion criteria (please state)

where were cases recruited (specify setting)?

how were cases recruited?

matching criteria clearly stated?

☐ yes ☐ no* ☐ not relevant

matching criteria

Sample *continued*

where were controls recruited (specify setting)?

how were controls recruited?

control group appropriate?

☐ yes ☐ no*

how many control groups used?

If more than one, please detail method of recruitment etc. as above

when was study conducted?

comparative table of demographic and clinical factors (please state key socio-demographic and prognostic variables, including proportions, mean, standard deviation, range as relevant for cases and controls)

variable	*cases*	*control*

power calculations included?

☐ yes ☐ no ☐ not stated

numbers required in each study group?

actual number in each group?

case

control

Before-after study design data extraction/validity checklist form

Author's conclusions

List specific reservations

Do you agree with the author's conclusions?

☐ yes ☐ no

Is the paper to be included?

☐ yes ☐ no**

Before-after study design data extraction/validity checklist form

After measurements *continued*

was it validated?

1

2

3

4

Analysis

Characteristics of participants (state key socio-demographic and prognostic variables, with relevant statistics)

Variable	**Baseline measurements**

if face to face interview/procedure > 80% approached participated?

☐ yes ☐ no** ☐ not stated

if telephone interview > 60% approached participated?

☐ yes ☐ no** ☐ not stated

if postal survey > 50% approached participated?

☐ yes ☐ no** ☐ not stated

response rate including numerator and denominator?

statistical analysis appropriate and adequate?

☐ yes ☐ no** ☐ not stated

statistical techniques used?

unit of analysis?

results (specify p-values, effect size and confidence intervals for each outcome)?

End point/outcome	*Result (p-value; effect size; confidence interval)*

confounding dealt with?

☐ yes ☐ no**

comments

Reviewer's judgement

findings generalizable to guideline population?

☐ yes ☐ no

clinically important differences in outcome?

☐ yes ☐ no

benefits outweigh harms/risk?

☐ yes ☐ no

results biologically plausible?

☐ yes ☐ no

subjective rating of risk of bias in study?

☐ low ☐ moderate ☐ high

Before-after study design data extraction/validity checklist form

* fatal flaw/reject ** less serious flaw requiring consideration in summing up study

Objective

Aim

hypothesis clearly defined?

☐ yes ☐ no*

design appropriate to the objective?

☐ yes ☐ no*

If no explain why and reject

Study population

study setting?

target population?

eligibility criteria stated clearly?

☐ yes ☐ no* ☐ not stated

inclusion criteria (please state)

exclusion criteria (please state)

sampling method?

☐ random ☐ stratified random

☐ quota ☐ convenience**

☐ cluster sample ☐ no detail**

sample representative of study population?

☐ yes ☐ no* ☐ not stated**

power calculations included?

☐ yes ☐ no** ☐ not stated

numbers needed

actual sample size

when was the study conducted?

Before measurements

what was measured?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

was it validated?

1

2

3

4

After measurements

what was measured?

1

2

3

4

who carried out the measurement(s)?

1

2

3

4

what was the measurement tool(s)?

1

2

3

4

Randomized controlled trial data extraction/validity checklist form

Analysis *continued*

intention to treat analysis?

☐ yes ☐ no** ☐ not stated

results (for each main end point)?

variable	*results (p-value; effect size; confidence interval)*

negative study without a power calculation?

☐ yes** ☐ no

cost of intervention (if available)

confounding satisfactorily dealt with?

☐ yes ☐ no** ☐ not stated

comments

Reviewer's judgement

findings generalizable to guideline population?

☐ yes ☐ no

clinically important differences in outcome?

☐ yes ☐ no

outcomes true or substitute?

☐ true ☐ substitute

benefits outweigh harms risk?

☐ yes ☐ no

results biologically plausible?

☐ yes ☐ no

subjective rating of risk of study bias?

☐ low ☐ moderate ☐ high

Author's conclusions

Do you agree with the author's conclusions?

☐ yes ☐ no

List specific reservations

Is the paper to be included?

☐ yes ☐ no**

Randomized controlled trial data extraction/validity checklist form

Outcome

what was measured at baseline? list

what was measured subsequently and how often ? list

who carried out measurements?

what was measurement tool(s)?

was tool(s) validated?

☐ yes ☐ no ☐ not stated

duration of follow-up period?

Analysis

characteristics of participants?

(please state key socio-demographic and prognostic variables)

variable	*test (statistics)*	*control (statistics)*

study groups similar at start of trial?

☐ yes ☐ no ☐ not stated

80% randomized sample included in analysis?

☐ yes ☐ no*

attrition rate for each group?
(specify numerator/denominator)

test

control

reasons for withdrawals given?

☐ yes ☐ no* ☐ not stated

characteristics of withdrawals similar in both groups?

☐ yes ☐ no ☐ not stated

follow-up period long enough to show full effects?

☐ yes ☐ no ☐ not stated

statistical analysis appropriate and adequate?

☐ yes ☐ no**

method of analysis?

unit of analysis?

Randomized controlled trial data extraction/validity checklist form

* fatal flaw/reject ** less serious flaw requiring consideration in summing up study

Objective

aim

hypothesis clearly defined?

☐ yes ☐ no*

design appropriate to the objective?

☐ yes ☐ no*

If no explain why and reject

Method

blinding?

☐ double blind ☐ single blind ☐ open

(Reject if open and could have been blinded)

allocation concealment?

☐ adequate ☐ inadequate** ☐ other*

Sample

inclusion criteria (please state)

exclusion criteria (please state)

unit of allocation

study population representative?

☐ yes ☐ no ☐ not stated

setting of study?

when was study conducted?

Sample *continued*

power calculations included?

☐ yes ☐ no

numbers required in each study group?

actual numbers recruited in each group?

test

control

if no power calculations, group sizes > 20?

☐ yes ☐ no*

Intervention

focus of intervention?

content of intervention?

intervention site?

person administering intervention?

was any training of personnel conducted prior to data collection?

☐ yes ☐ no*

how often was intervention received?

controls received?

lack of co-intervention?

☐ yes ☐ no*

lack of contamination?

☐ yes ☐ no*

Systematic review data extraction/validity checklist form

Author's conclusions

List specific reservations

Do you agree with the author's conclusions?

☐ yes ☐ no ☐ don't know

Is the paper to be included?

☐ yes ☐ no* ☐ don't know

Systematic review data extraction/validity checklist form

Type of review

unsystematic* ungraded systematic** systematic

Objective

Question clearly formulated?

☐ yes ☐ no ☐ don't know/not stated

Method*

explicit inclusion/exclusion criteria?

☐ yes ☐ no ☐ don't know/not stated

specify

types of participants

types of interventions

types of outcome measures

eligible study design

search strategy explicit?

☐ yes ☐ no ☐ don't know/not stated

databases searched described?

☐ yes ☐ no

explicit assessment of study validity?

☐ yes ☐ no* ☐ don't know/not stated

number of reviewers used stated?

☐ yes ☐ no ☐ don't know/not stated

reviewers blinded?

☐ yes ☐ no ☐ don't know/not stated

measure of reviewer agreement?

☐ yes ☐ no ☐ don't know/not stated

standardized method of data extraction?

☐ yes ☐ no ☐ don't know/not stated

**Reject if methods section not clear*

Data synthesis

qualitative overview?

☐ yes ☐ no

meta-analysis?

☐ yes ☐ no

studies appropriate to combine?

☐ yes ☐ no* ☐ don't know

subgroup analyses appropriate?

☐ yes ☐ no* ☐ don't know

discussion of consistency of data?

☐ yes ☐ no*

if relevant, sensitivity analysis conducted?

☐ yes ☐ no*

evidence tables displayed?

☐ yes ☐ no**

report any cost information

Reviewer's judgement

clinically important outcomes used?

☐ yes ☐ no**

'no evidence of effect' not interpreted as 'evidence of no effect'?

☐ yes ☐ no**

judgements about preferences (values) explicit?

☐ yes ☐ no

conclusions flow from reviewed evidence?

☐ yes ☐ no*

subjective rating of risk of bias?

☐ low ☐ moderate ☐ high

Appendix 3
Data extraction/ quality criteria forms

Contents

5.0 References

References that could not be traced

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4.0 Results

Future primary studies should pay more attention to current methodological standards for the conduct and reporting of research, such as the recently produced CONSORT statement (Altman 1996). There is also a need for the research literature to adopt a structured abstract format to assist reviewers and also to help authors focus on the essential detail when reporting research.

As application of the quality criteria would have resulted in the elimination of virtually everything retrieved, for some review questions the inclusion criteria were lowered after careful consideration (that is, the question was not one of effectiveness, prognosis, adverse effects). As previously mentioned, a study may have failed to properly address the main study question or hypothesis but it may have given insight into some other area of practice related to the reviews, for identifying future research topics and for information about local practice. Guideline developers are often faced with inadequate evidence; consequently, a variety of studies as well as expert opinion need to be considered (Hayward et al 1995). Some less than ideal qualitative and cross-sectional studies on the psychosocial impact of leg ulcers and experience of pain were included because of the insight offered into these often neglected areas of care. Similarly, although no studies of assessment could be found which fulfilled the Sackett (1991) criteria, some of the retrieved studies were able to contribute important clinical insights into the area of assessment and so were included. However, in relation to training/education the criteria were not lowered because of the cost implications of recommending training programmes of unproven worth.

Finally, as mentioned above, because studies were of mixed validity and there were insufficient data, statistical comparison between studies was not possible. Instead, trends and patterns in the literature are represented in a qualitative framework and in evidence tables on research included since 1991. Consequently, these evidence reviews in combination with expert opinion and well-respected published opinion will form the basis for clinical practice recommendations and are summarized in the rationale that accompanies each recommendation in the guideline recommendations document. Evidence tables for material included since 1991 and excluded studies are appended to the recommendation document.

5.0 References

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Hayward R, Wilson M, Tunis S et al. (1995) Users' guides to the medical literature. VII. How to use Clinical Practice Guidelines. A. Are the recommendations valid? *JAMA*, 274(7), 570-4.

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Sindhu F, Dickson R. (1997) Literature searching for systematic reviews, *Nursing Standard*, 11(41), 40-2.

4.0 Results

Comments on studies of assessment

There is a lack of primary studies on the assessment of leg ulcers, especially studies which examine the precision and accuracy of assessment and which meet the quality criteria outlined above. Most of the obtained studies were cross-sectional (see Table 3). This concurs with the observation that investigations into the precision and accuracy of the clinical examination have lagged behind similar studies of laboratory tests (Sackett 1992). There was a variety of studies examining the use of Doppler and manual palpation of pulses. Most of these studies were not conducted in a community setting but were thought to usefully inform practice. Wound measurement studies were more plentiful but, again, generally were not conducted in community settings. Some descriptive studies were found which investigated patients' experiences of pain and a few were found that examined bacterial assessment.

Comments on studies of education/training

Research on training and education is sparse and suffers from methodological flaws, poor reporting and use of inappropriate study designs. Typically, much of the research forthcoming in this area is derived from audit studies which commonly employ either before-after designs or inappropriate controls (eg. non-randomized), which do not control for confounding, or do not describe the educational interventions in sufficient detail to be useful.

Comments on studies of the psychosocial implications of venous ulcers

Research into tools to measure quality of life in patients with venous leg ulcers is at an early stage. Conclusions from some of the cross-sectional surveys and qualitative studies examining patients' experiences of leg ulcers were marred by the lack of an appropriate control group or comparative analysis and small sample sizes. In the absence of a control/comparison group it was difficult to ascertain whether the documented experiences of patients surveyed were related more to demographic features than to the fact that they had leg ulcers. However, some studies were found that used a control group of age- and sex-matched population norms and there has certainly been an increase in the number of studies examining these issues since Cullum's original review. In terms of educational strategies to improve patients' compliance there is a paucity of research, although some studies examined patients' reasons for not wearing compression hosiery.

The main shortcomings of the retrieved research are summarized below:

- critical appraisal of retrieved research was often hampered by insufficient reporting of methods and results
- many studies did not have or report: sufficient duration of follow-up to monitor recurrence rates; objective details of arterial/venous status, initial mean size of ulcers or duration of ulcer; or a definition of failure of progression to healing (important for studies evaluating the impact of assessment or education on patient outcomes)
- length of follow-up period was often not specified
- many studies did not specify sampling strategy, sampling frame or setting
- many studies appeared to use a convenience sample
- many studies had an inadequate case definition or simply did not report this crucial piece of information (eg. 'patients with leg ulcers...')
- ulcers of all aetiologies (arterial, venous and mixed) were frequently analysed as one group with no subgroup or covariate analyses
- claims of "effectiveness" were questionable where designs other than RCTs were used
- most of the nursing literature on assessment/diagnosis since 1992 relates to continuing education or non-systematic literature reviews, which often perpetuate confusion about the role of the nurse and medical specialists in the management of venous ulcers (a number of such articles were also unreferenced throughout the text, further diminishing their usefulness)
- a common error in analysis was multiple counting of individuals (ie. counting the number of leg ulcers in a study rather than patients) and subsequently not analysing data correctly (see Altman & Bland 1997). It was also common practice for number of limbs or ulcers to be reported but not number of patients
- another common statistical error was the use of the correlation coefficient to measure agreement between two methods of measurement
- a number of psychosocial studies did not use validated instruments. Instruments or questionnaires devised for the purpose of a study did not appear to have undergone rigorous reliability studies or gave no information on any testing that the instrument had undergone
- precise estimates of outcomes were not possible due to the lack of outcomes-focused research in the areas reviewed and also because of the lack of comparability of patients, settings, measurements across studies and often inadequate presentation of statistics (eg. no confidence intervals)

4.0 Results

Table 2: Common reasons for rejecting at 2nd sift n=11

- no information on sampling method
- no control group (cannot support author's conclusion)
- non-random sampling
- outcome assessment not blind
- inappropriate study design
- did not control for confounding
- follow-up rate not specified
- small sample size
- no definition of healing
- no definition of failure to heal
- results not stratified by aetiology
- inappropriate analysis
- no information on content, duration etc. of intervention
- poor reporting overall
- no baseline measurements
- inclusion/exclusion criteria not clear
- initial mean size of ulcers not reported
- uneven group sizes

It was sometimes the case that an article addressed more than one study question (for example, effectiveness of treatment and patient compliance) and that while the study may have been rejected on how it attempted to answer one study question (eg. using a non-RCT to address a question of effectiveness) it was able to give insight into another study objective (eg. patient views on treatment). It was therefore possible that a study rejected as evidence for one topic may have been used as evidence for another.

4.3 Quality of studies

The quality of the evidence reviewed for all topics was generally poor and there was a moderate level of bias in most of the included studies. There was a thin line between the accepted and rejected studies, but what usually distinguished the accepted from the rejected was multiple methodological errors and/or poor and inadequate reporting and/or unwarranted claims of cause and effect in the rejected articles.

Table 3 shows review sub-topic by design of accepted studies. Again, it should be emphasized that a study included in one review sub-topic may have also informed another topic because additional data were collected or the results were also generalizable to another related area (this was especially true of assessment and of psychosocial issues where data were also collected on patients' experiences of pain). However, the articles were grouped under the main study question they primarily addressed.

Table 3: Review topic by study design (since 1991)

Review topic	RCT	controlled clinical trial	cohort	population matched/ case-control	cross-sectional	before-after	case studies	qualitative	retrospective audit	total
Assessment (including clinical predictors, bacterial assessment, surveys of current practice)	2					5	1			8
Wound measurement						6				6
Detection of arterial impairment (Doppler accuracy, pulse palpation, progression of arterial disease)			1	1	5	1				8
Atypical ulceration				1	2		1			4
Psychosocial/compliance			3	5	5			4		17
Training	2				4	2			2	10
Pain			2		2			2		6
Total										59

3.0 Analysis

The method of synthesizing the studies depended upon the quality, design and heterogeneity of studies identified within each topic. Heterogeneity was explored by examining influential factors such as type of wound, type of patient, type of intervention and care setting. However, results were combined qualitatively as in all topics there were differences in patient populations, outcome measurements, settings, study design and conduct.

4.0 Results

4.1 Number of articles identified

For assessment, a 'quality filter' search pertaining to assessment and diagnosis was used. This produced a highly specific search which produced only a few hits (Medline=4; CINAHL=9). The search was then widened to include the following terms: ASSESSMENT OR DIAGNOSIS. This produced a large amount of material (unsystematic overviews, continuing education articles and case studies) unsatisfactory for the evidence review. However, both searches were necessary to capture all relevant material.

For the other two topics, searching was more straightforward.

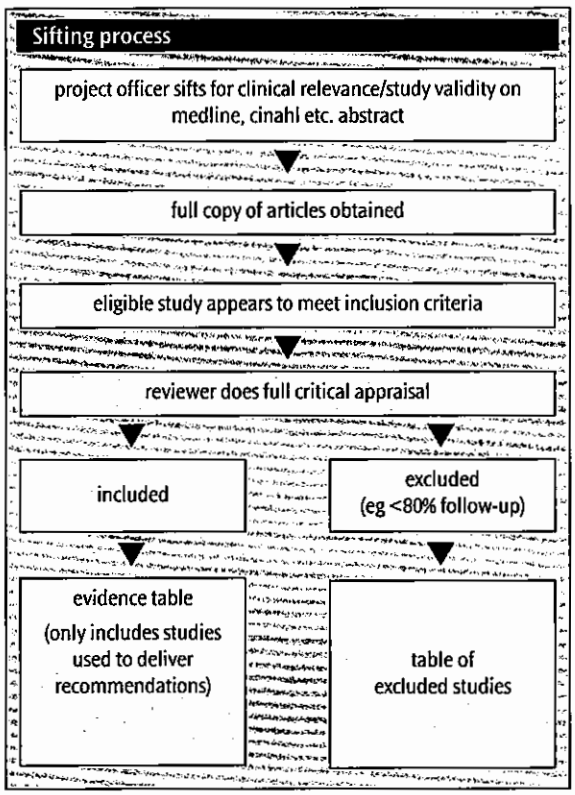
Table 1 shows that after identifying 227 articles, 59 studies were accepted.

Table 1

Stages of the sifting process	Number of articles
Number of references obtained	227
Number rejected at first methodological sift	157
Number accepted for full review	70
Number rejected at second methodological sift	11
Number accepted to provide evidence base for guideline	59

4.2 Reasons for rejecting studies

Reasons for rejecting studies at the second sift are outlined in Table 2. A combination of fatal and non-fatal flaws, poor reporting and inappropriate analysis was common. Poor and inadequate reporting of the research resulted in outright rejection. It was usually the case that more than one flaw (fatal or non-fatal) was present and flaws and poor reporting often went hand in hand.



(adapted from North of England Guideline Development Project 1996)

Methods sections were not reviewed with title and abstract of the article blinded, because information on study methodology was often contained in the introduction or results sections of the articles, a problem which has been well documented (Cullum 1997; Sindhu 1997). Usually, a full copy of the article had to be read, since the study title was not always informative about the abstract, which in turn was not always indicative of the study methods used. However, recent research indicates that independent evaluation of the overall quality of studies is not significantly different between blinded and unblinded reviewers (cited in *BMJ* 1997; 315: 766).

2.9 Limitations of methods

The primary methodological limitation was that the British Library was unable to obtain or purchase 7 articles requested and that articles were restricted to those written in English. These articles are referenced in full at the end of section 5. Because of the problems inherent in assessing the potential value of an article from the database abstract, comment on whether or not these articles were serious omissions is unable to be provided. The impact of restricting inclusion to those articles fully published in English is similarly unable to be ascertained, although it is well recognized as a source of publication bias (Cochrane Collaboration Handbook 1996).

The other limitation is that a sole reviewer reviewed the retrieved literature. However, the resulting literature review and evidence tables were sent to researchers from the CEBN (Cullum and Nelson) for critical feedback and to see if there were any serious inclusion/exclusion errors.

Fatal flaws by study design

RCTs

- no blinding of outcome measurement (if could have been blinded)
- no report of an approach to allocation concealment
- no power calculation and group sizes less than 20
- < 80% randomized sample included in analysis

Cohort

- diagnostic criteria not stated clearly
- no evidence that sample representative of the population from which they were drawn
- <80% followed up (unless alternative source of data used and specified)

Case-control

- matching criteria not clearly stated or adequate
- inclusion/exclusion criteria not clear or inadequate
- <80% response rate (unless alternative source of data used and specified)

Systematic reviews

- no explicit assessment of validity of included studies
- no clear methods section
- studies inappropriate to combine
- sub-group analyses inappropriate
- sensitivity analyses not conducted (if relevant)

Cross-sectional

- eligibility criteria not explicit
- sample drawn not representative of population

Studies of assessment/diagnosis

- inadequate case definition
- unblinded comparisons with 'gold standard'

Qualitative

- no respondent validation of results
- analysis and interpretation procedures unclear
- interpretations not grounded by data

Although there is a degree of subjectivity involved in making these decisions, the use of standardized quality criteria was thought to minimize subjectivity in the appraisal process.

In addition, the reviewer was also required to judge if the study contained a risk of high, moderate or low bias, again taking into consideration factors relevant to the assessment of validity, such as allocation concealment, intention to treat analysis, sample sizes etc. This allowed studies to be qualitatively assessed and weighted according to their reliability to enable a hierarchy of evidence to be constructed.

Data were extracted as follows (depending on the study design and review question): design, objective(s), methods, participants/setting, sampling strategies, measurement tools, interventions, outcomes, length of follow-up, attrition, results, analysis.

The data extraction and quality checklist forms were piloted on a sample of 10 studies by 2 reviewers. Subsequent data extraction and validity assessments were made by one unblinded reviewer, who had previous experience in critical appraisal and a background in nursing (though not specifically in leg ulcer care), epidemiology and biostatistics and also research experience.

2.8 Decisions about inclusion/exclusion

An initial sift on the basis of the abstract of retrieved articles, sorted articles according to obvious clinical relevance and design errors. Full versions of articles were obtained if they satisfied the basic inclusion criteria stated above. Where the validity of the study was unclear, the study was reappraised.

The sifting process is detailed overleaf.

2.0 Methods

2.6 Data handling

The database Idealist was used to store references to allow cross-referencing by key words.

2.7 Article appraisal and data extraction

Standardized critical appraisal sheets incorporated both a structured data extraction form to record details from studies in a reproducible fashion and quality criteria pertinent to each research design (see appendix 3). These were used to assess articles for applicability of findings, validity, design characteristics and study conduct in a reproducible fashion and were based on formats recommended by both the Cochrane Collaboration (1996) and the NHS Centre for Reviews and Dissemination (1997).

These quality checklists assessed internal and external validity and also items not directly related to validity, such as whether a power calculation was done, adequacy of reporting and appropriateness of study design. Typical threats to the internal validity of leg ulcer assessment studies would be lack of a blinded comparison with a 'gold standard', or non-random sampling. Threats to external validity are commonly posed in leg ulcer research by the use of atypical leg ulcer patients, for example by including only those with very small leg ulcers or the lack of clarification of any inclusion or exclusion criteria used in the selection of leg ulcer patients (Cullum 1994).

Criteria specific to leg ulcer research were also used to assist appraisal (Alexander House Group 1992; Cullum 1994). Although these criteria obviously do not relate to each and every review question, they were used to guide the appraisal process where relevant.

Additional quality criteria for leg ulcer studies

- prior calculation of sample size
- clear inclusion/exclusion criteria (major risk factors known to influence ulcer healing should be controlled by inclusion/exclusion criteria or stratification): The most important prognostic factors are: i) duration of present ulcer episode; ii) ABPI of ≥ 0.8; iii) other diseases that impair wound healing (eg. diabetes)
- control treatment reasonable (all non-trial treatments should be standardized)
- sufficient duration (patients should be followed-up until their ulcer heals completely or they reach the end of the maximum observation time set for the study – 6 months is considered adequate)
- appropriate and consistent measurement (should be documented at each follow-up period by tracing ulcers by same observer)
- details of arterial/venous status (eg. Doppler measurement of ABPI)
- initial mean size of ulcers reported (for both groups of patients or matched for ulcer size)
- all patients accounted for
- definition of failure of progression of healing
- severe ischaemia excluded from analysis
- intention to treat analysis, including patients referred elsewhere

There were two main categories of flaws in the quality checklist: 'fatal' (as indicated by * on data extraction/quality checklist forms) and those that were considered minor (for example, risk of Type II error; no power calculations; inadequate description of inclusion/exclusion criteria for entry into the study etc. – indicated by ** on data extraction/quality checklist forms). The 'fatal flaw' criteria were developed following other authors (Dowell et al 1995; Greenhalgh 1997; North of England Evidence Based Guideline Development Project 1996). Articles with a fatal flaw were rejected outright. Minor flaws were not considered sufficient grounds to reject a study but required explicit consideration in summing up the value of the study. Articles with multiple minor flaws (Hadorn 1996) and/or those with inadequate reporting of results and methods were also rejected.

Fatal flaws for each of the major study designs are shown below.

Staff training/education

The objective of this review was to examine the most effective means of training in leg ulcer management. This would include interventions to improve specific techniques (for example, bandaging, Doppler assessment) or complete educational courses encompassing leg ulcer management.

Preferred study design

Preferred studies were randomized controlled trials, in order to rule out the possibilities of confounding with a degree of certainty, and also to be certain of the effectiveness of the methods of training and education models tested. Ecological studies where comparisons are made between, for example, populations rather than between individuals, and before-after studies (both designs commonly used in this area of research), mean it is almost impossible to rule out confounding as a possible explanation for an observed association.

In addition, research examining training had to report:

- clear inclusion/exclusion criteria, including skill-mix, level of prior training etc., and appropriate adjustment in the analysis if relevant
- impact on knowledge
- appropriate duration of follow-up (minimum 6 months) to see if performance deteriorated over time and whether standards of practice changed (Oxman 1994)
- preferably clinically relevant patient outcomes (improvements in healing rates, decreased recurrence rates, proportions of patients receiving appropriate assessment and management) and training outcomes (improvements in knowledge, assessment, bandaging techniques).
- detailed description of the educational intervention (content, source, recipient, timing and format)

2.4 Collection of published research

Published literature from 1992 until mid-1997 was accessed by searching MEDLINE and CINAHL for all topics. English abstracts were used to assess foreign language papers. In addition, PSYCHLIT and SOCIOLIT were searched for psychosocial and compliance studies, EMBASE and HEALTHSTAR for training/education and EMBASE and BIOSIS for assessment. The Cochrane Library and DARE databases were also searched for trials and systematic reviews.

The search strategies were used in combination with recurrent MeSH terms and words in the title and abstracts of relevant articles retrieved. These strategies were devised in consultation with a specialist systematic review librarian at the Cairns Library, John Radcliffe Hospital and were done for each review question. Relevant terms were exploded and wild card characters were used to ensure all forms of words were included.

Hand-searches of the following journals for all topics were conducted for 1992–1997: British Journal of Dermatology, British Medical Journal, Journal of Clinical Nursing, Journal of Vascular Nursing, Journal of Wound Care, Professional Nurse, Research in Nursing and Health, Phlebology and the Journal of Tissue Viability.

Reference lists of studies were reviewed to identify other published and unpublished research.

Studies published in duplicate were only included once and the better reported study was used.

2.5 Collection of 'grey' and unpublished literature

SIGLE and DISSERTATION ABSTRACTS were searched for all topics. Reference lists of all articles retrieved were scanned for unpublished material. The multidisciplinary consensus group, which consisted of clinical and research experts in leg ulcer care (see appendix 1), was also asked to nominate any unpublished research that had been missed by these search strategies.

2.3 Review questions

Assessment

For this topic the main review question was: what is the most reliable and valid method of assessing patients with leg ulcers?

This topic encompasses the following: the reliability and validity of a clinical examination of leg ulcers; the reliability and validity of wound evaluation and measurement, Doppler studies and manual palpation of pulses; pain and bacteriological assessment.

Preferred study design

Articles on method of diagnosis/assessment are generally divided into three categories: pilot studies (eg. reproducibility studies); formal analysis (comparing method of assessment/diagnosis with a 'gold standard' reporting sensitivity and specificity); and review articles. Therefore, for demonstrating whether a new/existing diagnostic test or method of clinical examination or wound assessment was valid and reliable, the preferred study design was a randomized controlled trial, cohort or cross-sectional study in which both the test and the 'gold standard' were performed (see Sackett 1991). As there were no RCTs, the study design criteria were broadened to include non-RCTs.

Studies were analysed for what they had to say about the precision and accuracy of the clinical examination and components of leg ulcer assessment which includes Doppler studies, pulse palpation and wound evaluation. Using criteria developed by Sackett et al (1991) such studies must:

- examine inter-rater and intra-rater reliability
- have a clear definition of the study population
- have a clear description of the assessment/diagnosis technique
- evaluate a patient sample that includes an appropriate spectrum of mild and severe, treated and untreated disease and individuals with different but commonly confused disorders
- use an independent, blind assessment of the technique described and a 'gold standard'.

Studies primarily had to address patients with venous, arterial, mixed aetiology, diabetic, rheumatoid, or malignant ulcers and ideally examined the impact of assessment methods on patient outcomes (referral rates to specialists, appropriate management of ulcer leading to improved healing rates etc.). Patients would include those presenting for the first time with a leg ulcer or presenting with leg ulcer recurrence.

Wound measurement studies at least had to have examined reproducibility, preferably in a community setting.

For bacterial assessment, longitudinal studies which monitored the clinical progress of patients with leg ulcers were preferred.

Several other related sub-topics, such as pain assessment, prevalence of ulcers other than venous and surveys of nurses' assessment practices, were also reviewed. These used different study design criteria such as cohort or cross-sectional designs, and the validity criteria for these designs are included in the data extraction/quality checklists (see appendix 3).

Psychosocial implications of leg ulceration

The main study questions encompassed by this heading were:

- what is the psychosocial impact of leg ulcers on patients?
- what strategies are most effective for promoting compliance with treatment in patients with leg ulcers?

Preferred study designs

Studies investigating the psychosocial implications of leg ulcer disease were preferred if they:

- performed a comparative analysis
- used a random sample of subjects
- used well-validated measures of psychosocial functioning and compliance

Well-conducted qualitative designs were also acceptable for examining patients' views of the impact of leg ulcers on their quality of life.

Studies investigating methods of improving compliance with treatment must have used a randomized controlled design and reported improved patient outcomes such as improved healing rates, decrease in recurrence, satisfaction with care, and give objective details of arterial/venous status (ABPI should be ≥ 0.8 for venous ulcers).

2.0 Methods

Methods used to conduct the systematic review are based on those detailed in the Cochrane Collaboration Handbook (1996) and CRD Guidelines for Undertaking Systematic Reviews of Research and Effectiveness (1997). Guidance was also sought from published work of other guideline developers (Waddell et al 1996; North of England Evidence Based Guideline Development Project 1996).

2.1 Aims of review

To critically appraise the research literature since the end of 1991 in the following areas:

- the assessment of patients with leg ulcers
- the psychosocial implications of leg ulcers and strategies to enhance patient compliance with treatment
- the effectiveness of training and education strategies on leg ulcer care

We also aimed to identify gaps in the research in all of the above areas.

2.2 Criteria used to select articles for inclusion

The emphasis was on identifying only research of high reliability directly related to the review topics. Articles were eligible for inclusion if:

i they were published/written up between 1992 and mid-1997

ii they were primary research

iii they were not case reports

iv methodology and results were reported to the highest standard (ie. there were no omissions in details about conduct of the study) as time did not permit contacting authors for missing details

v they related to patients with leg ulcers primarily being managed in outpatient or community settings

Studies relating to pre-operative or post-operative assessment and surgical management of leg ulcers were excluded, as were methods of assessment such as segmental limb pressure, pulse volume recordings, duplex scanning, transcutaneous oxygen tension determination, photoplethysmography and air plethysmography.

Additional criteria specific to the review questions are outlined in the following sections.

1.0 Introduction

This appendix describes the methods used to update aspects of an original critical review produced in 1994 and also the methods used to undertake a review on training and education which was not included in the original review. The purpose of updating Cullum's (1994) original critical review on the nursing management of leg ulcers was to provide a sound scientific basis for deriving evidence-linked recommendations on the assessment of patients with venous leg ulcers for primary health care workers who provide the bulk of leg ulcer care, to provide recommendations on the most effective method of training/education in leg ulcer management and to provide recommendations on the quality of life and compliance issues faced by this group of patients. The guideline development process is detailed separately in 'guideline objectives and methods of guideline development' and the clinical practice recommendations are included in 'recommendations for assessment, compression therapy, cleansing, debridement, dressings, contact sensitivity, training/education and quality assurance'. In this current review, the sections on the assessment of leg ulcers and psychosocial implications of leg ulcer disease (including quality of life and compliance with treatment) were updated using the same quality criteria and search strategies as the previous author. The research literature for all topics was reviewed from 1992 until mid-1997 (inclusive). In terms of education/training which was not covered by the previous review, the decision was made to review literature from 1992 until mid-1997 only, as the management of venous ulcers has changed considerably since the early 1990s and training/educational interventions would only be relevant if they addressed current principles of scientifically evaluated care.

Resources did not permit updated systematic reviews on the following topics: risk factors; prevalence; prevention of recurrence; management of ulcers other than venous; and determinants of healing. Topics chosen for updating were those that were likely to be of most use to nurses and other primary health care practitioners delivering care to leg ulcer patients in the community.

Abstract

Objective

To update aspects of an original systematic review (Cullum 1994) for the purpose of providing an up-to-date evidence base for clinical practice recommendations in the following areas: the assessment of patients with leg ulcers; the psychosocial implications of leg ulcers; and the effectiveness of training programmes on leg ulcer care *(NB: A systematic review of compression treatment for venous leg ulcers was completed by the CRD (Fletcher et al 1997) and this was used as the evidence base for recommendations on compression therapy for venous ulcers).* Recently completed reviews by the CRD and CEBN on cleansing, debridement and dressings were used as the evidence base for recommendations in these areas.

Methods

Systematic review of research since the end of 1991 until mid-1997, using search strategies and methods of the previous author. Electronic searches of relevant databases and hand searches of relevant journals were undertaken. Experts were consulted to identify research that may have been missed.

Study selection

Assessment of patients with leg ulcers: studies comparing methods of assessment/diagnosis with a 'gold standard' reporting sensitivity and specificity.

Training and education: randomized controlled trials of well-described educational interventions with adequate follow-up periods.

Psychosocial implications of leg ulcer disease: age-sex-matched comparison with population norms or qualitative studies.

Results

For all areas the research evidence was of variable quality. Use of convenience samples and poor reporting characterized much of the retrieved research. Consequently, for some areas, the inclusion criteria were lowered and supplemented with expert opinion.

Conclusion

Guideline developers are often faced with inadequate evidence. There are very few studies in these areas utilizing what is considered to be the 'gold standard' study design. Both qualitative and quantitative designs were lacking in rigour and suffered from inadequate reporting of methods. Consequently, a variety of studies as well as expert opinion needed to be considered to supplement the evidence base for some recommendations.

Appendix 2
Methods of updating original systematic review: leg ulcer assessment, psychological implications of leg ulcer disease and new review on training/education on leg ulcer care

Contents

Appendix 1 Contributors to the guideline

Consensus Group Members

* original consensus conference participant who also reviewed updated recommendations

** only reviewed updated recommendations

no asterisk=original consensus conference participant who was unable to be contacted or did not reply in response to request to review updated guidelines

(Please note that the places of employment of the original consensus conference participants have been updated as far as possible)

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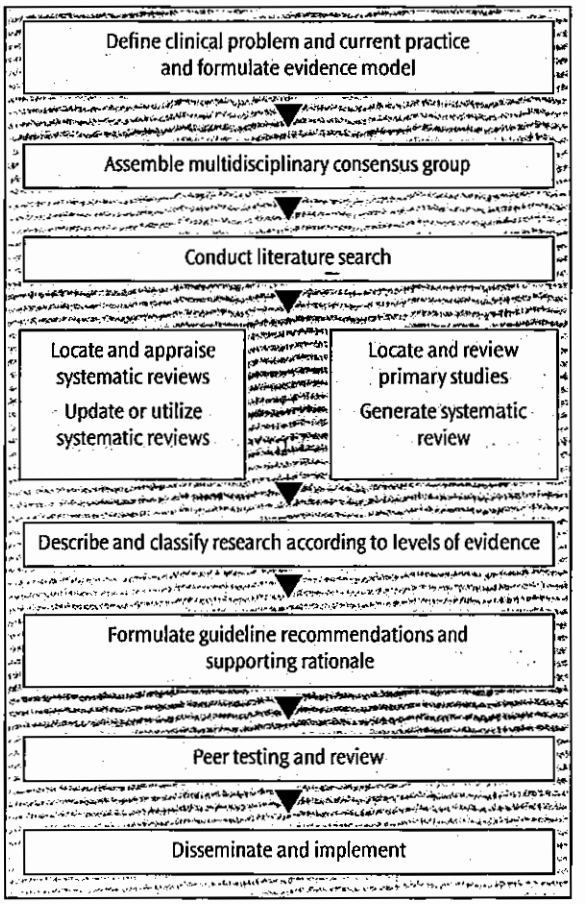
24 Recommendations for future work on this guideline

1 Areas not updated for the present guideline, such as risk assessment, prevalence, preventive strategies and organization of care, should be reviewed in 2 years time. An updating of the core areas covered here should also be undertaken. Reviews relevant to leg ulcer management are being prepared, maintained and disseminated by the Cochrane Wounds Group (Cullum is the Co-ordinating Editor).

2 Costs associated with doing a new or updated systematic review should be separate from the costs of the guideline development process. There should be two separate budgets which recognize that the skills, resources and time required for undertaking a systematic review are different from the guideline development process and that endeavours of this nature are, in fact, two separate projects. Alternatively, the systematic review should be undertaken by an organization with a track record in this work (for example, the NHS CRD, University of York) who can give adequate intellectual and supervisory support to the development of a systematic review. The guideline component of the work should be funded to be supported by a small group of clinical and research experts who have a commitment to evidence-based care, to provide guidance for the project and inform the recommendation formulation, and who are able to provide expert advice where there is no evidence. Such a group should meet every 6–8 weeks to review the guideline's progress and to assist with difficult methodological and clinical decisions.

25 Summary of guideline development process



23 Issues arising from guideline development

1 The limited resources available for the project meant that one reviewer was used for updating sections of the original review by Cullum (1994). This included searching, sifting, appraising, final inclusion decisions and compiling evidence tables. This means that inclusion decisions and interpretation of the evidence may have been subject to reviewer bias. However, to safeguard against this, documents were circulated to the consensus group and other members of the project team knowledgeable in leg ulcer management and systematic review methods (Cullum and Nelson). However, the reader should be aware of this potential limitation.

2 For the updated sections of the original literature review (excluding the section on compression therapy), there was insufficient time to write to authors to request information on methods and analysis where this was inadequate or lacking. Consequently, such articles were excluded.

3 For the updated sections of the literature review (as distinct from the EHCB review), unpublished literature was only accessed through word of mouth and searching SIGLE and dissertation abstracts databases. Consequently, it may be that some relevant research was missed. Likewise, another source of publication bias may have arisen because only articles written in English were obtained, due to insufficient resources for translation.

4 Two members of the consensus group expressed concerns regarding the inclusion criteria for studies (specifically relating to the effectiveness of compression therapy). Specifically, it was felt that although some of the larger studies done on leg ulcer care were not randomized controlled trials (RCTs), an RCT format was inappropriate or impossible under the circumstances of those particular studies. However, the guideline authors believe that an evidence-based approach in which only those studies which have used the most appropriate study design for the research question are sought, is a strength of the guideline. This concurs with both NHSE guideline appraisal criteria (NHSE 1996) and the criteria developed by Cluzeau et al (1997).

5 Formulating guideline recommendations on assessment or diagnosis proved difficult and time-consuming. This difficulty was compounded by the lack of agreement regarding what constitutes adequate training for primary health care professionals on the assessment and management of leg ulcers and a lack of well-conducted and designed studies on the accuracy and reliability of assessment by primary health care professionals. Several of the consensus group members wanted more detail on assessment practice than could be practically contained within the remit of a clinical guideline without giving it a textbook flavour.

6 While the evidence shows wide variation in the practice of leg ulcer care, necessitating recommendations that specify adequate and appropriate training, we were unable to recommend particular training programmes. There are a number of locally run programmes, but there does not appear to have been an overall evaluation of the effectiveness of these programmes. Guidance was sought from appropriate organizations about what constitutes 'adequate and appropriate training from a recognized body' in this area of care, but unfortunately this question remains unanswered.

7 The guideline has not been piloted prior to submission to the NHSE. This will be part of the National Leg Ulcer Sentinel Audit Project as described in section 22.

8 The work has not been reviewed by a guideline methodologist but the guideline has been submitted for appraisal of methods by Cluzeau and colleagues at the Health Care Evaluation Unit, St. George's Hospital Medical School, London.

9 Finally, the reader should be mindful that, as with any clinical guideline, recommendations may not be appropriate for use in all circumstances. Clearly, a limitation of any guideline is that it simplifies clinical decision-making processes and recommendations (Shiffer 1997). Decisions to adopt any particular recommendation must be made by the practitioner in the light of available resources, local services, policies and protocols, the particular patient's circumstances and wishes, available personnel and equipment, the clinical experience of the practitioner and knowledge of more recent research findings.

20 Policy and organizational considerations

A number of issues related to policy and organization of services for leg ulcer care arose during the consensus conference in 1994. It was agreed that these would affect the delivery of optimal care to people with leg ulcers. These concerns do not lend themselves to be adequately formulated as clinical practice recommendations and are briefly outlined here. They include the following:

- there is a need for all members of the multidisciplinary health care team representing both primary and secondary care, who have undergone the appropriate training, to be involved in the delivery and management of leg ulcer care
- there should be dedicated, recognized training programmes on leg ulcer care as the pre-registration education and training of doctors and nurses in wound care is currently variable and should be improved
- a nurse specialist qualification in the management of people with leg ulcers or wounds generally (including leg ulcers), underpinned by a recognized training programme, should be developed
- there should be a communication interface established between hospital and community services, which allows for the sharing of joint protocols and clarifies the role of each member of the health care team.

21 Patient considerations

There is a growing body of research on the impact of leg ulcers on patients' quality of life (Cullum & Roe 1995; Flett et al 1994; Franks et al 1992; Lindholm et al 1993; Phillips et al 1994; Price & Harding 1996; Walshe 1995). Leg ulcer patients have much in common with patients with other chronic diseases. This may include social isolation, loss of income and reduced self-esteem. Although the considerations raised by these studies are not amenable to clinical practice recommendations, it is expected that the health professionals using this guideline are sensitive to these issues. Importantly, the practitioner should be aware that effective treatment (high compression therapy for venous ulcers resulting in improved healing rates) may help diminish those factors which affect quality of life (Cullum & Roe 1995) and ensure that decisions regarding therapy are discussed with the patient.

Patient compliance and patient acceptability of compression bandaging has been examined in a few studies (Johnson 1988; Samson & Showalter 1996; Taylor 1993; Travers et al 1990). Patients' reasons for inability to comply with compression therapy include being uncomfortable at night, perceiving the dressing as being a more important factor in healing than compression therapy, expense, difficult to apply (compression stockings), and too hot. However, there have been no studies of the extent to which patients may be able to participate in the management of their ulcers or of the most effective method of maximizing compliance with venous leg ulcer therapy, and only a few studies of patient acceptability of compression bandaging. Again, the practitioner should have an understanding of the factors which may hinder patient compliance with therapy.

In terms of patient information and education, although studies have found that patients may not remember or know the cause of their leg ulcer (Hamer et al 1994) and that patients lack knowledge of wound care for venous therapy, particularly compression therapy (Chase 1997), further research is needed to develop educational packages appropriate for the differing needs and requirements of leg ulcer patients (Hamer et al 1994). In the absence of such research, it was suggested by consensus group members that education of the patient by the health professional delivering their care should not be 'one-off' but that patients should be offered ongoing education about leg ulcer disease and rationale for treatment appropriate to their treatment stage.

22 Audit criteria

The consensus group meeting in 1994 agreed that a 'gold standard' leg ulcer service requires the following attributes: accessibility to patients, to be determined by local need, equitable, applicable, audited through standard documentation or a minimum data set, be delivered to an agreed standard and be patient responsive.

Evidence-based audit criteria are being developed which will be based on this guideline and will include elements of structure, process and outcome. This work is being undertaken as part of a national sentinel audit project funded by the NHSE, in partnership with the RCN, CEBN, Eli Lilly National Clinical Audit Centre, the Royal College of Physicians, The Royal College of General Practitioners and the Tissue Viability Society.

Where the evidence clearly indicates that one technique is more effective than others, or when the evidence showed no difference in the effectiveness of various methods, this was noted in the rationale. In the absence of clearly persuasive scientific evidence, expert judgement, expressed as consensus, was used to inform the guideline. Similarly, conventional practice endorsed by experts is included where the evidence in support of alternative practices is weak. Diversity of expert opinion is flagged in the rationale.

15 Format of recommendations

Recommendations were not graded separately from the evidence as the evidence grade alone was thought to give guideline users a clear and simple indication of the strength of evidence underpinning each recommendation. Furthermore, all recommendations are strongly supported irrespective of the evidence grade accorded to them; recommendations without 'hard' research evidence are not any less strongly recommended than those with a strong research-base underpinning them.

The rationale that accompanies each recommendation has been kept to a minimum to avoid excessive verbiage which might inhibit the use of the guideline. The main purpose of the rationale is to give an abridged summary of the evidence supporting each guideline recommendation. Further details are contained in the original evidence reviews and evidence tables appended to the recommendations document.

16 Expected health benefits

Quantification of the expected health benefits resulting from the application of the recommendations was not possible due to the low quality and heterogeneity of much of the research literature. Consequently, an expected rate of patient outcome, for example as a result of reliable and accurate assessment or effective management, cannot be provided.

17 Costs associated with recommendations

There is an absence of economic evaluations in this area of health care. Therefore, costs of the various techniques were not explicitly considered in developing the guideline, except to acknowledge the lack of resources available in many settings to carry out all aspects of the guideline. However, since compression therapy improves healing rates and can significantly reduce recurrence rates of venous leg ulcers, it will reduce the time spent by practitioners in the management of leg ulcers; this approach is therefore likely to be more cost-effective than management without adequate compression.

18 Peer review and revision

Drafts of the updated literature review were sent out to researchers with an interest in leg ulcer management (Cullum & Nelson) for comment. As previously discussed, drafts of the guideline recommendations were sent out to the multidisciplinary consensus group for comment and endorsement and to provide expert opinion for aspects of practice for which little or inadequate scientific evidence exists. The final product was circulated also to the Southern Tissue Viability Nurse Specialists and regional chairpersons of the same organization, for advice regarding dissemination and implementation of the guidelines and also the most appropriate format for clinicians.

19 Review date

Resources permitting, it is envisaged that the guideline will be updated 2-yearly to include research and systematic reviews published since mid-1997.

was updated and circulated to those original members of the consensus group who agreed to provide comment on the revised recommendations (24/29 from the original consensus group and 4 others recruited since the original consensus process). Group members were sent draft recommendations and asked to indicate on standardized forms if they agreed with each recommendation statement, rationale and the grading of the evidence, and to provide open-ended comments if desired. Another consensus conference was deemed unnecessary as the previous recommendation statements had been agreed already and discussed at the conference. The RCN guideline project officer co-ordinated this process and made necessary amendments (mainly related to reorganization of material, correction of typographical errors, and wording). Comments from consensus group members which required an expert judgement relating to clinical or research issues were referred to Cullum and Nelson for consideration. All guideline documents were then sent for endorsement to the consensus group before submission to the NHSE. Group members were requested to contact the RCN only if they felt they could not approve the guideline in its entirety.

The original recommendations (unpublished) did not significantly alter as a result of the updated evidence base, although a number of policy-related recommendations arising from the consensus conference are included here under 'policy and organizational implications of the guideline' (rather than in recommendation format). This outlines some of the issues the consensus group felt needed to be considered to optimize leg ulcer care but could not be easily formulated into clinical practice recommendations. Similarly, recommendations from the review of the psychosocial and compliance research were found to be difficult to formulate (due mainly to the weak evidence base and lack of investigation of strategies to enhance compliance). Consequently, some 'common sense' statements based on this material are included below under 'patient considerations'.

Guideline steering group

A group comprising representatives of professional organizations who had, or were involved in, developing national clinical guidelines gave advice on guideline methodology. This group met every 6 months but members were available for consultation as required (see appendix 1).

13 Data synthesis

Although meta-analysis was undertaken for the compression therapy systematic review (EHCB, CRD 1997), for the updated evidence reviews there was considerable heterogeneity of study design, patients, interventions, outcomes and settings. For these areas the data synthesis focused on providing a critical review of the type and quantity of evidence using methods described by Slavin (1986), which then provided an evidence-linked rationale for each recommendation. The direction, magnitude and significance of effects, and major issues affecting the applicability and validity of data were considered in the reviews.

14 Grading of evidence

Evidence was graded I, II or III, adapted from Waddell et al (1996) as follows:

Grade I Generally consistent finding in a majority of multiple acceptable studies

Grade II Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies

Grade III Limited scientific evidence which does not meet all the criteria of acceptable studies, or absence of directly applicable studies of good quality. This includes published and unpublished expert opinion.

This method was chosen because most of the existing methods for ranking levels of evidence relate to intervention studies (Canadian Task Force 1979; Hadorn et al 1996). As not all of the topics covered in this guideline address questions of effectiveness, a uniform method of weighting the evidence for all the reviews was considered more appropriate. The method allows guideline developers to grade a variety of studies as well as expert opinion (Hayward et al 1995).

The grading was undertaken by 3 people with different research backgrounds after data synthesis was completed. Suggestions for grading made by the consensus group members were also incorporated when relevant. The evidence grade is given under 'strength of evidence' for each recommendation. The grading was based on the number of 'gold standard' studies retrieved for each review question, the quality of evidence and the consistency and applicability of findings.

What was considered as evidence

Research based evidence was sought for all topics according to pre-set criteria. Details of search methods, inclusion/exclusion criteria, methodologic checklists and review methods are detailed in the methods document and the EHCB (CRD 1997) appended to the recommendation document.

In general, when considering effectiveness of treatment or interventions, evidence provided by well-conducted randomized controlled trials was considered to be more reliable than that derived from cohort or case-control studies. These observational studies, in turn, were ranked above expert opinion. However, for questions other than effectiveness, other study designs were regarded as the 'gold standard' (see table below).

Study design criteria by review question

Review question	Study design
effectiveness of compression therapy	randomized controlled trial (RCT); systematic review
assessment of leg ulcers (included comparisons of different methods of assessment as well as the accuracy and reliability of different methods of assessment; Doppler studies, pulse palpation, wound measurement, adverse effects of inappropriate diagnosis)	RCTs, cohort and cross-sectional (depending on review question), systematic review
effectiveness of different staff training and education strategies	RCT; systematic review

Where evidence was lacking or was weak, expert opinion formed the basis of the recommendation.

Multidisciplinary consensus group

The original recommendations were based on the review by Cullum (1994) and a consensus conference of invited experts (held in September 1994) and organized by the Department of Nursing of the University of Liverpool. Thirty-one experts from various disciplines (identified by regular publication of clinical or research papers on leg ulcer management, or by their roles in purchasing or public health and stated interest in leg ulcers) were invited (29 attended) to discuss and agree guidance in specific areas of leg ulcer care where scientific evidence was lacking or inconclusive. Briefing papers, along with the systematic review of research, were circulated to delegates prior to the conference.

The following disciplines and professions, involved in leg ulcer care and service delivery, were represented at the conference:

- purchasers
- providers
- community and hospital nursing
- surgery
- dermatology
- general practice
- nursing homes
- public health
- nurse education
- Department of Health

A list of delegates is attached at the end of this chapter, and many of these have commented on various drafts of this updated guideline.

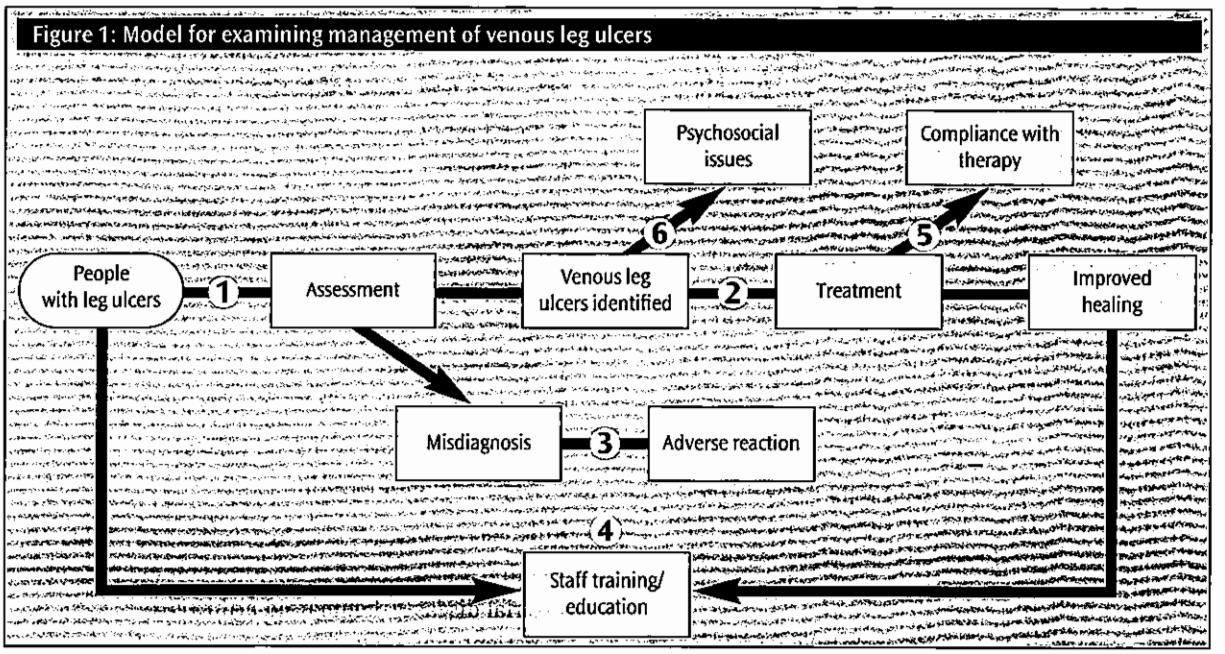
Delegates were divided into four small groups, each with a facilitator to discuss and agree management strategies in the following main areas:

- the assessment of leg ulcer patients
- the management of leg ulcer patients
- implications for education and training of health care staff
- quality assurance implications of implementing the guideline

Each of the four aspects of leg ulcer care was tackled by all groups and then the conclusions fed back to the plenary session. The Chair was responsible for ensuring that the main panel reached consensus on the day.

Consensus was achieved when delegates either voiced agreement or when no one voiced disagreement on the specific issues raised. All the sessions at the conference were tape recorded and the tapes were transcribed. A modified Delphi technique was used to achieve consensus on the draft guidelines after the conference. The discussion and decisions reached on the day were collated, turned into draft consensus guidelines and posted back to delegates for comment. Twenty-two out of 29 delegates gave feedback; the majority of comments expressed agreement, with only minor changes suggested. The process of feedback was repeated (twice) until consensus was achieved. Delegates' feedback was circulated anonymously and verbatim with each redraft to give everyone the relative strength of feeling voiced for each aspect of the guidelines. The consensus process relates mainly to the wording of recommendations and to those where there was poor research available.

Following the updating of sections of the original review and the completion of the EHCB (CRD 1997), the evidence base of the original recommendations



The guideline project officer co-ordinated all aspects of guideline development, updated sections of the original review which were not covered by the EHBC (CRD 1997) and produced the review on staff education/training using systematic review methods. This work was checked by the original author (Cullum) and was then used with the EHCB (CRD 1997) and the ongoing CRD/CEBN reviews to provide the rationale and evidence base for the guideline recommendations. The updated work had input from Cullum and Nelson, from the CEBN, who also provided guidance on ranking the strength of evidence for each recommendation, advised on additional research where required and updated the evidence on cleansing, debridement and dressings in the light of new systematic reviews on these topics.

Evidence model

Following Woolf (1991) an evidence model was developed to represent the areas to be covered by the guideline. It also shows the possible linkages between each of the review questions.

The linkages provided by the model produced the following questions which the guideline addressed:

Linkage 1:
What evidence is there for the reliable and accurate assessment of a person with a leg ulcer in the identification of suitable candidates for compression bandaging?

Linkage 2:
What is the most effective method for treating venous leg ulcers?

Linkage 3:
What adverse effects result from inappropriate/ inadequate diagnosis of a leg ulcer patient?

Linkage 4:
What is the most effective training/education method in the management of leg ulcers?

Linkage 5:
What is the most effective means of ensuring compliance with therapy?

Linkage 6:
What are the psychosocial implications of leg ulcer disease?

The variable quality of the research addressing linkages 5 and 6 meant that it was difficult to formulate clinical practice recommendations on these topics; consequently, salient points arising from examination of this material are included here under 'patient considerations'.

7 Where the guideline is applicable

The practice settings for which all sections of the guideline are applicable are those where any primary health care practitioner is responsible for the management of venous leg ulcers within the UK. This is likely to be either a district nurse, or practice nurse.

8 Definition of a leg ulcer

A leg ulcer is defined as an area of discontinuity of epidermis and dermis on the lower leg, persisting for 4 weeks or more (Cullum et al 1997).

9 The epidemiology of leg ulceration

Leg ulceration has a point prevalence of 0.16%–0.18% in the UK (Callam et al 1985; Cornwall et al 1986). Prevalence increases with age and affects approximately twice as many women as men (Callam et al 1988; Cornwall et al 1986; Lees & Lambert 1992). Leg ulcer disease is typically cyclical and chronic, with periods of complete healing followed by recurrence, and is a major cause of morbidity, suffering and health service costs (Bosanquet 1992; Callam et al 1988; Roe & Cullum 1995). Leg ulcer disease is strongly associated with venous disease; however, arterial disease is present, alone or with venous problems, in about 20% of cases (Callam 1989). In a large population study in Scotland, 20% of leg ulcers had been open for 2 years (Callam et al 1987). There is wide variation in recurrence with reulceration rates of 26% (Franks et al 1995) to 69% at one year being reported (Monk & Sarkanay 1982). Variation in recurrence rates and the chronicity of leg ulcers partly reflect variable approaches to care delivery and management. Surveys have shown wide variation in their clinical management (Roe & Cullum 1995; Stevens et al 1997) and numerous types of wound dressings, bandages and stockings are used in treatment and prevention of recurrence (Freak 1996). (This section is largely taken from the following references: Cullum et al 1997; EHCB CRD 1997).

10 Cost of leg ulcers to the community

In 1989, the cost of treating leg ulcers was crudely estimated at between £300 and £600 million per year (Wilson 1989) and the human cost is inestimable.

11 Types of leg ulcer

Leg ulceration may be caused by a number of underlying pathologies, including venous disease, arterial disease, rheumatoid arthritis and diabetes. A patient may have any one or a combination of these conditions contributing to the development of an ulcer.

12 Guideline development method

The guideline development process is based on both current 'gold standard' methodology proposed by other guideline developers (Eccles 1996; Waddell 1996; Royal College of Psychiatrists 1998; Woolf 1991) and criteria used to appraise the robustness of national guidelines (Cluzeau et al 1997).

This guideline is a hybrid document, the recommendations for which are based on various sources as described above. Important sources were the original consensus recommendation statements agreed in 1994 at the consensus conference (details below), the recent EHCB (CRD 1997), updated sections of the original review (Cullum 1994), ongoing reviews undertaken for the NHS HTA programme by CRD/CEBN and consensus group opinion where the evidence was of poor quality or equivocal.

Topics selected for review were chosen both on the basis of their practical relevance to primary care practitioners and because improvements in the management of these areas will have the greatest impact on patient outcomes.

The guideline is evidence-linked, rather than evidence-based, as a number of recommendations for practice were solely or partially based on expert consensus opinion (both published and unpublished), due to the inadequate and weak research base, particularly in the areas of assessment, referral, staff education/training and quality assurance.

4 What the guideline does not cover

- Specialized assessment methods, such as segmental limb pressure, pulse volume recordings, duplex scanning, transcutaneous oxygen tension determination, photoplethysmography and air plethysmography, that primary health care professionals are unlikely to use in everyday clinical practice
- Specialized medical assessment of ulcers
- The treatment of ulcers other than venous
- Surgical/medical/pharmacological/non-nursing interventions
- Textbook type instructions on undertaking Doppler measurement of ankle/brachial pressure index (ABPI), compression bandaging and other areas covered by the guideline
- The guideline is primarily concerned with clinical practice, not organizational models of leg ulcer care. However, interested readers are referred to a recently published randomized controlled trial on the most cost-effective methods of organizing leg ulcer care (Morrell et al 1998) and the EHCB (CRD 1997) which also discusses this issue.

5 Funding

This project has been funded by the National Health Service Executive with additional support from the University of York, and the Department of Health and Personal Social Service, Northern Ireland who funded Andrea Nelson.

6 Who the guideline is intended for

Health professionals

The guideline is primarily intended for primary health care professionals (mainly nurses) managing patients with venous leg ulcers. However, the guideline is not a textbook or training manual and cannot bridge all competency levels. The UKCC determines that the practitioner should 'acknowledge any limitations in your knowledge and competence and decline any duties or responsibilities unless able to perform them in a safe and skilled manner' (UKCC 1996:9). In the light of this, it is strongly recommended that anyone involved in the delivery of leg ulcer care has had adequate training in Doppler and other methods of leg ulcer assessment, compression bandaging techniques and leg ulcer management. It is also strongly recommended that anyone not fully competent in any or all of these areas should refer the patient to an experienced and adequately trained health professional (for example, leg ulcer nurse specialist, general practitioner, medical specialist, as appropriate). The consensus group view was that there is a need to make training in the assessment and management of leg ulcers a mandatory part of general practitioner and community nurse training courses.

The guideline can also be used as a reference for nurses, health professionals, patients, carers, managers and commissioners of health care requiring information about current recommendations on assessment and management of venous leg ulcers.

Patients

Assessment

The assessment section recommendations covers *the assessment of all patients* presenting with leg ulcers of unknown cause, as an accurate differential diagnosis is an essential part of the management. Consequently, mixed aetiology, arterial, rheumatoid, diabetic and malignant ulcers are briefly discussed in relation to differentiating between these and the targeted focus of the guideline.

Management

Patients with ulcers other than uncomplicated, accurately diagnosed venous leg ulcers are not covered by the management recommendations. Although mixed aetiology (venous/arterial) ulcers are briefly discussed in this section, it is expected that local protocols will determine the appropriate management of patients with these ulcers.

Patients for whom this section of the guideline is intended are adult patients formally diagnosed with venous disease and who have an ABPI reading of ≥0.80 as performed by a health professional with formal training in Doppler assessment.

The recommendations pertaining to these areas were informed by the following systematic reviews:

The psychosocial implications of leg ulcer disease, including impact of leg ulcers on patients' quality of life; measurement of quality of life; strategies to enhance patient compliance with treatment *(updated from Cullum 1994)*.

The assessment of a patient with a leg ulcer *(updated from Cullum 1994)*. The interventions under consideration are methods of assessing leg ulcers including Doppler studies, pulse palpation, wound evaluation and measurement and assessment of pain.

The effectiveness of venous ulcer management strategies and interventions *(from EHCB, CRD 1997 and ongoing work by the CEBN and CRD)*. This includes: compression bandaging, prevention of recurrence, pain relief, cleansing, debridement and dressings.

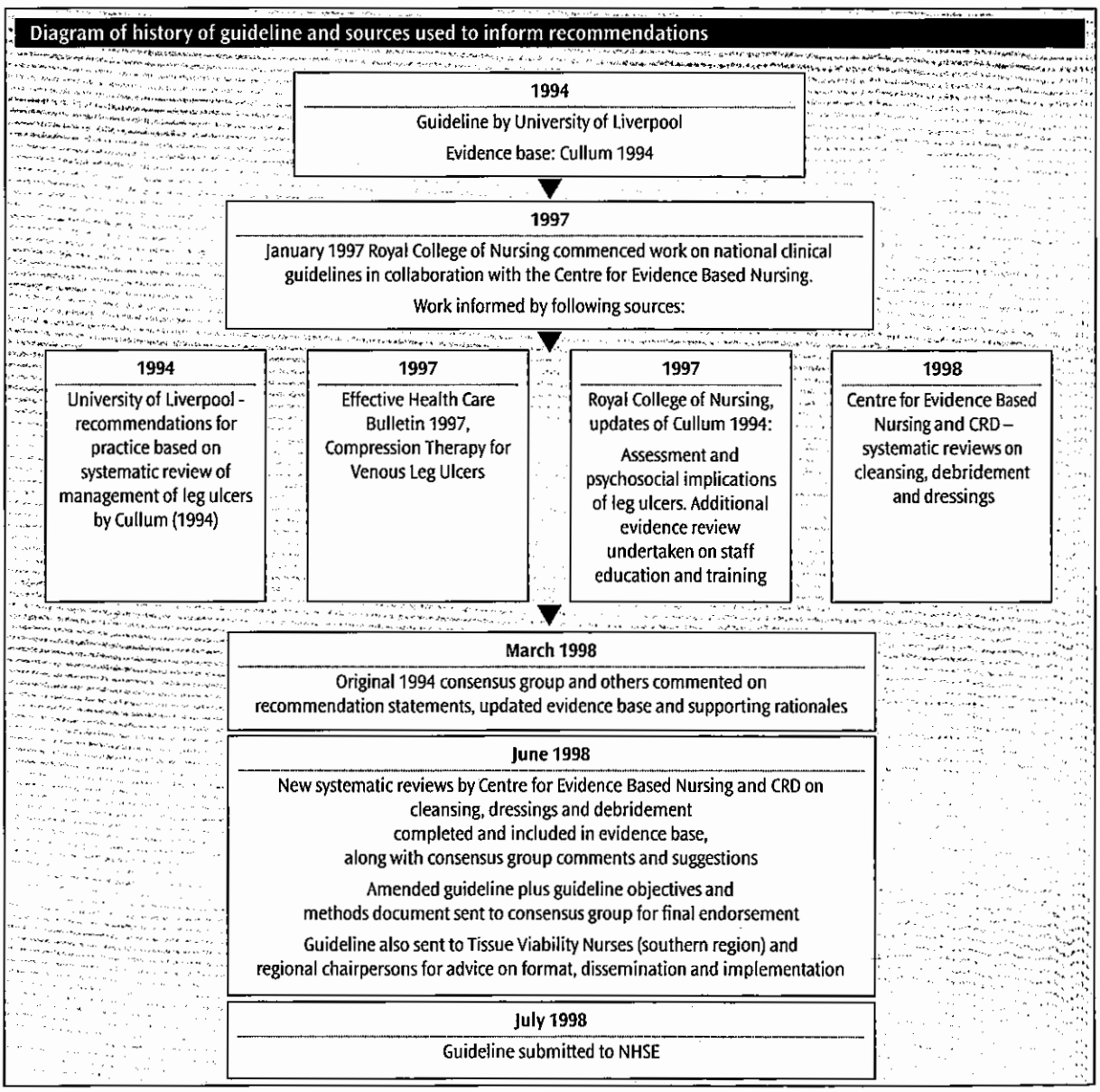
The effectiveness of education/training strategies in the management of leg ulcers *(new review)*.

Quality assurance *(from EHCB, CRD 1997)*.

Reviews on aetiology, prognosis, prevalence, risk factors and healing determinants of leg ulcers were not updated, in order to maintain a manageable focus within the resources dedicated to the guideline. However, some of the guideline recommendations do draw on earlier work on these topics (Cullum 1994), particularly the assessment section. Similarly, research pertaining to leg elevation, exercise, weight control and diet was not reviewed.

Of relevance to those involved in leg ulcer care is that the Royal College of General Practitioners is currently producing a guideline on non-insulin dependent diabetes which will include a section on diabetic foot ulcers and will be available in 1999.

The diagram below summarizes the history of the guideline and how the various pieces of work link together.



1 Introduction

In 1996 the National Health Service Executive (NHSE) commissioned the Royal College of Nursing (RCN) to complete an evidence-linked clinical guideline for primary health care professionals on the management of uncomplicated venous leg ulcers. This builds on previous work undertaken in 1994 on an NHSE funded guideline. The remit was to update the evidence base of the 1994 guideline recommendations, and this was undertaken in collaboration with the Centre for Evidence Based Nursing (CEBN) at the University of York. Accordingly, the evidence base for these clinical recommendations is based on updated sections of an earlier systematic review (Cullum 1994), an evidence review of staff training/education, the 1997 Effective Health Care Bulletin (EHCB) on compression therapy for venous ulcers (NHS Centre for Reviews and Dissemination (CRD) 1997) and expert opinion where the evidence was weak or lacking. The guideline has been developed to direct multidisciplinary care towards clinically appropriate and cost-effective interventions based on the best scientific evidence where available (Shiffman 1997).

The technical report comprises the following documents:

- The guideline objectives and development method (part 1 of this document), with the following appendices:
  i. Contributors to the guideline
  ii. Methods of updating original systematic review: leg ulcer assessment, psychological implications of leg ulcer disease and new review on training/education on leg ulcer care
  iii. Data extraction/quality criteria forms
- The guideline: recommendations for practice with rationale and strength of evidence, with the following appendices:
  i. Evidence tables for updated sections
  ii. Effective Health Care Bulletin on Compression Therapy for Venous Leg Ulcers (CRD 1997)

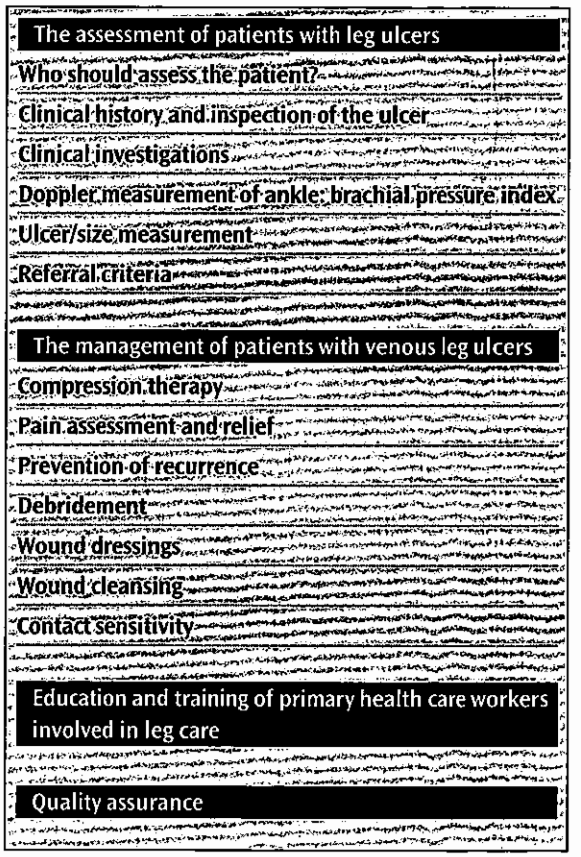
The EHCB on compression therapy is appended to the recommendation document, so its methods and evidence tables are not duplicated here.

2 Aims of the guideline

- To provide health professionals with evidence-linked recommendations on leg ulcer assessment and management in order to reduce variations in the management of venous ulcers
- To reduce the likelihood of unproven and harmful methods of assessment and management being practised
- To highlight research gaps in reviewed topics

The main recommendations are aimed at directing practitioners to the most effective method of assessment and treatment of uncomplicated venous leg ulcers, and at discouraging the practice of strategies which do not have convincing or sufficient evidence of effectiveness. Morbidity associated with harmful and ineffective practices should be reduced and treatment costs lowered.

3 What the guideline covers



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