

PRIORITY BRIEFING

The purpose of this briefing paper is to aid Stakeholders in prioritising topics to be taken further by PenCLAHRC as the basis for a specific evaluation or implementation research project. This paper was compiled in 2–3 days.

Are the multidisciplinary foot care and foot protection teams in the South West Peninsula effective in reducing diabetic foot complications?

Original Submitted Question

Question ID: 1

Question type: Implementation

How could we implement a structured training package delivered by a multidisciplinary team to people with Type 2 diabetes within 3 months of being identified as high risk of foot ulcers, with the aim of reducing the presentations of foot complications?

Current problem: The recently published The NHS Atlas of Variation in Healthcare (DaSilva and Gray 2010) identifies the South West of England as worst in relation to the incidence of major amputations in people with Type 2 diabetes, although this study did not take into account the prevalence of diabetes in a region, the number of specialist centre's and the social, ethnic case mix.

Current NICE guidelines on type 2 diabetes on prevention and management of foot problems state that people with high risk of foot ulcers should be seen between every one to three months by a foot protection team. The guidance also suggests that research needs to be carried out to assess the appropriate level and combination of risk factors at which patients should be categorised as at high risk for ulceration and be offered attendance on a protection programme.

A paper by Donohoe et al (2000) suggests that provision of integrated care arrangements for the diabetic foot has a positive impact on primary care staffs' knowledge and patients' attitudes resulting in an increased number of appropriate referrals to acute specialist services. This work suggests that patients who have been identified as at risk or high risk can benefit from additional support but in the longer term no implementation of a structured education package has been followed up.

The existing evidence suggests that the delivery of a structured education and follow up care package is required to educate and support patients and reduce incidence of acute foot complications. A trained member of a foot protection team could deliver this package of care, ideally a podiatrist or health care professional with specific foot health knowledge.

Service and setting: Some work is already being done locally in North Devon with the introduction of a multi-disciplinary team in June 2009 to support NICE guidelines and care of people with foot care emergencies and foot ulcers. Preliminary data suggests that this intervention has reduced the rate of below knee amputations.

Population: Patients with Type 2 diabetes who following their diabetes check up

have been categorized as high risk but have no previous history of foot ulceration.

Proposed solution: We need to implement and evaluate a method for identifying patients at 'risk' and provide them with a structured one to one education package that supports patients to perform daily preventive self-care and to encourage behaviours that minimize precipitating factors of foot ulceration.

This will be a two tiered approach; short term to establish the validity of the education package by examining how much of the information the patients have retained and put into practice after 6-12 months. Secondly; long term to provide an education package and follow up at 5-10 years. This will be evaluated using data about incidence of acute hospital admissions for foot complications and presentation for foot care at GP surgeries to demonstrate the education packages validity. A questionnaire will be filled in by participants to evaluate quality of life factors.

The structured education package will include:

- Inspection of patients feet
- Vascular assessment/onward referral
- Intensive foot care education – detailing internal/ external factors that may have a role in development of foot ulcers
- Footwear and insole discussion
- Positive self care foot care behavior
- Contact details in case of emergency.

Outcomes: Success will be measured by:

- Improved adherence to preventative self care measures of the diabetic foot,
- Reduction in presentation of foot ulcers and ultimately a reduction in minor and major amputations.
- Decrease in costs to NHS by reducing presentations at GP Surgeries and ultimately acute admissions for diabetic foot problems.
- Reduce cost of treatment of foot ulcers through earlier presentation of problems.
- Improved quality of life for patients and carers.

This implementation project has been developed in partnership with and active involvement of members of the Diabetes UK North Devon Voluntary Group.

*Please note that the details included in the box are from the original submission and have been edited where necessary for clarity and precision

Definitions and Note on Executive Prioritisation Stage

Diabetic foot complications: A spectrum of complications arising from long-standing or uncontrolled diabetes, where the multifactorial effects of impaired blood flow to the foot, nerve and sensation problems, and other complex factors, adversely impact on the normal healing processes of the foot. The range of conditions may present as ulcers, gangrene, infections of the skin, bone or other tissues of the foot,

bone deformities, and other conditions in the foot. These complications result in amputations for some patients.

Foot protection team (FPT): The 2011 National Minimum Skills Framework (NMSF) guidelines recommend that this shall be a multidisciplinary team with specialist expertise in the surveillance and prevention of the foot of people with diabetes from developing into diabetic foot complications. This team works in the community and primary care setting. This team provides

- information and education in various media formats about foot protection
- regular recall and review by specialist podiatrists
- discussion and agreement of plans to support the patient in managing their condition
- referral and close interaction with the multidisciplinary foot care team (e.g. orthotist for special footwear and other interventions aimed at minimising the risk of trauma (when appropriate))
- early referral and intervention for foot lesions
- shared long-term management with other health care providers of people with successfully treated diabetic foot

Multidisciplinary foot care team (MFCT): the NMSF also recommends the formation of this other team: a specialised multidisciplinary team, working together or in close communication, providing rapid access (usually within 24 hours) for the assessment and management of people with diabetes who develop diabetic foot for the first time or those with established diabetic foot. The team includes a core of highly trained specialist podiatrists and orthotists, nurses with training in the dressing of diabetic foot wounds, and diabetologists with expertise in diabetic lower limb complications. Other combinations of staff which the team needs to either include, or have ready access to, are:

- vascular, orthopaedic and/or plastic surgeons
- other medical staff including microbiologists
- diagnostic and Interventional radiologists
- diabetes specialist nurses
- plaster theatre nurses
- other nursing staff

Members of the MFCT will usually be based in a hospital and members will be readily available for consultation with other health care teams. Outpatients will be referred to this team for appropriate care and the team will refer patients back to the community for those whose diabetic feet have been successfully treated.

Members of the FPT might also be members of the MFCT, although there is a distinction between the settings and purpose of the teams i.e. FPTs are based more in community and primary care and are more concerned with prevention; while MFCTs are with management of active diabetic foot complications.

PenCLAHRC Executive Prioritisation Stage

The original question focusses on the effectiveness of *an education package for patients delivered by podiatrists*. At the PenCLAHRC Executive, first stage prioritisation meeting, this question was considered. The Executive noted the existence of a number of multidisciplinary teams across the SW Peninsula concerned with prevention and management of diabetic foot problems. The discussion considered whether it would be more appropriate to alter the submitted question, and prioritised a question focussed on the effectiveness of foot care services for people with diabetes and diabetic foot problems i.e.

“Are multidisciplinary foot care and protection teams in the South West Peninsula effective in reducing diabetic foot complications?”

Stakeholders are asked to consider both the original question, which focusses on the effectiveness of education provided by podiatrists, and the substantially altered question which was prioritised by the Executive. The priority briefing includes information on current uncertainties regarding the effectiveness of educational packages (the original question, although this was submitted as an Implementation Issue).

It will be necessary to establish the preferred focus of the question prior to voting on this topic at the Stakeholder meeting.

The Health Problem:

The prevalence of diabetes in the UK is around 4%. Figures from the 2010 South West Regional Health Summit on Diabetes show that in the South West region, 224,000 people aged over 16 are diagnosed with diabetes, equating to 5.1% of the over 16 population. By 2030, the total estimated prevalence in the region may be 486,000, or 9.4% of the population.

Diabetes UK reports that approximately 15% of people with diabetes develop foot ulcers at some stage in their lives and around 15% of foot ulcers result in amputation, which may be below or above the ankle. It is estimated that up to 80% of these amputations may be preventable. Amputation is associated with mortality, with up to 70% of people dying within five years of operation. This shows the importance of the development of foot complications as an indication of general health status in diabetes and, in some cases, the influence of amputation as an important adverse event carrying independent risks of further decline. Morbidity associated with diabetic foot complications is significant, prior to and beyond amputation. Despite this, in 2007/8, nearly a quarter (23%) of people with diabetes did not have a “foot check”.

There is some evidence that the burden of diabetic foot is higher in the South West than the rest of England. The NHS’s Right Care Atlas of Variation in Health Care

reveals that the five year incidence of major amputations in the South West in 2009 is 3 in 1000 people compared to the 2.4 in 1000 ratio for England.

The treatment of diabetic foot complications is costly. Diabetes UK reports that in 2007 around £9 billion (10%) of the NHS budget was spent on diabetes. And of this, approximately £500 million a year is spent on the management of diabetic foot complications, and about £200 million spent on amputations.

Guidelines:

NICE has produced a range of guidance relating to diabetic foot care, including a revised Clinical Guideline on the management of diabetic foot problems in hospital (2011) and a new Quality Outcome Framework indicator in 2011/12

- *“People with or at risk of foot ulceration receive regular review by a Foot Protection Team in accordance with NICE guidance, and those with foot problems requiring urgent medical attention are referred to and treated by a Multidisciplinary Foot Care Team within 24 hours”*

Current guidelines do not specify who should provide patient education, and they suggest that different models, approaches and means of delivery of patient education should be further investigated, as there is still insufficient evidence on the best method to provide patient education.

NHS Priority:

Regional

Long term conditions are highlighted as a priority in the ambitions of the SW Strategic Priorities Framework, 2008-2011. Diabetes is amongst the most important long term conditions involving most sectors within the NHS and with significant opportunities for health gain through effective self-care and consistent high quality health service delivery.

Local

Diabetes clearly falls within a range of priority areas for local commissioners, although the condition itself is not specifically identified as one of the 26 priorities for the ‘World Class Commissioning’ Programme. For example:

- all four PCTs have identified “Helping people to stay healthy”;
- Devon has identified “Reduce mortality rates from causes amenable to healthcare”;
- Cornwall has identified “Deliver new and existing targets set by the Care Quality Commission or within the NHS Operating Plan (the ‘Minimum Guarantee’)” (which includes diabetes related targets)
- All four PCTs are working towards becoming world class commissioning organizations by 2012.

Existing Research:

Published research

We identified two relevant Cochrane reviews in this area; one on the use of complex interventions in the prevention of diabetic foot ulceration¹ and one on the effects of patient education for the prevention of diabetic foot ulceration².

In the review of complex interventions, the authors report that the intervention in two of the five studies included a multidisciplinary team, although these were not structured exactly as envisaged in the UK guideline documents.^{3,4}

In both trials, there were interventions aimed at (a) direct patient care (how patients are managed), which was termed 'patient level interventions' and (b) interventions aimed at the health system and structures, termed by the reviewers as 'structural level interventions'.

In McCabe and colleagues' 1998 trial³, patient level interventions included a foot ulceration risk assessment and weekly diabetic foot clinic visits. The structural level interventions were: 'continuity of care' (e.g. appointment reminder letters), and 'changes in scope and nature of benefits and services' (more intensive follow up of at risk patients).

In McMurray and colleagues' 2002 trial⁴, patient level interventions include an individualized plan of care, individualized self-management education, written educational information, regular foot status monitoring and motivational coaching. And their structural interventions were 'revision of professional roles', 'clinical multidisciplinary teams', 'continuity of care' and 'formal integration of services'.

One of the five trials reported a statistically significant improvement on amputation and foot ulceration incidence³. However, the reviewers suggest that the methods used in this study may have introduced a degree of bias (such as uncertain allocation concealment and blinding) and therefore the results should be viewed with caution and further research is necessary to confirm the findings¹.

There are also some studies with less robust designs (for example those not implementing an intervention and/or those not randomly allocating respondents to intervention groups) that suggest multidisciplinary teams providing care for individuals with, and prevention against diabetic foot ulceration may help reduce rates of diabetic foot ulcers and amputations⁵⁻⁷.

As for the Cochrane review on patient education for diabetic foot², eleven trials were included. The reviewers were able to identify three types of educational package interventions:

- i) Foot care education as part of general diabetes education compared with usual care - which had three trials
- ii) Non-intensive foot care education compared with no intervention – two trials
- iii) Intensive compared with brief educational interventions for diabetic foot (six trials)

Four of these trials looked at prevention of ulcers or amputations as outcomes. Three of the four trials implemented an intensive education package and one of them looked at foot care education as part of education for diabetes in general. One of these four trials found that patient education was effective in reducing the incidence of foot ulcers or amputations. The reviewers noted however that this trial had a high risk of bias. The other three studies, one of which had the least risk of bias amongst all eleven included trials, did not find that patient education was effective in reducing the incidence of these complications. The reviewers however did not pool the results of these studies as they were markedly different from each other.

As for the patients' foot care knowledge, the review found a positive short-term effect of education on this outcome in five of the eight RCTs in which this outcome was assessed.

In general however, the review found that most of the studies had a risk of bias (such as not recruiting enough participants, unclear blinding, unconcealed allocation of intervention, risk of selective reporting of results, etc). The one trial with low risk of bias found that limited patient education did not result in a beneficial effect on the outcomes of amputation or ulcer prevention. The review concludes that overall, little evidence is available to support the effectiveness of patient education for the prevention of diabetic foot complications, and that foot care knowledge and patient behaviour seem to be positively influenced by diabetic foot education in the short-term.

Ongoing research

Searches in BioMed Central's Current Controlled Trials, the International Standard Randomised Controlled Trial Number registry, the US clinicaltrials.gov, and the World Health Organisation's International Clinical Trials Registry Platform revealed no ongoing research evaluating the effectiveness of

- i) multidisciplinary teams to prevent or care for diabetic foot
- ii) education packages to prevent complications of diabetic foot

Feasibility:

The Exeter Integrated Footcare programme has similar aims to those described above - to detect high-risk patients and to provide them education and footcare. Two consultants from the Exeter Diabetes Team have indicated that they would be interested in being involved in this project if it is prioritized.

References:

1. Dorresteijn, J.A.N., D.M.W. Kriegsman, and G.D. Valk, Complex interventions for preventing diabetic foot ulceration. Cochrane Database of Systematic Reviews, 2010(1).

AB: BACKGROUND: Ulceration of the feet, which can lead to the amputation of feet and legs, is a major problem for people with diabetes mellitus, and can cause substantial economic burden. Single preventive strategies have not been shown to reduce the incidence of foot ulceration to a significant extent. Therefore, in clinical practice, preventive interventions directed at patients, health care providers and/or

the structure of health care are often combined (complex interventions). OBJECTIVES: To assess the effectiveness of complex interventions on the prevention of foot ulcers in people with diabetes mellitus compared with single interventions, usual care or alternative complex interventions. A complex intervention is defined as an integrated care approach, combining two or more prevention strategies on at least two different levels of care: the patient, the healthcare provider and/or the structure of healthcare. SEARCH STRATEGY: Eligible studies were identified by searching the Cochrane Wounds Group Specialised Register (28/05/09), the Cochrane Central Register of Controlled Trials (CENTRAL, 28 May 2009), Ovid MEDLINE (1950 to May Week 3 2009), Ovid EMBASE (1980 to 2009 Week 21) and EBSCO CINAHL (1982 to May Week 4 2009). SELECTION CRITERIA: Prospective randomised controlled trials (RCTs) which compared the effectiveness of combinations of preventive strategies, not solely patient education, for the prevention of foot ulcers in people with diabetes mellitus, with single interventions, usual care or alternative complex interventions. DATA COLLECTION AND ANALYSIS: Two review authors were assigned to independently select studies, to extract study data and to assess risk of bias of included studies, using predefined criteria. MAIN RESULTS: Only five RCTs met the criteria for inclusion. The study characteristics differed substantially in terms of health care settings, the nature of the interventions studied and outcome measures reported. In three studies that compared the effect of an education centred complex intervention with usual care or written instructions only, little evidence of benefit was found. Two studies compared the effect of more intensive and comprehensive complex interventions with usual care. One of these reported improvement of patients' self care behaviour. In the other study a significant and cost-effective reduction of lower extremity amputations (RR 0.30 (95% CI 0.13 to 0.71)) was achieved. All five included RCTs were at high risk of bias; with hardly any of the predefined quality assessment criteria met. AUTHORS' CONCLUSIONS: There is no high quality research evidence evaluating complex interventions for preventing diabetic foot ulceration and insufficient evidence of benefit. COMBINING STRATEGIES TO AVOID FOOT ULCERS IN PATIENTS WITH DIABETES MAY ONLY BE EFFECTIVE IN THOSE AT HIGH RISK: Foot ulcers (open sores) are common in people with diabetes mellitus (type 1 and type 2), especially those with problems in the nerves (peripheral neuropathy) and/or the blood supply to their legs (peripheral vascular disease). People with ulcers due to diabetes will sometimes need an amputation (surgical removal of part of the limb). Foot ulcers not only lead to physical disability and loss of quality of life, but also to economic burden (health care costs, industrial disability). The aim is therefore to prevent foot ulcers occurring, for example, by showing patients with diabetes how to look after their feet or by prompting doctors to check their patients' feet more often. The results of single prevention strategies alone have so far been disappointing therefore, in clinical practice, preventive interventions directed at patients, health care providers and/or the structure of health care are often combined. In this review of trials of complex, preventive interventions, we found insufficient evidence that these combined approaches can be effective in reducing foot problems.

2. Dorresteijn, J.A.N., D.M.W. Kriegsman, W.J. Assendelft, and G.D. Valk, Patient education for preventing diabetic foot ulceration. Cochrane Database of Systematic Reviews, 2010(5).

AB: BACKGROUND: Ulceration of the feet, which can result in loss of limbs and even death, is one of the major health problems for people with diabetes mellitus.

OBJECTIVES: To assess the effects of patient education on the prevention of foot ulcers in patients with diabetes mellitus. **SEARCH STRATEGY:** Eligible studies were identified by searching the Cochrane Wounds Group Specialised Register (22 December 2009), the Cochrane Central Register of Controlled Trials (Cochrane Library 2009 Issue 4), Ovid MEDLINE (1950 to November Week 3 2009), Ovid MEDLINE In-Process & Other Non-Indexed Citations (Searched 22/12/09), Ovid EMBASE (1980 to 2009 Week 51) and EBSCO CINAHL (1982 to December 22 2009). **SELECTION CRITERIA:** Prospective randomised controlled trials (RCTs) which evaluated educational programmes for preventing foot ulcers in people with diabetes mellitus. There was no restriction on language of the publications. **DATA COLLECTION AND ANALYSIS:** Two review authors independently undertook data extraction and assessment of risk of bias. Primary end-points were foot ulceration or ulcer recurrence and amputation. **MAIN RESULTS:** Eleven RCTs were included. Three studies described the effect of foot care education as part of general diabetes education compared with usual care. Two studies examined the effect of foot care education tailored to educational needs compared with no intervention. Finally, six studies described the effect of intensive compared with brief educational interventions. Pooling of outcome data was precluded by marked, mainly clinical, heterogeneity. Four RCTs assessed the effect of patient education on primary end-points: foot ulceration and amputations. One of these studies reported a statistically significant benefit of one hour group education after one year of follow-up in people with diabetes who were at high risk for foot ulceration; RR amputation 0.33 (95% CI 0.15 to 0.76); RR ulceration 0.31 (95% CI 0.14 to 0.66), however this study was at high risk of bias and may have overestimated the effect due to a unit of analysis error. One similar, but methodologically superior study did not confirm this finding; RR amputation 0.98 (95% CI 0.41 to 2.34); RR ulceration 1.00 (95% CI 0.70 to 1.44). The other two studies did not detect any effect of education on ulcer incidence or amputation but were underpowered. Patients' foot care knowledge was improved in the short term in five of eight RCTs in which this outcome was assessed, as was patients' self reported self care behaviour in the short term in seven of nine RCTs. The effects on callus, nail problems and fungal infections were described in five of the included studies, of which only two reported temporary improvements after an educational intervention. Only one of the included RCTs was considered to be at low risk of bias. **AUTHORS' CONCLUSIONS:** Most of the RCTs included in this review are at high or unclear risk of bias. In some trials, foot care knowledge and self reported patient behaviour seem to be positively influenced by education in the short term. This, however, must be viewed with caution. The ultimate goal of educational interventions is preventing foot ulceration and amputation but only four RCTs reported these outcomes and only two reported sufficient data to examine this. Based on these two studies, we conclude that there is insufficient robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence. Future research should focus on evaluating the effect of more comprehensive and/or intensive prevention strategies which may also include patient education (complex interventions). This review of high level studies found that educating people with diabetes about the need to look after their feet seems to improve people's foot care knowledge and behaviour in the short term. There is insufficient evidence that education alone, without any additional preventive measures, will effectively reduce the occurrence of ulcers and amputations.

3. McCabe, C., Stevenson, RC, Dolan, AM, Evaluation of a diabetic foot

screening and protection programme. *Diabetic medicine*, 1998. 15(1): p. 80-4.

We set out to evaluate a clinical foot-screening programme in terms of primary outcomes (reductions in the incidence of ulcers and lower limb amputation) and process outcomes (compliance with screening, the number of patients not completing the programme and the use of chiropody services and prescribed footwear and cost). All but 4 of 2001 patients attending a general diabetic out-patient clinic were allocated randomly to index and control groups. The exceptions were patients who presented with active ulcers and were placed in the index group. Primary and secondary screening programmes identified 128 high risk patients in the index group and these were admitted to the foot protection programme. At 2-year follow-up, 11 fewer ulcers were reported from the index group. There were 7 amputations (1 major, 6 minor) in the index group and 23 (12 major and 13 minor) in the control group. The differences were not statistically significant for ulceration or minor amputations but significant for major amputations ($p < 0.01$). The total cost of the 2-year programme was pounds sterling 100,372 (1991-92 costs), with a mean cost per patient of approximately pounds sterling 100. Taking pounds sterling 12,000 as a conservative estimate of the cost of a major amputation, the foot clinic was cost-effective in terms of amputations averted. The process outcomes were much less satisfactory. Cost-effectiveness could have been improved if it had been possible to improve patient compliance.

4. McMurray, S.D., G. Johnson, S. Davis, and K. McDougall, Diabetes education and care management significantly improve patient outcomes in the dialysis unit. *American journal of kidney diseases : the official journal of the National Kidney Foundation*, 2002. 40(3): p. 566-575.

Background: The incidence of diabetes mellitus, particularly type 2, is increasing in the general population. Similarly, the incidence of patients with diabetes mellitus who develop end-stage renal disease has increased concomitantly in the dialysis facility to 44% of patients starting dialysis therapy with diabetes mellitus as their primary diagnosis. The aim of this study is to determine whether intensive education and care management of diabetes could improve glycemic control, alter patient behavior, and reduce complications in the setting of the dialysis unit. Methods: Eighty-three patients were allocated to either the control group or study group based on their day of dialysis treatment. All patients were followed up for a year. Patients in the study group underwent a diabetes education program and were followed up by a care manager who provided self-management education, diabetes self-care monitoring/management, motivational coaching, and foot checks. Results: The control group baseline foot risk category worsened from 2.7 to 3.3 ($P < 0.05$), whereas it was unchanged in the study group (2.2 to 2.0). There were no amputations in the study group versus five amputations in the control group ($P < 0.05$). Ten patients in the control group were hospitalized with diabetes- or vascular-related admissions versus one patient in the study group ($P < 0.002$). Hemoglobin A1c levels declined from 6.9 to 6.3 in the study group, whereas results of the control group were unchanged ($P < 0.005$). Diabetes-related quality-of-life scores increased in the study group from 76 to 86 ($P < 0.001$ versus the control group). There was a significant improvement in self-management behavior in all six categories evaluated in the study group versus the control group. Dialysis centers were recognized by the American Diabetes Association to provide diabetes education. Conclusion: A program of intensive diabetes education and care management in a dialysis unit is effective in providing significant improvements in patient outcomes, glycemic control,

and better quality of life in patients with diabetes mellitus. © 2002 by the National Kidney Foundation, Inc.

5. Dargis, V., O. Pantelejeva, A. Jonushaite, L. Vileikyte, and A.J. Boulton, Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study. *Diabetes Care*, 1999. 22(9): p. 1428-1431.

OBJECTIVE: To assess the ability of a multidisciplinary approach to diabetic foot care to reduce the incidence of recurrent ulceration and amputations compared with standard care in a 2-year prospective study. **RESEARCH DESIGN AND METHODS:** A total of 145 patients with a past history of neuropathic foot ulcers but no evidence of peripheral vascular disease entered the study. Subjects were screened for their neuropathic and vascular status at baseline, and all received identical foot care education. The intervention group (n = 56) was followed by the multidisciplinary team of physicians, nurses, and podiatrists with regular podiatry and reeducation every 3 months and the provision of specialty footwear as required. The standard treatment group was followed in local clinics on a trimonthly basis and received identical screening and education at baseline. **RESULTS:** There were no significant differences at baseline in age (intervention 59.2+/-13.4, standard treatment 58.5+/-11.5 years), duration of diabetes (14.0+/-7.1 vs. 15.6+/-7.8 years), or neuropathic status (vibration perception threshold [VPT]: 31.1+/-12.1 vs. 33.9+/-11.3 V, neuropathy disability score [NDS]: 8.1+/-1.4 vs. 7.9+/-1.7). All patients had an ankle brachial pressure index (ABPI) of >0.9 and at least one palpable foot pulse. Significantly fewer recurrent ulcers were seen in the intervention group than in the standard treatment group during the 2-year period (30.4 vs. 58.4%, P < 0.001). **CONCLUSIONS:** This prospective study has demonstrated the effectiveness of a multidisciplinary approach to diabetic foot care together with the provision of specialty footwear in the long-term management of high-risk patients with a history of neuropathic foot ulcers.

6. Larsson, J., A. Stenström, J. Apelqvist, and C.D. Agardh, Decreasing Incidence of Major Amputation in Diabetic Patients: a Consequence of a Multidisciplinary Foot Care Team Approach? *Diabetic Medicine*, 1995. 12(9): p. 770-776.

The purpose of this retrospective study was to evaluate the changes in diabetes-related lower extremity amputations following the implementation of a multidisciplinary programme for prevention and treatment of diabetic foot ulcers in a 0.2 million population with a 2.4 % prevalence of diabetes. All diabetes-related primary amputations from toe to hip from 1 January 1982 to 31 December 1993 were included. In 294 diabetic patients, 387 primary major (above the ankle) or minor (through or below the ankle) amputations were performed, constituting 48 % of all lower extremity amputations. The annual number of amputations at all levels decreased from 38 to 21, equalling a decrease of incidence from 19.1 to 9.4/100 000 inhabitants (p = 0.001). The incidence of major amputations decreased by 78% from 16/1 to 3.6/100 000 inhabitants (p<0.001). The absolute number of amputations with a final level below the ankle showed no increase, but their proportion increased from 28 to 53 % (p<0.001) and the reamputation rate decreased from 36 to 22 % (p<0.05) between the first and last 3-year period. Thus, a substantial long-term decrease in the incidence of major amputations was seen as well as a decrease in the total incidence of amputations in diabetic patients. Seventy-one per cent of the

amputations were precipitated by a foot ulcer. These findings indicate that a multidisciplinary approach plays an important role to reduce and maintain a low incidence of major amputations in diabetic patients

7. Armstrong, D.G. and L.B. Harkless, Outcomes of preventative care in a diabetic foot specialty clinic. *The Journal of Foot and Ankle Surgery*, 1998. 37(6): p. 460-466.

The purpose of the study was to report the incidence of ulceration, reulceration, and amputation in 341 patients treated in a multidisciplinary clinic over the course of 3 years. Patients enrolled were 57.8% male, with a mean age of 53.2 ± 11.8 years. All were assessed using the University of Texas Diabetic Foot Classification System. Of these patients, 118 fell into category 0 (protective sensation intact), 98 into category 1 (loss of protective sensation, LOPS), 77 into category 2 (LOPS with deformity), and 48 into category 3 (LOPS, deformity, previous history of ulcer or amputation). Outcomes assessed included any incident ulcerations or amputations. The authors stratified patients based on their compliance to follow up appointments. Non compliance was defined as missing >50% of scheduled appointments in any calendar year. Thirty of the above subjects were classified as noncompliant. Prior to analysis, the authors initially stratified subjects into compliant and noncompliant groups. If further stratified by foot category, the incidence of ulceration in the compliant group was 0 for diabetic foot categories 0 and 1, 3.5/1,000/ year for category 2, and 18/1,000/year for category 3. One category 3 patient required a partial first-ray amputation. The yearly incidence of amputation for the entire cohort was therefore 1.1/1,000/year. For categories 0-2 the incidence was 0, and for category 3, it was 9/1,000/year. Patients stratified into the noncompliant group were approximately 54 times more likely to ulcerate than patients who returned regularly for their scheduled care (81.8% ulcer prevalence vs. 5.4%, $p < .0001$, OR = 54.0, CI = 7.5-1, 425.0). Additionally, noncompliant category 3 patients were over 20 times more likely to receive an amputation than their compliant counterparts (45.5% amputation prevalence vs. 2.7%, $p < .002$, OR = 2.5-819.0). The study concluded that multidisciplinary diabetes care team, which includes aggressive foot care and consistent treatment-based risk classification, may be effective in profoundly mitigating the occurrence and recurrence of diabetic foot sequelae, including ulceration and amputation. Furthermore, patient noncompliance to routine preventative care appears to be associated with a significantly higher prevalence of ulceration and amputation.