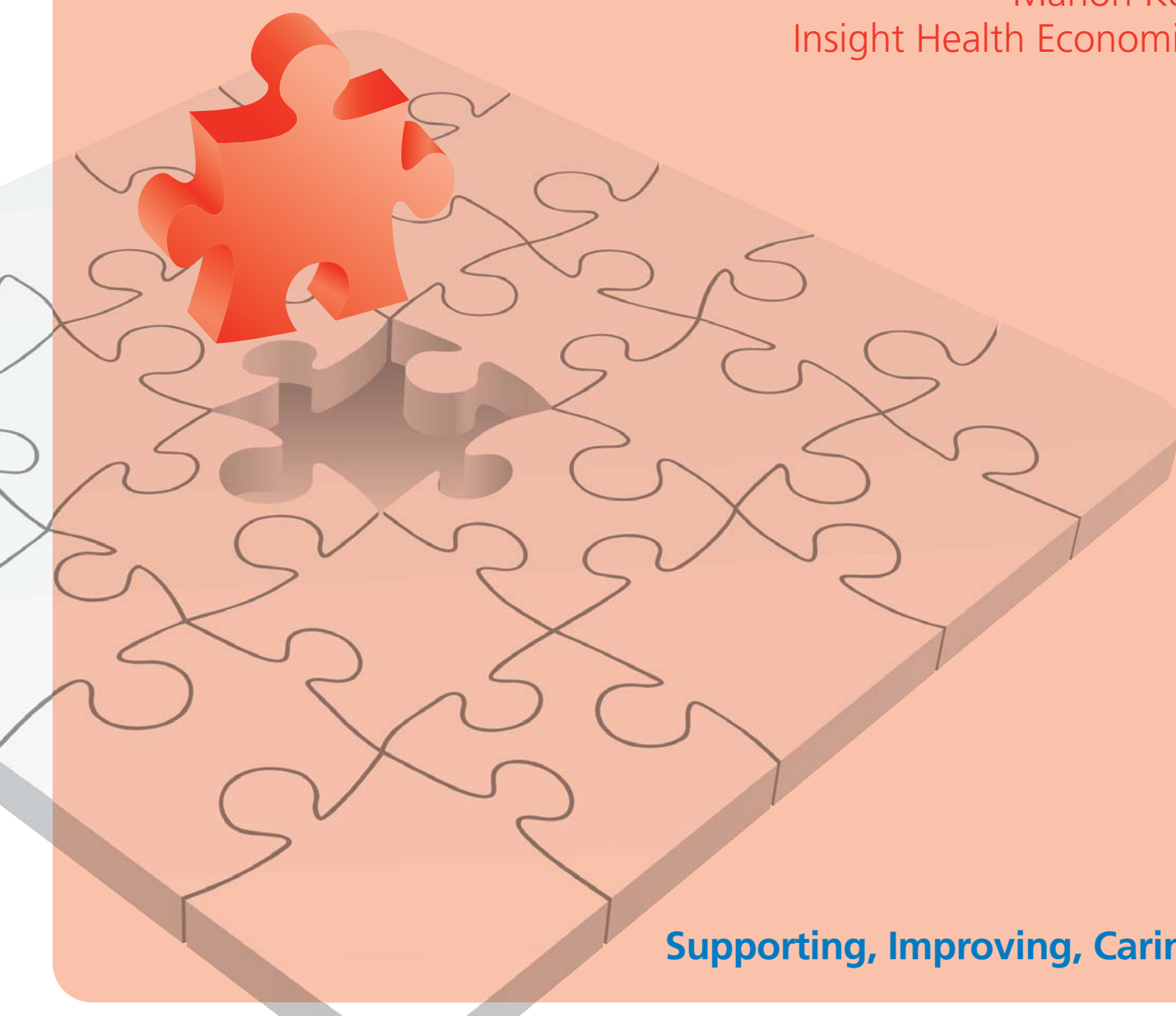


Foot Care for People with Diabetes: The Economic Case for Change

Marion Kerr
Insight Health Economics



Supporting, Improving, Caring

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Abbreviations

APHO:	Association of Public Health Observatories
HES:	Hospital Episode Statistics
HRG:	Healthcare Resource Group
MDT:	Multidisciplinary diabetic foot care team
PbR:	Payment by Results
PSSRU:	Personal Social Services Research Unit
NDA:	National Diabetes Audit
NICE:	National Institute for Health and Clinical Excellence
ONS:	Office for National Statistics
PCT:	Primary Care Trust
QALY:	Quality-adjusted life-year
QOF:	Quality and Outcomes Framework
RCT:	Randomised controlled trial
SF-6D:	Short Form 6D
SF-36:	Short Form 36
STARRS:	Short Term Assessment, Rehabilitation and Reablement Service
YHPHO:	Yorkshire and Humber Public Health Observatory
WTE:	Whole-time equivalent

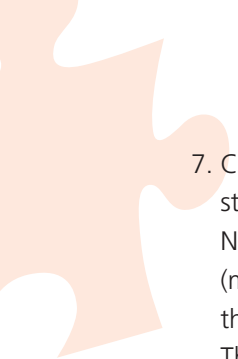
Executive Summary

1. Around 6,000 people with diabetes undergo leg, foot or toe amputation each year in England. Many of these amputations are avoidable. The risk of lower extremity amputation for people with diabetes is more than 20 times that of people without diabetes. Major amputation rates in people with diabetes vary ten-fold across primary care trusts.
2. Around 61,000 people with diabetes are thought to have foot ulcers at any given time, approximately 2.5% of the diabetes population.
3. Ulceration and amputation substantially reduce quality of life, and are associated with high mortality. Studies suggest that only 50% of patients with diabetes who have had an amputation survive for a further two years. Even without amputation, the prognosis is poor. Only around 56% of people with diabetes who have had ulcers survive for five years.
4. In 2010-11, the NHS in England spent an estimated £639 million–£662 million, 0.6–0.7% of its budget, on diabetic foot ulceration and amputation (Table A).

Table A Estimated cost of ulceration and amputation in people with diabetes, England, 2010–11

	Lower estimate	Upper estimate
Primary, community and outpatient care	£306,508,970	£323,062,601
Accident and emergency		£849,278
Inpatient care – ulceration	£213,151,916	£213,151,916
Inpatient care – amputation	£43,546,901	£48,896,735
Post-amputation care	£75,807,423	£75,807,423
Total	£639,015,210	£661,767,953

5. The focus of this paper is on costs to the NHS, but ulceration and amputation also impose costs on patients and their carers, through lost working days and reduced mobility. These work and mobility effects also entail costs to the public purse through reductions in tax revenue, increases in benefit payments and use of social care resources. If all these effects were taken into account the total cost of diabetic foot ulcers and amputations, both to the public sector and to society as a whole, would be higher than the figures set out in this paper.
6. Clinical evidence suggests that there is considerable potential to improve the quality of foot care for people with diabetes. Targeted preventive services can identify those at risk of ulceration and improve outcomes, and rapid access to multi-disciplinary foot care can lead to faster healing, fewer amputations and improved survival.

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7. Clinical and economic evidence suggests that multidisciplinary diabetic foot care teams (MDTs) with strong links to community podiatry services can improve patient outcomes and generate savings for the NHS that substantially exceed the cost of the team. For example, lower-extremity amputation rates (major and minor combined) at James Cook University Hospital, Middlesbrough, fell by two-thirds after the introduction of an MDT. The annual cost of the team is estimated, in 2010–11 prices, at £33,000. The annual saving to the NHS from averted amputations is estimated at £249,000, more than seven times the cost of the team. Monetised quality-adjusted life-year (QALY) gains (at a value of £25,000 per QALY) over a 5-year perspective for a 1-year cohort of patients who averted major amputation are estimated at £151,000.
 8. It is believed that around one-fifth of hospitals providing inpatient care for people with diabetes have no MDT. In many areas of the country there are no clear pathways for referral of increased-risk or high-risk patients to foot protection teams, or for rapid referral of patients with new ulcers to MDTs, as recommended in clinical guidelines from the National Institute for Health and Clinical Excellence (NICE).

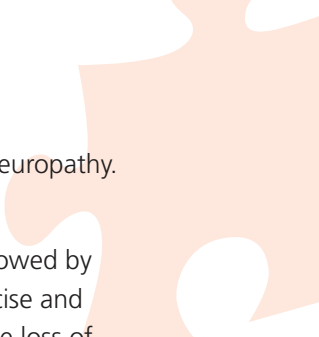
Introduction

9. The purpose of this paper is to summarise the health economic evidence relating to foot care in diabetes, and to examine the potential for quality and productivity improvements.
10. A pragmatic review of available clinical and economic evidence has been conducted, identifying relevant papers and assessing the robustness of the evidence presented. A systematic review of all available evidence has not been conducted and is beyond the scope of this paper. A systematic review of interventions for foot ulcers in diabetes was published in 2012¹.
11. The National Institute for Health and Clinical Excellence (NICE) published clinical guidelines for the prevention and management of foot problems in type 2 diabetes in 2004,³ guidelines for type 1 diabetes in 2011,² and guidelines for inpatient management of diabetic foot problems in 2011.⁴ NICE Diabetes in Adults Quality Standards (2011) include a standard relating to foot care.⁵ A National Minimum Skills Framework for commissioning foot care services for people with diabetes was published in 2011.⁶ Diabetes UK and NHS Diabetes published *Putting Feet First*, guidance on the management and prevention of diabetic foot disease in hospitals, in 2009,⁷ and NHS Diabetes published a commissioning guide for diabetes foot care services in 2010.⁸ This paper takes the standards set out in these publications as a framework. Reference is made to the evidence reviewed in these publications, where appropriate.
12. The paper is divided into four sections. Section I examines the scale of the problem – the incidence and prevalence of foot problems in diabetes, the impact on quality of life, prognosis and mortality, and available evidence on the quality of current care. Section II examines clinical and economic evidence on the potential to improve foot care in diabetes, and for such improvements to be cost effective and/or cost saving. Section III sets out cost estimates of current foot care for people with diabetes in England. Section IV examines the impact of MDTs on patient outcomes and NHS costs.

Section I The Scale of the Problem

Chapter 1. Incidence and Prevalence of Foot Ulceration and Amputation in Diabetes

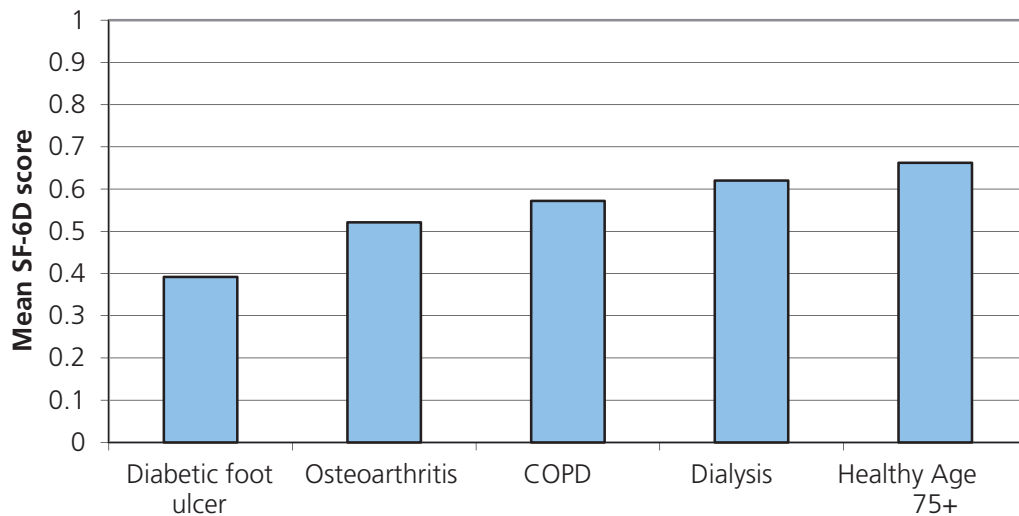
13. Foot complications are common in people with diabetes. A community based study of 811 people with type 2 diabetes from 37 general practices in Manchester, Salford and Sheffield in 1994 found that 5.3% had current or past foot ulcers.⁹ An earlier study of all diabetic patients in ten GP practices found the prevalence of past or present foot ulceration was 7.4%, as compared with 2.5% in a non-diabetic comparison group¹⁰. The Oxford Community Diabetes Study found foot ulcer prevalence of 7% in diabetic patients aged 60 years or more.¹¹
14. A community-based study of 9,710 diabetic patients in North-West England, published in 2002, found an average annual incidence of foot ulcers of 2.2%.¹² (This figure relates to the percentage of patients experiencing at least one new foot ulcer in a year. As some patients are likely to have ongoing ulcers from previous years, the total number of patients with foot ulcers in a year cannot be extrapolated from these figures).
15. Data on foot ulcer incidence and prevalence in diabetes are not collected at national level in England. In Scotland the SCI-DC Network extracts diabetes-related data from almost all GP practices and specialist diabetes clinics. 2.5% of the diagnosed diabetes population in Scotland had current foot ulcers at the beginning of December 2010.¹³ Data from one English foot care clinic, Salford Royal NHS Foundation Trust, indicate that approximately 2.5% of the local diabetes population have foot ulcers at any given time.¹⁴
16. If it is assumed that national ulceration rates in England are similar to those in Scotland and Salford, we can estimate that 61,400 people with diabetes in England have foot ulcers at any given time. This figure is based on the diagnosed diabetes population in England, as measured in the Quality and Outcomes Framework (QOF).¹⁵ This is likely to be an under-estimate, as it does not include people who have undiagnosed diabetes. The Association of Public Health Observatories recently estimated that total diabetes prevalence may be as much as 27% higher than the figure derived from QOF registers.¹⁶
17. As indicated above, the prevalence of diabetic foot ulcers (current or past) has been estimated at 5–7% of the diabetes population. This would suggest that around 130,000–180,000 people with diabetes have current or past foot ulcers. Again, these figures are based on the diagnosed diabetes population, as recorded in the QOF. The true figure may be higher in view of undiagnosed diabetes prevalence.
18. The burden of diabetic foot disease is likely to increase; the incidence of type 2 diabetes is rising and contributory factors to foot disease, such as peripheral neuropathy and vascular disease, are present in more than 10% of people at the time of diagnosis of type 2 diabetes.¹⁷
19. The National Diabetes Audit (NDA) estimated that approximately seven out of every 10,000 people with diabetes underwent a major lower extremity amputation in 2009–10, and 13 out of 10,000 had a minor amputation.¹⁸ A recent study found that there were 25.1 lower extremity amputations (major and minor) a year for every 10,000 people with diabetes between 2007 and 2010. The risk of a person with diabetes undergoing a lower extremity amputation was estimated at 23 times that of a person without diabetes.¹⁹
20. It is considered likely that many such amputations and much of the morbidity associated with foot ulcers are avoidable. The St. Vincent Declaration (1989) called for a 50% reduction across Europe in amputations for diabetic gangrene.²⁰

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21. The complications of the diabetic foot include peripheral arterial (or vascular) disease and neuropathy. Neuro-ischaemia is a combination of these two complications.
22. In peripheral arterial disease the large blood vessels supplying the lower limbs become narrowed by atheroma resulting in reduced blood flow to the legs and feet. This can cause pain on exercise and impaired skin nutrition, which in turn can lead to ulceration and impaired healing. Complete loss of blood supply results in gangrene which can be local or extensive depending on the extent of the vascular lesion.
23. Neuropathy, or nerve damage, causes loss of sensation, which increases the risk of undetected injury and skin ulceration. Neuropathy can also give rise to altered foot shape, resulting in areas on the plantar surface of the foot being subjected to high pressure on walking or standing. These areas, if not protected, can ulcerate.
24. Neuro-ischaemic feet are also prone to ulceration from localised pressure damage. Ulcers related to neuro-ischaemia are less likely to heal than other ulcers and have a greater risk of progressing to gangrene and amputation because of impaired blood supply.
25. All foot ulcers are susceptible to infection, which can spread rapidly causing extensive tissue destruction. Infection is the main reason for major amputation in neuropathic feet. Infection is also commonly the final pathway to amputation in ischaemic and neuro-ischaemic feet. Infection in the feet can spread elsewhere through the blood, with potentially life-threatening consequences.

Chapter 2. Impact of Ulceration and Amputation on Quality of Life

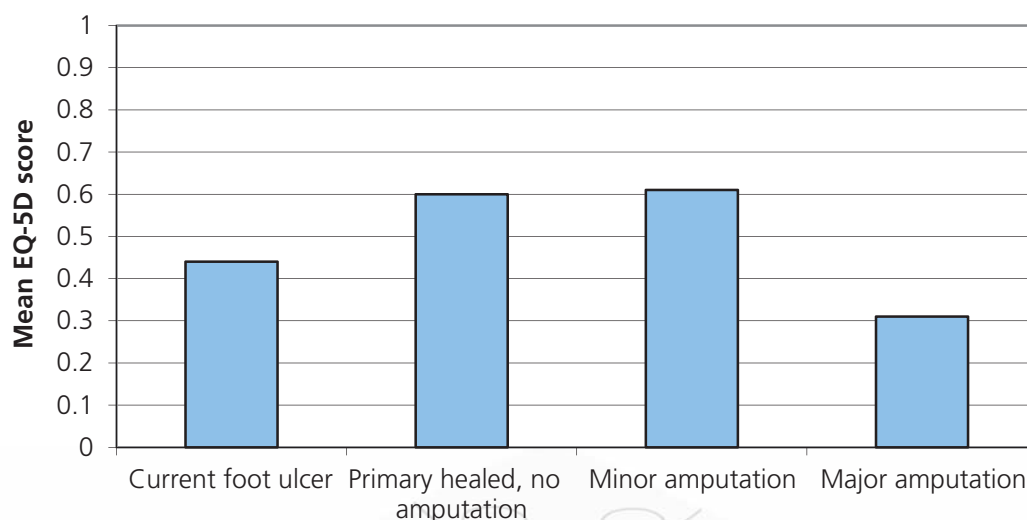
26. Ulceration and amputation substantially reduce quality of life, and are associated with increased mortality. Some foot ulcers are extremely painful, and treatment often requires that a considerable amount of time is spent on clinic visits, hospitalisation and frequent changes of wound dressings. This can impinge on many aspects of patients' family and working lives. Amputations and the resulting disability can result in long-term changes to patients' mobility, living conditions, and relationships.
27. A review of literature on the quality of life of patients with foot complications associated with diabetes noted that there were very few data on the life experiences of patients with infection and diabetic foot ulceration.²¹
28. Many different questionnaires and interview techniques are used for the assessment of quality of life, and utility scores for individual health states can vary widely depending on the technique adopted. If cost utility analyses are used to inform healthcare resource allocation decisions, it is important that there is comparability across the studies used.
29. A recent randomised controlled trial (RCT) of the use of three dressing preparations in the management of chronic foot ulcers used the Short Form 6D (SF-6D) instrument to assess quality of life.²² The study included 229 patients who had foot ulcers with a cross-sectional area of between 25 and 2500 mm² and of at least six weeks duration at enrolment. Patients who had ulcers extending to tendon, periosteum or bone, infection of bone or soft tissue infection requiring treatment with systemic antibiotics at enrolment were excluded.
30. SF-6D scores are derived from patient questionnaires covering six domains: pain, mental health, vitality, physical functioning, social functioning and role limitation. An index score between 0 and 1 is derived (with 1 representing perfect health) by attaching weights to each level in each domain. These weights are derived from valuation of health states in general population surveys.
31. Mean scores for patients with foot ulcers in the dressing preparation RCT ranged from 0.37 to 0.40, depending on the type of dressing and trial stage. For illustration purposes, these scores may be compared with those recorded in health economic studies for patients with a range of long-term conditions, as shown in Figure 1. (For strict comparison, one would require matched patient groups and use of the same weighting system. However, the approach shown here may provide some indication of the quality of life of foot ulcer patients relative to those with other conditions).
32. The SF-6D scores from the RCT suggest that the quality of life of patients with foot ulcers is lower than that of patients with osteoarthritis (0.52), or Chronic Obstructive Pulmonary Disease (0.62),²³ and lower than that of patients undergoing dialysis (0.67)²⁴. It should be noted that the foot ulcer scores are derived from a patient group without conditions such as severe peripheral arterial disease. As such conditions are associated with increased ulcer duration and increased complication rates, it is possible that quality of life is lower in excluded patients than in the study sample.

Figure 1. Health-related quality of life (SF-6D) scores for people with diabetic foot ulcers and other long-term conditions, and for healthy people aged over 75 (Source: Jeffcoate et al.,²² Brazier et al.,²³ Davison et al.²⁴)



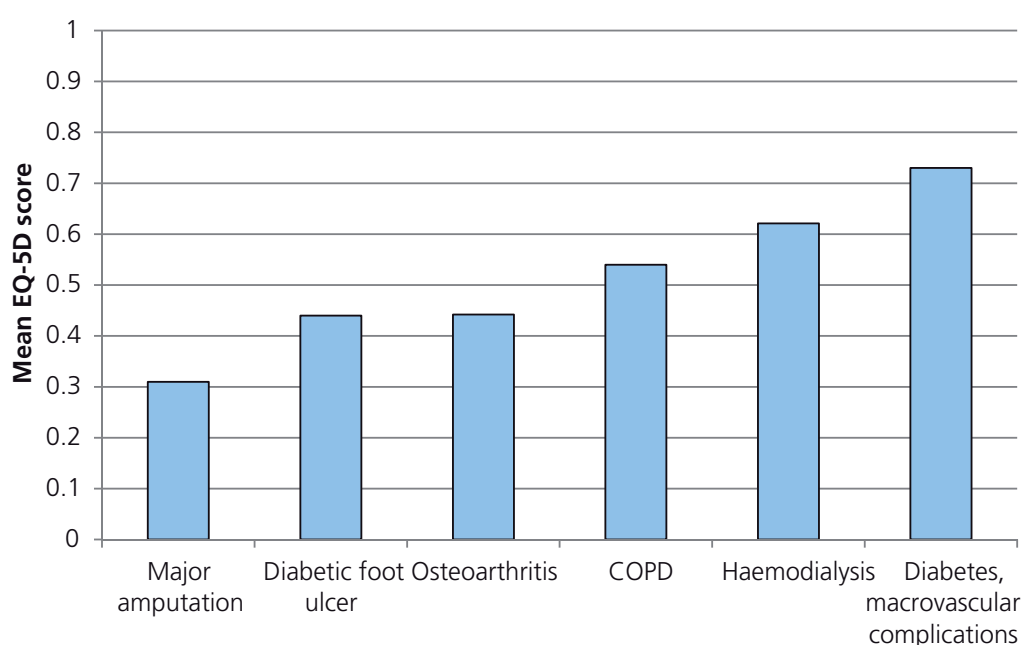
33. A Swedish study used the EQ-5D instrument to estimate the quality of life of people with diabetic foot disease.²⁵ EQ-5D scores are derived from patient questionnaires covering five domains: mobility, pain/discomfort, anxiety/depression, ability to care for oneself, and ability to perform usual tasks.
34. Questionnaires were sent to 457 patients treated by a multidisciplinary diabetic foot care team (MDT) between 1995 and 1998. A mean index score of 0.44 was derived for patients with current foot ulcers (without previous amputation), 0.6 for those whose ulcers had healed without amputation, 0.61 for those who had undergone minor amputation and 0.31 for patients who had undergone major amputation, as shown in Figure 2.

Figure 2. EQ-5D scores for patients with foot ulcers and amputation (Source: Ragnarson Tennvall et al.²⁵)



35. EQ-5D, like SF-6D, can be used for economic evaluation. However, quality of life scores for individual health states can vary substantially depending on the measurement instrument used. If cost utility analyses are used to inform healthcare resource allocation decisions, it is important that there is comparability across the studies used. For this reason, NICE has specified that EQ-5D is the preferred measure for cost effectiveness analysis in the NHS in England.²⁶
36. The EQ-5D scores from the Swedish study have been compared with those recorded with the same instrument for patients with type 2 diabetes with macrovascular complications (but no foot ulcers) and with scores for patients with a range of other long-term conditions, as shown in Figure 3. Again, these comparisons should be treated as illustrative. To achieve perfect comparability, it would be necessary to ensure matched populations and use of the same weighting system across studies.
37. Broadly, the EQ-5D comparison confirms the findings of the comparison of SF-6D scores, suggesting that patients with diabetic foot ulcers have a lower health-related quality of life than people with chronic obstructive pulmonary disease (COPD) or those on haemodialysis²⁷. (The score for osteoarthritis is relatively low in EQ-5D compared with SF-36).
38. Scores for people with diabetes who have undergone major amputation are lower than for all other groups examined here. (It should be noted however that the major amputation scores are based on small patient numbers). Scores for patients with foot ulcer and for people who have undergone amputation are considerably lower than those for people with type 2 diabetes and macrovascular complications who do not have foot ulcers.²⁸

Figure 3. Health-related quality of life (EQ-5D) scores for people with diabetic foot ulcers and other long-term conditions (Sources: Ragnarson Tennvall et al,²⁵ U.K. Prospective Diabetes Study Group,²⁸ Brazier et al,²³ Wasserfallen et al.²⁷)

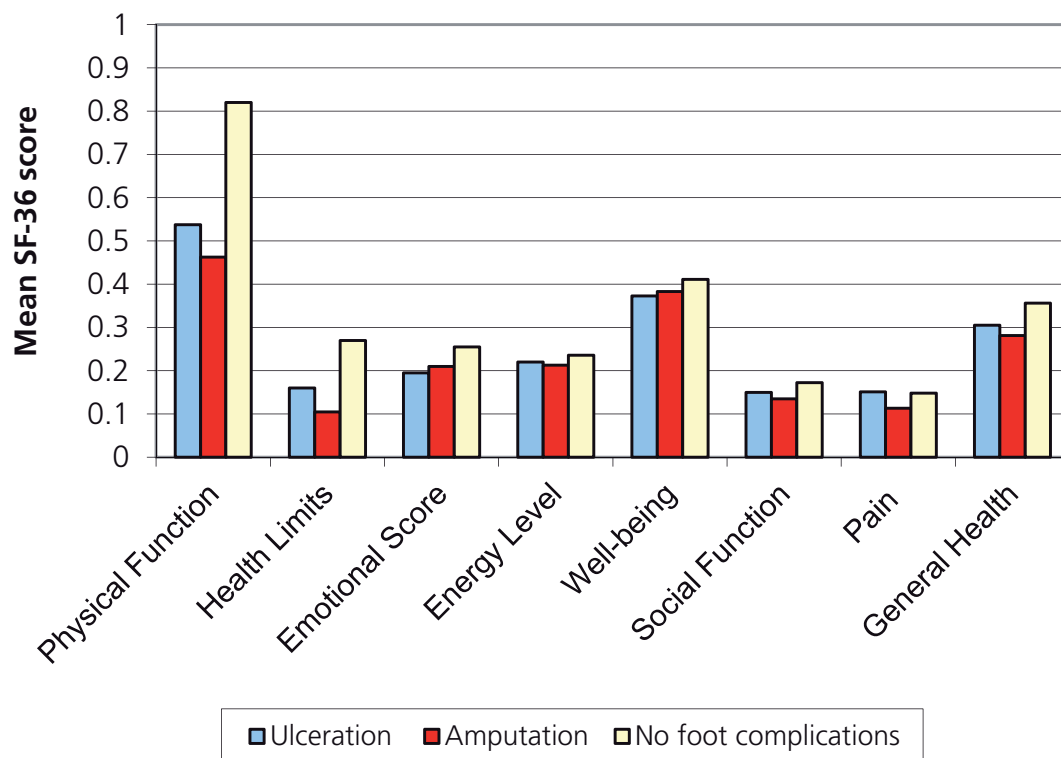


39. Other studies have used instruments or methods that do not produce a single index score. These results cannot be used for health economic analysis. They can however aid understanding of quality of life impacts within individual quality of life domains, such as pain, physical function and energy level.
40. A U.S. study assessed the quality of life of two focus groups of patients and a control group, each consisting of 20 people with diabetes.²⁹ The first focus group was undergoing treatment for diabetic

foot ulcers or active Charcot foot arthropathy. The second focus group was receiving follow-up care at least 6 months after lower extremity amputation. The control group had no evidence of foot morbidity but did have evidence of peripheral neuropathy, as indicated by insensitivity to the Semmes-Weinstein 5.07 (10g.) monofilament.

41. While this study did not produce a single index score for health-related quality of life, scores were produced for sub-scales of SF-6D. Scores were lower in both the foot ulcer and amputation groups than in the control group. The negative impact on health-related quality of life was not statistically different between the ulcer and amputation groups, suggesting that ulcers and amputations have similar impacts on health-related quality of life. It should be noted however that patient numbers in this study were small. The results are shown in Figure 4.

Figure 4. SF-36 scores for diabetic patients with foot ulcer, lower extremity amputation, and peripheral neuropathy without foot complications (Source: Willrich A. et al.²⁹)

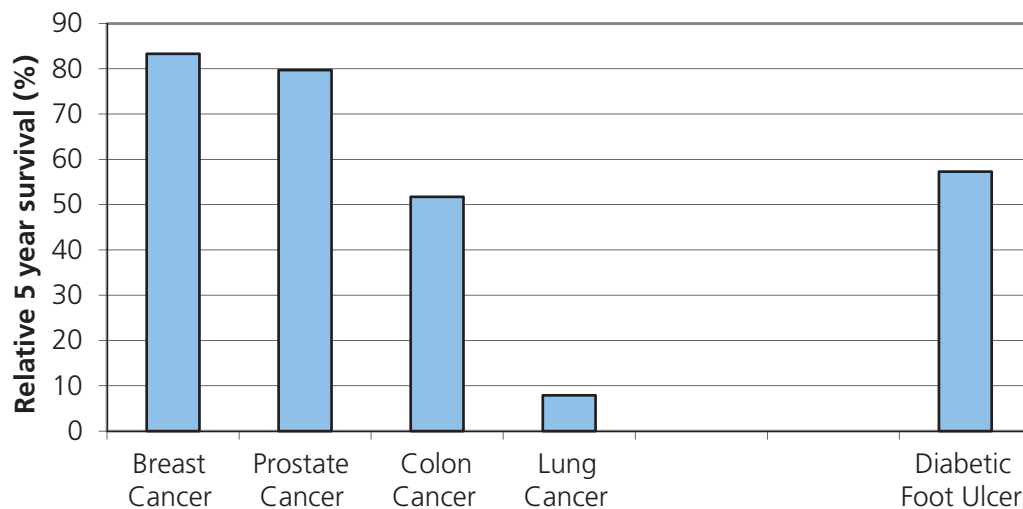


42. Another U.S. study used three sub-scales of the SF-36 general health survey to assess the quality of life of diabetic patients with and without a history of ulceration, and with and without a history of amputation³⁰. It found that both those with a history of ulceration and those who had undergone amputation rated their quality of life significantly poorer for physical functioning than did the control group. Mean scores for the ulceration group (44.3) were lower than for those who had amputation (49.1). These compared with a mean score of 69.8 for patients without ulcers and 69.1 for those without amputation. Lower quality of life on the pain and general health perception indices were also reported for both the ulceration and amputation groups, relative to the diabetic control group.

Chapter 3. Prognosis and Mortality

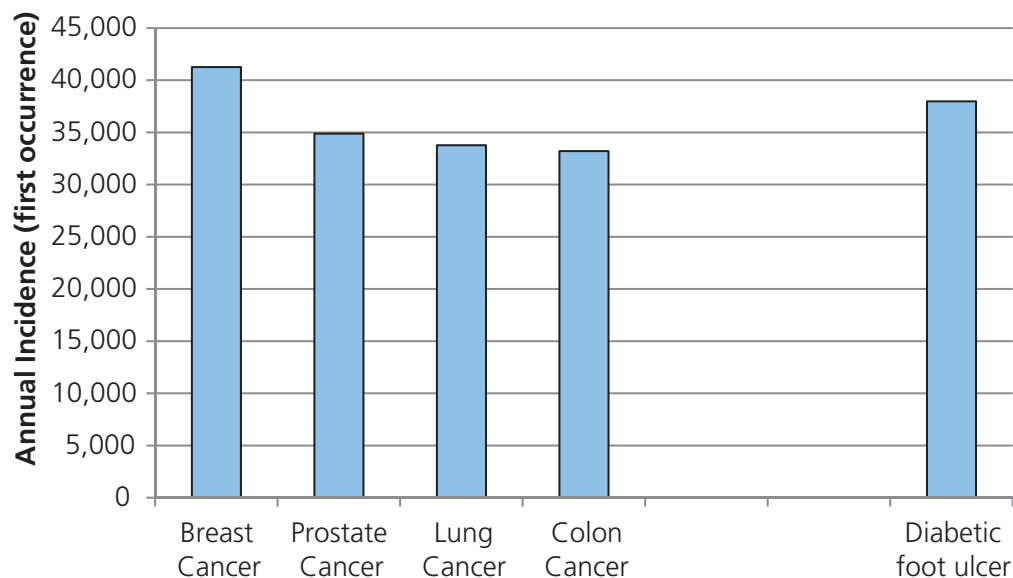
43. Only two thirds of diabetic foot ulcers eventually heal without surgery^{31,32,33}. Up to 28% may result in some form of amputation.³⁴ Patients who have had a foot ulcer are at increased risk of further ulceration.
44. A 2005 study of all (370) patients referred to a specialist foot clinic in Nottingham over 31 months found that 231 (62.4%) became ulcer-free at some stage. Five of these were excluded from the study because of an earlier amputation. Ninety-one of the remaining 226 (40.3%) developed a recurrent or new ulcer after a median 126 days.³³ A UK RCT of the use of dressing preparations found that 26% of those whose ulcers healed during the trial had active ulceration at 3-month follow-up.²² A study examining the role of foot care education in secondary ulcer prevention in patients with newly healed ulcers found that the incidence of ulceration at 12 months was 41% in both the intervention and control groups.³⁵
45. In a 6.5 year follow-up study of 94 consecutive patients with diabetic foot ulcers admitted to a French hospital the primary healing rate was 77.5%. However, 60.9% of these patients experienced further ulceration and 43.8% underwent amputation within a mean follow-up period of 79 months.³⁶ A Swedish study of 558 consecutive patients found that 34% developed a new foot ulcer within one year, and 70% within five years.³²
46. There are many studies indicating that the prognosis of patients who have undergone a major amputation is poor; the limb on the other side is at risk, and research suggests that only around 50% of patients who have had a major amputation survive for a further two years.³⁷ A recent study using Hospital Episode Statistics (HES) data and Office for National Statistics (ONS) mortality data for England showed a 1-year mortality rate of 32.7% for patients who underwent non-traumatic major amputation in diabetes in 2004-05. For those who had minor amputation, the 1-year mortality rate was 18.3%.³⁸ Five-year cumulative mortality for patients with diabetes undergoing a first major amputation has been estimated at 68%³⁹ to 78.7%.⁴⁰ The Strong Heart Study of the American Indian population found that lower extremity amputation in diabetes was a significant predictor of all-cause mortality (hazard ratio 2.2 after mean follow up of 8.7 years) after adjustment for potential confounders including age, diabetes duration, Body Mass Index, albuminuria and LDL cholesterol.⁴¹
47. Even without amputation, diabetic foot ulcers are associated with high levels of mortality. A 5-year mortality rate of 44% was observed in a study of patients presenting with new ulcers at a Liverpool foot clinic.⁴² In the French study cited above, the mortality rate after average follow-up of 6.5 years was 51.7%.³⁶ A Swedish study found a 5-year mortality rate of 42% in patients who experienced primary ulcer healing.³²
48. The 5-year mortality rate observed in the Liverpool study⁴² (44%) is similar to that for patients with colon cancer and very much higher than mortality rates for patients with breast cancer and prostate cancer.
49. Figure 5 shows relative age-adjusted 5-year survival rates for the four most common cancers, taken from Office for National Statistics (ONS) data⁴³, and estimated relative survival for diabetic foot ulcers, based on data from the Liverpool study. Relative survival is the ratio of the observed survival and the survival that would have been expected if the patients had only experienced the background mortality seen in the general population.
50. In the case of diabetic foot ulcers, unlike cancers, there are no routine data sets that provide information on incidence, survival, or patient-level characteristics. Incidence and survival rates must therefore be estimated, and are subject to a degree of uncertainty. The survival estimate shown here is extrapolated from the Liverpool study population, and it is not possible to adjust exactly for expected survival. In order to produce an illustrative relative survival estimate, the Liverpool survival figure has been adjusted to allow for expected survival in the general population aged 70–74 years. Using this adjustment it is estimated that 5-year relative survival for patients with diabetic foot ulcer is around 57%. This compares with 83% for patients with breast cancer and 52% for those with colon cancer.

Figure 5. Five-year relative survival rates for the four most common cancers (Source: ONS) and estimated 5-year relative survival rate for patients with diabetic foot ulcer (Estimate derived from: Moulik P.K et al.⁴²)



51. In order to understand the societal impact of these diseases, it is also necessary to consider incidence rates. It is estimated that in 2010-11 54,000 people with diabetes experienced new foot ulcers, and of this group around 38,000 were experiencing foot ulceration for the first time. (These figures are based on diagnosed diabetes prevalence recorded in the QOF and foot ulcer incidence figures from the North West Diabetes Foot Care Study¹²). The number of patients experiencing diabetic foot ulceration for the first time was higher than the numbers diagnosed in 2010 with lung, prostate and colon cancer. Breast cancer was the only cancer with an annual incidence (41,000) higher than the incidence of primary diabetic foot ulcers, as shown in Figure 6.

Figure 6 Annual incidence of the four most common cancers (Source: ONS) and estimated annual incidence of primary diabetic foot ulcers (Estimates derived from Abbott et al.¹² and QOF diabetes prevalence data¹⁵)



52. It is important to note that while high mortality may be *associated* with diabetic foot ulcers, this does not imply that deaths in these patients can be *attributed* to foot ulceration. In many cases, patients with diabetic foot ulcers have related cardiovascular disease and advanced diabetes complications. Studies suggest that mortality is higher in diabetic foot ulcer patients with ischaemia, renal impairment or pre-existing cardiovascular disease than in those without these comorbidities.⁴⁴

Chapter 4. Quality of Foot Assessment and Care

53. NICE clinical guidelines set out the principles of good quality assessment and care.^{2,3,4} These were supplemented by a National Minimum Skills Framework for commissioning foot care services for people with diabetes in 2011.⁶
54. It is not possible systematically to assess the quality of care against these principles, as national datasets do not measure the activities set out in these documents. However, the available evidence on the quality of foot care will be summarised here.
55. The QOF contains two indicators relating to diabetic foot assessment.¹⁵ The indicators for 2010-11 are shown in Table 1.

Table 1. QOF indicators for diabetic foot care, 2010-11

DM09 The percentage of patients with diabetes with a record of the presence or absence of peripheral pulses in the previous 15 months.
DM 10 The percentage of patients with diabetes with a record of neuropathy testing in the previous 15 months

56. Underlying achievement rates against these indicators in 2010-11 were 91.6% and 91.4% respectively, indicating that almost all GP practices received the maximum payment for diabetic foot assessment. GP practices are allowed to exception report (or exclude) patients from the denominator for a QOF indicator if patients fail to attend appointments or if treatments are contra-indicated. Exception rates for diabetic foot indicators DM09 and DM10 were 5.8% and 5.9% respectively, indicating that approximately 86% of diagnosed diabetes patients received a foot check as specified in the QOF. However, the indicators do not measure the percentage of patients who receive appropriate follow-on care in keeping with their level of foot risk.
57. The NDA provides data on the percentage of patients in participating GP practices who have received a routine foot review during the 15 month period covered by the audit (1 January to 31 March in the following year). In 2009–10 85.2% of type 2 and 67.8% of type 1 diabetes patients covered were recorded as having received a routine foot review. The rates varied across primary care trusts (PCTs) from 67.21% to 88.69%.¹⁸
58. The NDA also reports the incidence of minor and major amputation among people with diabetes. The incidence of major amputation for England was recorded as 0.07% (7 per 10,000 people with diabetes) and the incidence of minor amputation as 0.13% (13 per 10,000 people with diabetes) in 2009–10. The incidence of major amputation ranged from 0 to 0.16% across PCTs, and the incidence of minor amputation ranged from 0.03% to 0.35%.
59. It is known that, historically, diabetes has been under-recorded in Hospital Episode Statistics (HES), and this can lead to under-estimation of diabetes-related amputations. The NDA matches the NHS numbers of people with diabetes (sourced from primary and secondary care records) with NHS numbers in HES. All amputations in people whose primary or secondary care records show a diabetes diagnosis are therefore included in the NDA figures.

60. Comparison of NDA data over the seven years from 2003–04 to 2009–10 suggests that there has been a marked increase in the percentage of patients receiving routine foot reviews from 29% in the first year to 84% in 2009–10, as shown in Figure 7. There has also been a decline in the incidence of both major and minor amputations in the diabetes population (from 0.10% to 0.07% and from 0.14% to 0.13% respectively), as shown in Figure 8. In the case of major amputations, the figure declined each year from 2003–04 to 2006–07 and levelled off at 0.07% from 2006–07 to 2009–10. In the case of minor amputations, while the rate in 2009–10 was lower than that in 2003–04, there were year-on-year increases in 2005–06 and 2007–08.
61. It is important to note that while there may have been a reduction in the *incidence* of amputation among people with diabetes, the absolute *number* of diabetes-related amputations is rising sharply, as the prevalence of type 2 diabetes increases. A recent study has shown that the number of type 2-diabetes-related minor amputations in England almost doubled between 1996 and 2005 and the number of type 2-diabetes-related major amputations increased by 43%.³⁸

Figure 7. Percentage of patients receiving routine foot review, England, 2003–10 (Source: NDA¹⁸)

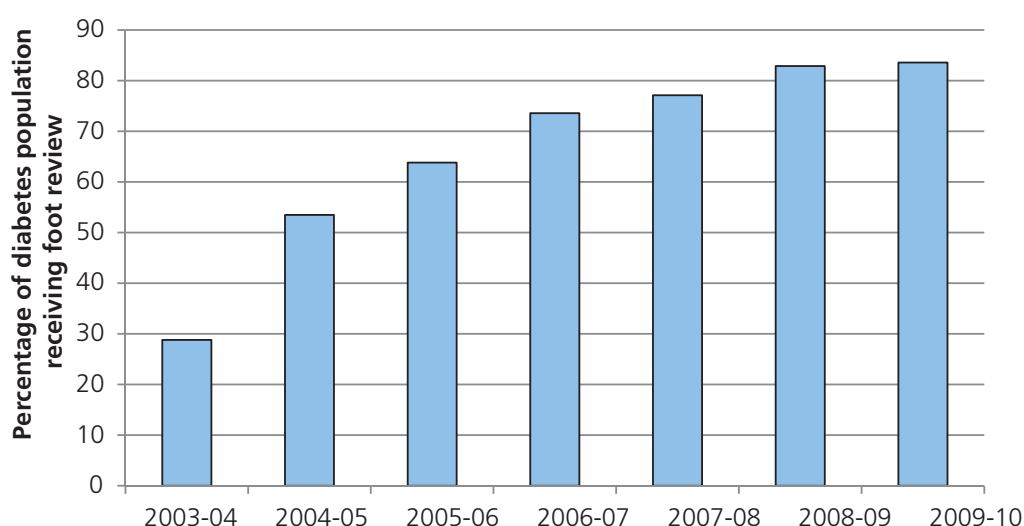
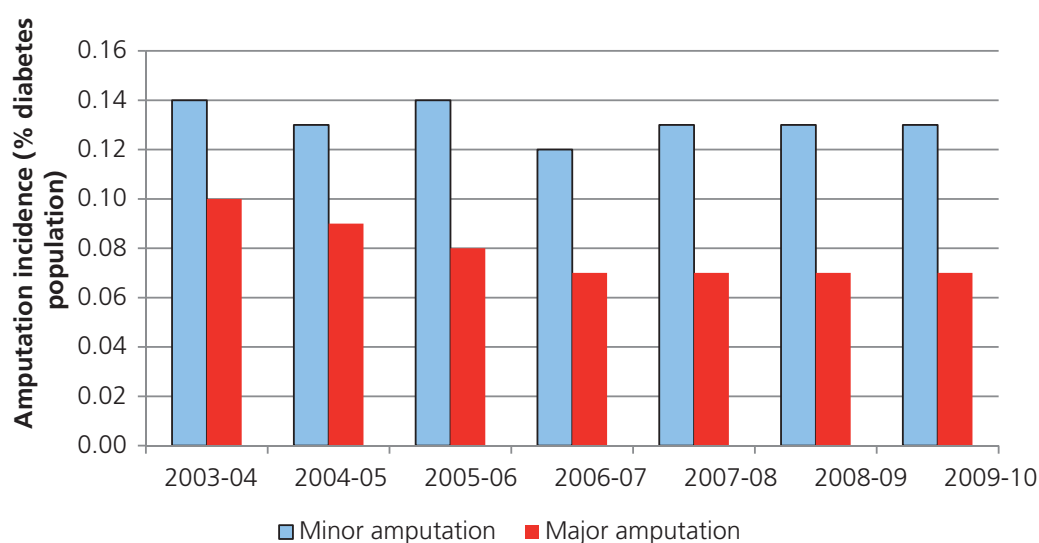


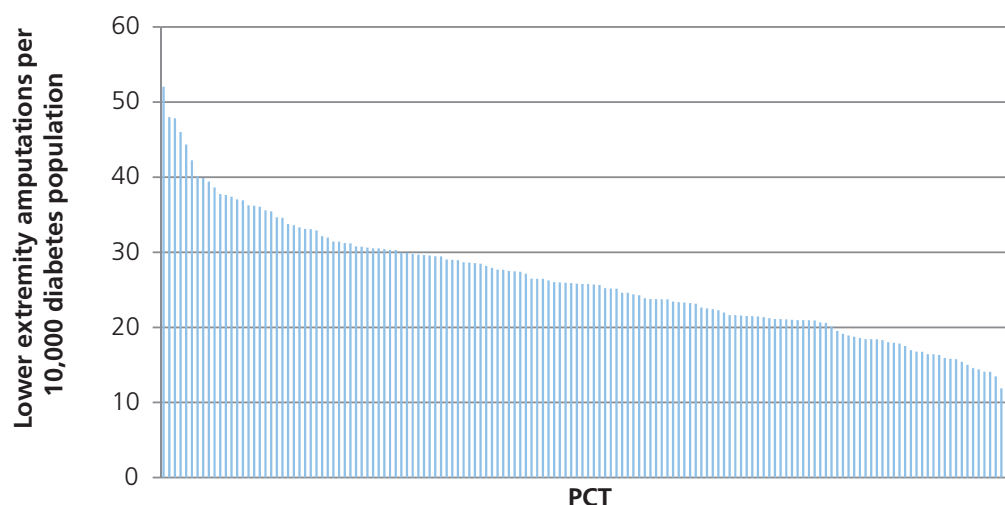
Figure 8. Incidence of major and minor amputation among those diagnosed with diabetes, England, 2003–10 (Source: NDA¹⁸)



62. A recent study reports that, over a 3 year period to 2010, lower extremity amputation rates (major and minor) in people with diabetes varied 8-fold across PCTs.¹⁹ The incidence of amputation (major or minor) per 10,000 person years for people with diabetes was 25.1 for England, with PCT rates ranging from 6.4 to 52.5. The rate in people with diabetes was 23 times that in the non-diabetes population. For major amputations, the variation across PCTs was 10-fold. The study found that the incidence of amputation was negatively correlated with the proportion of the population from Asian ethnic groups and Black ethnic groups.

63. Updated figures for 2008–11 have been produced by the Yorkshire and Humber Public Health Observatory (YHPHO). Over this time period the incidence of lower extremity amputation (major and minor) varied across PCTs from 8.4 to 52, as shown in Figure 9. More detailed PCT-level data on amputation rates and foot-related admissions in diabetes are available from Diabetes Health Intelligence.⁴⁵

Figure 9. Lower extremity amputations (major and minor) per 10,000 person-years in people with diabetes, 2008–11, by PCT (Source: Diabetes Health Intelligence⁴⁵)



64. Amputation figures require careful interpretation. Amputation rates can be affected by many factors, including quality of primary care, delays in presentation or referral, availability and quality of specialist resources, population demographics and prevailing medical opinion.⁴⁶ A high incidence of amputation does not necessarily reflect adversely on the quality of specialist services.
65. It has sometimes been argued that the optimal use of minor amputation will lead to prevention of major amputation, and that an inverse relationship should be observed between the two types (the 'Hi-Lo' ratio).⁴⁷ However, a recent study suggests that there is no evidence for such a relationship in England: PCTs with a high incidence of minor amputations tend also to have a high incidence of major amputations.¹⁹
66. Care is also needed in comparing amputation rates at local level owing to variability between providers in the quality of coding.
67. Figures 10 and 11 show the percentage of patients receiving a routine foot review and the incidence of major and minor amputation, respectively, by PCT. It can readily be seen that there is little or no correlation between foot review performance and amputation incidence. This may be because QOF indicators do not measure the quality of foot inspection or follow-on care, or because there is a 'lead time' between effective early identification of risk and reduction of the most extreme outcomes. It may also be related to deficiencies in the amputation data, as outlined above.

Figure 10. Incidence of major amputation and routine foot review by PCT, as percentages of people with diabetes, 2009-10 (Source: National Diabetes Audit¹⁸)

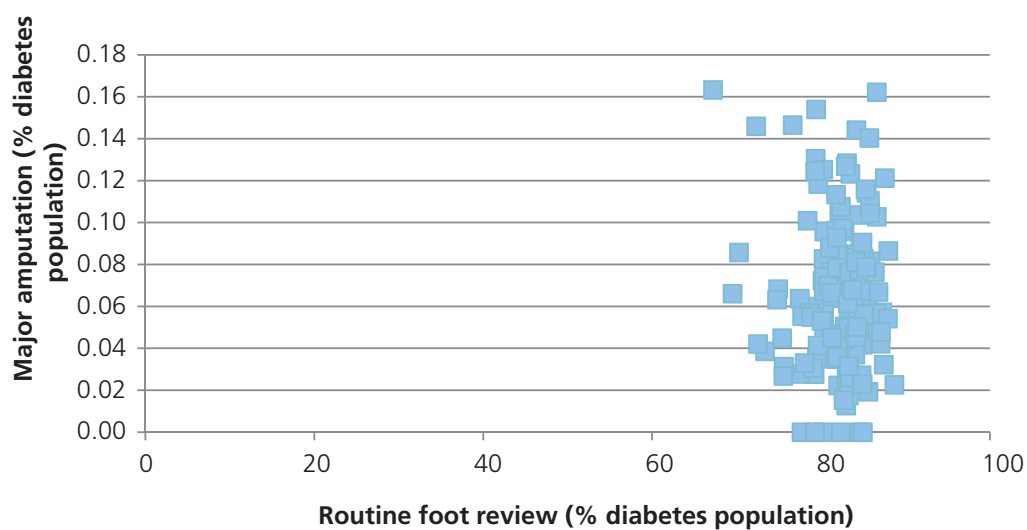
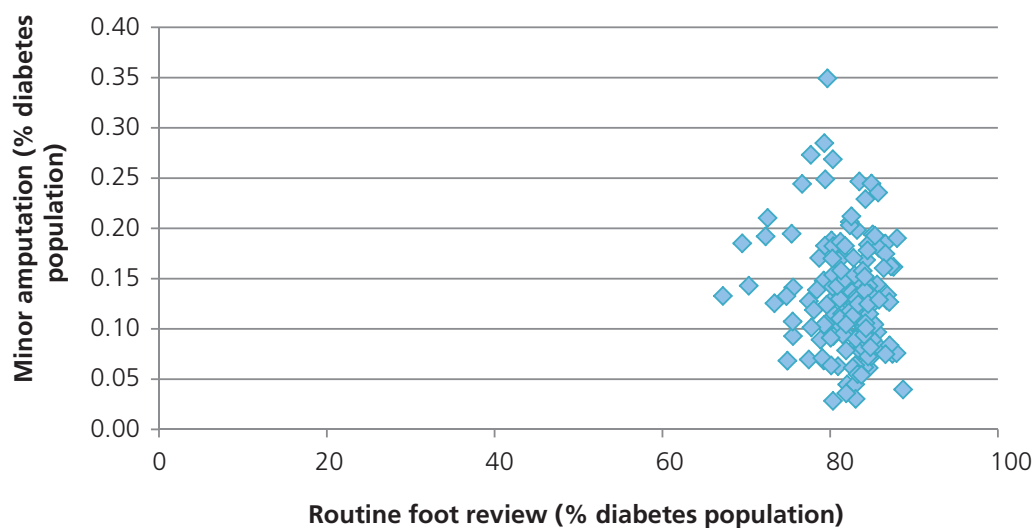


Figure 11. Incidence of minor amputation and routine foot review by PCT, as percentages of people with diabetes, 2009-10 (Source: National Diabetes Audit¹⁸)



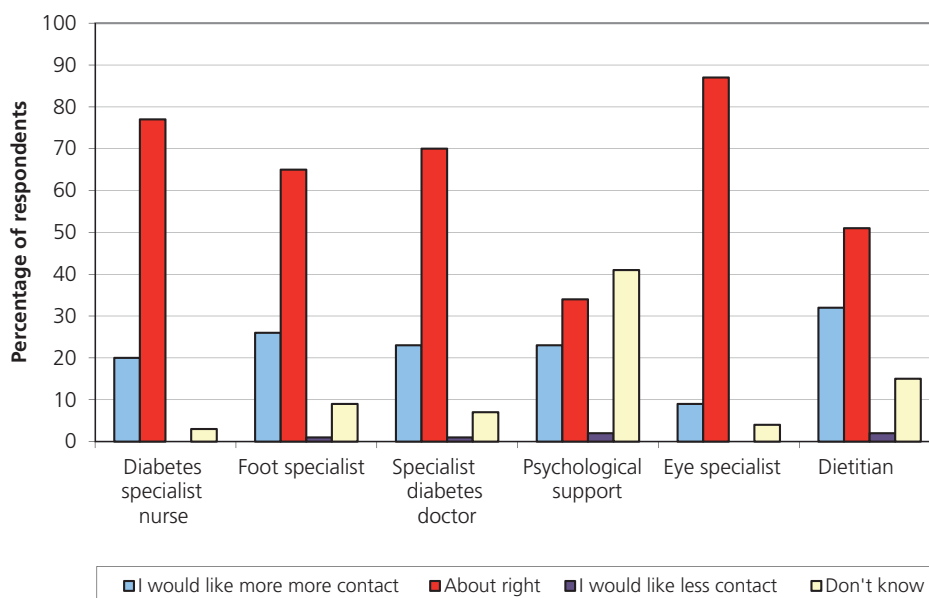
68. As indicated above, there is a dearth of data for most aspects of diabetic foot care. There are currently no national data on the provision of services, quality of care, or outcomes for patients along most of the patient pathway. Even in the acute setting, routine data sets do not capture the quality of foot care or provide information on outcomes apart from amputation.
69. The National Diabetes Inpatient Audit provides a fuller picture of the acute section of the pathway.⁴⁸ In 2010, only 22.6% of inpatients with diabetes included in the audit had documentation in their case notes of a foot examination within 24 hours of admission. A further 4.9% of inpatients had a documented examination of their feet later in their hospital stay. Almost three quarters of inpatients with diabetes had no documented foot examination during their inpatient stay.
70. Five per cent of all inpatients with diabetes had been admitted specifically for foot disease. 9.4% had a foot complication when admitted to hospital and a further 1.3% developed a foot complication during their hospital stay. (In total, 2.2% developed a new foot complication while in hospital, including patients who had foot problems when admitted and developed further problems during their stay). Of those who developed new foot complications in hospital, almost half (49.6%) had no input from an MDT.
71. Of the sites which provided information about hospital characteristics, 21.4% did not have an MDT. The composition of MDTs is shown in Table 2.

Table 2. Composition of MDTs, National Diabetes Inpatient Audit 2010

	Foot team member	Not member but accessible	Not accessible
Vascular surgeon	42.3%	55.4%	2.4%
Diabetologist	75.0%	23.8%	1.2%
Specialist podiatrist	78.0%	17.3%	4.8%
Diabetes specialist nurse	46.4%	51.8%	1.8%
Interventional radiologist	5.4%	79.2%	15.5%
Orthopaedic surgeon	13.7%	79.2%	7.1%
Tissue viability nurse	13.1%	79.2%	7.7%
Microbiologist	11.9%	83.9%	4.2%
Orthotist	34.5%	60.1%	5.4%

72. Another insight into the quality of foot care comes from the Diabetes UK patient survey.⁴⁹ In the 2009 survey, 26% of patients said they would like more access to a foot specialist (as shown in Figure 12), and 14% identified faster access to foot screening as the thing that would most improve the quality of their diabetes care.

Figure 12. Diabetes UK patient survey results, 2009



Section II Evidence on Clinical and Cost Effectiveness of Diabetic Foot Care

Chapter 5. Clinical Impact of Diabetic Foot Interventions

73. Key evidence on interventions to improve the quality of outcomes for patients with diabetes who have foot problems, or are at risk of such problems, will be summarised here. It is not the intention in this paper to provide a comprehensive review of the literature. The Scottish Intercollegiate Guidelines Network (SIGN) conducted a systematic literature review to inform their 2010 guidelines on the management of diabetes, including diabetic foot disease.⁵⁰ They searched literature from 2003–09. A review of earlier literature was conducted for the 2004 NICE guideline.² This section should be read in conjunction with the literature summaries provided in those guidelines. Where possible, evidence from English studies has been used here, as it is believed that the organisation of services and payment mechanisms are important factors in facilitating or impeding change, and therefore examples from within the English NHS are most likely to be relevant to decision makers. Where necessary, these have been supplemented with international evidence.

74. It is important to note that comparison between studies is difficult because of differences in factors such as population selection, baseline values and definition. For example, major amputation may be defined differently across studies, and substantial levels of reduction may be easier to achieve if baseline levels are unusually high. Direct comparison cannot therefore be made between outcome figures or rates of change reported in different studies, except where this has been undertaken in meta-analysis with appropriate adjustment for relevant variables.

75. The evidence in this section will be presented in the following categories:



Ulcer prevention

- assessment and care of patients at risk
- patient education



Ulcer management


- early expert assessment
- multidisciplinary foot team
- cardiovascular risk reduction

Ulcer prevention – assessment and care of patients at risk

76. NICE clinical guidelines recommend annual foot screening of all diabetic patients and targeting of preventive and treatment interventions to those at high risk.^{2,3,4} The National Minimum Skills Framework sets out the skills and knowledge required for both routine basic assessment and expert assessment of the foot at increased risk.⁶

77. A systematic review of 16 studies quantified the value of diagnostic tests, physical signs, and elements from the patient's history in predicting the likelihood of foot ulcers.⁵¹ It found that diagnostic tests and physical signs that detect peripheral neuropathy were helpful in predicting the risk of diabetic foot ulceration.

78. High vibration perception thresholds using a biothesiometer or a tuning fork, high plantar pressure and 10g. monofilaments appeared to be reliable methods to identify those at risk of future ulceration. Absent ankle reflexes and limited joint motion were also found to increase the risk of foot ulceration. Evidence concerning the predictive value of other physical signs such as HbA1c and ankle brachial indices, and of diabetes duration, was less clear.
79. A more recent meta-analysis has concluded, however, that glycaemia (elevated HbA1c) is associated with a substantial increase in the risk of eventual lower extremity amputation.⁵² Based on an examination of 14 studies, the authors found that the overall relative risk for lower extremity amputation was 1.26 for each percentage point increase in HbA1c. The increase in amputation risk probably arises through increased incidence of neuropathy and peripheral arterial disease.
80. Further studies have found that risk stratification can identify those at increased risk of foot ulceration.⁵³ A prospective observational follow-up study of 3,526 patients with diabetes attending for routine diabetes care found that foot ulceration at follow-up (1.7 years) was 83 times more common in high-risk patients and six times more common in moderate-risk patients than in those classified as low-risk. The tool used for risk stratification involved assessment of patient history, foot pulses, monofilament sensation and presence of foot deformity.
81. The impact of assessment and care services on ulcer incidence is difficult to quantify. No large-scale RCTs have been identified in the literature. Indeed there are practical obstacles to such a trial in the general diabetes population as very large patient numbers would be required to demonstrate effectiveness. There is evidence that ulcer prevention services can have an impact on amputation rates, in particular for high-risk groups such as renal dialysis patients with diabetes. A summary of available literature is provided below.
82. A diabetic foot screening and protection programme at the Royal Liverpool University Hospital between 1989 and 1993⁵⁴ allocated 1997 patients attending a general diabetic outpatient clinic randomly to index and control groups. (An additional four patients who had active ulcers were placed in the index group). The control group received usual care, while the index group received foot screening and risk stratification. Those in the index group judged at high risk of ulceration were entered into a foot protection programme. A diabetic foot clinic provided foot care, support hosiery, protective shoes and advice to this group. At 2-year follow-up a statistically significant difference in major amputation rates was reported between the index and control groups (one major amputation in the index group and twelve in the control group). There were no statistically significant differences in the rates of ulceration and minor amputation between the two groups. The evaluation also reported that the service was cost saving as the cost of amputations for the control group exceeded the cost of the screening and protection service for the index group.
83. An Austrian study assigned 91 diabetic patients with healed foot ulcers randomly to a group that received monthly specialist chiropodist care and to a control group.⁵⁵ After a median follow-up of 386 days, 38% of patients in the chiropodist care group had experienced new foot ulcers, compared with 57% of patients in the control group. Analysis of patient records indicated that some patients in the control group had regular chiropodist care (at least once every five weeks, on average) while some patients in the intervention group had no or infrequent chiropodist care. New ulcers occurred in 36% of patients who had received regular chiropodist care, and in 55% of those who received infrequent or no chiropodist care.
84. Care must be taken, however, in extrapolating from this study to the English NHS. Chiropodist consultations are not generally included in routine care in Austria, whereas in England they are more widely available. It cannot be assumed that the difference observed between the intervention and control groups would be replicated in a situation where chiropody care is provided as part of routine care.

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85. In a U.S. study, 83 diabetes patients receiving kidney dialysis were randomised to study and control groups.⁵⁶ Patients in the study group underwent a diabetes education programme and were followed up by a care manager who provided self-management education, diabetes self-care monitoring, motivational coaching, and foot checks. The baseline foot risk category in the control group worsened from 2.7 to 3.3, 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.
86. A systematic review of evidence on the efficacy of methods advocated for the prevention of diabetic foot ulcers in primary care⁵⁷ reported on a Dutch randomised trial examining the impact of podiatric care on ulceration in diabetic people with neuropathy. The index group (235 people) received podiatric care at least twice a year and the control group (263 people) received no podiatric care. During the trial duration (≤ 3 years) there was no difference in the incidence of foot ulcers, but the podiatric care group had fewer deep ulcers (6 vs. 12) infected ulcers (1 vs. 10) and hospital admission days (24 vs. 346). It has not been possible, however, to review the Dutch trial in detail here as the data have not been published in a peer-reviewed journal
87. The systematic review concluded that periodic foot inspections were effective interventions to prevent ulceration, but that screening foot examinations were unlikely to reduce the incidence of foot complications unless they led to appropriate specialist referrals.

Ulcer prevention – patient education

88. NICE recommends foot care education for all those at risk of foot ulcers.² Studies of the effectiveness of structured education programmes for patients do not produce clear-cut results. A Cochrane review⁵⁸ assessing the effects of patient education on prevention of foot ulcers in patients with diabetes examined eleven RCTs. It concluded that there was insufficient robust evidence that limited patient education alone was effective in achieving clinically relevant reductions in ulcer and amputation incidence.

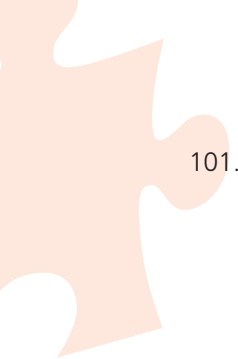
Ulcer management – early expert assessment

89. NICE recommends that those with foot care complications or foot ulcers should be referred to an MDT within 24 hours.² The National Minimum Skills Framework recommends rapid expert assessment of all foot ulcers, inflamed foot lesions and newly occurring foot pain.⁶
90. There is evidence that early expert assessment of patients with foot ulcers reduces amputation rates and times to healing. Many of the studies in this area focus on neuropathic ulcers.
91. A 5-year study at City Hospital, Nottingham⁵⁹ of all patients with neuropathic foot ulcers and without evidence of peripheral arterial disease or infection showed that 96.3% of all ulcers $<1 \text{ cm}^2$ at first assessment healed without amputation, compared with 87.7% of those with area of $1\text{--}3 \text{ cm}^2$ and 71.9% of those with area $>3 \text{ cm}^2$. There was also a direct relationship between ulcer duration at first assessment and cross-sectional area, and a positive correlation between ulcer duration at first assessment and overall time to healing.
92. Logistic regression based on a pooled analysis of individual patient data from the standard care arms of five RCTs in the USA identified ulcer area, ulcer duration and the race of the patient as factors that contribute to healing.⁶⁰

93. A cohort study at a multicentre wound care network in the USA reported that the percentage of patients with diabetic neuropathic foot ulcers who did not heal by the 20th week of care decreased from 66% in 1988–90 to 49% in 1999. The improvement was attributed to earlier referral, smaller ulcer size at referral and a higher proportion of lower-grade wounds at referral (wounds without exposed tendons, ligaments or joints and without infection).⁶¹
94. A 2001 study of patients at the Manchester Royal Infirmary and at a centre in the USA found that ulcer area at presentation correlated with time to healing. Ulcer area at presentation was greater in patients who went on to have amputations than in those whose ulcers eventually healed. In this study, 67% of ulcers were neuropathic.⁶²

Ulcer management – multidisciplinary diabetes foot care team

95. As indicated above, NICE recommends that those with foot care complications or foot ulcers should be referred to an MDT within 24 hours.² The National Minimum Skills Framework says that the majority of established foot ulcerations require management by a specialist multi-disciplinary team.⁶
96. A number of studies present evidence that MDTs can reduce the rate of amputations. Care is needed, however, in comparing study results as the composition and function of such teams varies. Some teams, for example, focus only on hospital-based care while others include outreach services and community-based early intervention services.
97. An 11-year study at Ipswich Hospital found that the annual incidence of major lower extremity amputation per 10,000 people with diabetes fell by 82% from 41.4 to 6.7 following the introduction of an MDT providing outpatient and inpatient care.⁶³ The annual incidence of minor lower extremity amputation per 10,000 people with diabetes fell by 21% from 11.8 to 9.3. The study authors argued that prospective audit and yearly analysis of performance were likely to have contributed to the improvements reported. They also pointed out that during the study period, there were improvements in vascular, radiological and microbiological services as well as in multidisciplinary working.
98. A 5-year study in South Tees studied amputation incidence before and after the establishment of a dedicated diabetic foot care team with a community- based chiropody service. This included establishment of care pathways and protocols for managing diabetic foot problems, with input from a vascular surgeon, orthopaedic surgeon, orthotist, diabetic chiropodists, and a diabetologist. The annual major lower extremity amputation rate fell by 76% from 31.1 in the first year of the study (before the implementation of the team) to 7.6 per 10,000 people with diabetes in the final year. The minor lower extremity amputation rate fell by 61% from 25.4 to 10.0 per 10,000 people with diabetes.
99. The relative risk of a person with diabetes undergoing any lower extremity amputation was reduced from 46 times that of a person without diabetes at the start of the study to 7.7 times that of a person without diabetes at the end of the five years. The study pointed out that during the period there was an increase in the use of angioplasty in people with diabetes, and increased use of medication to modify cardiovascular risk. It is possible that these interventions contributed to the reduction in amputations.
100. A Swedish study found that the annual incidence of diabetes-related major amputations decreased from 16 to 3.6 per 100,000 inhabitants (i.e. general rather than diabetes population) over a 14-year period after the implementation of a multidisciplinary programme for the prevention and treatment of diabetic foot ulcers.⁶⁵ The proportion of minor amputations increased from 28% to 53%, though there was no increase in the absolute number of such amputations. The re-amputation rate in the Swedish study decreased from 36% to 22% between the first and last three year periods. The reductions achieved were in the context of a high baseline incidence in this long-term study.

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101. In Torbay, an open-access foot care clinic was established in 2006 with an MDT comprising weekly input from a diabetologist, two podiatrists and an orthotist, fortnightly input from a vascular surgeon and an orthopaedic surgeon, and support from tissue viability nurses, microbiologists, diabetes liaison nurses and radiologists as required. Between 2006 and 2009 the service reported (in unpublished data) that the major amputation rate for diabetic patients fell from 31.47 to 10.15 per 10,000 people with diabetes. The 3-year average fell from 27.87 in 2004–06 to 9.69 in 2007–09.⁶⁶
102. A study in Southampton presented evidence (published to date in abstract only) that a diabetic foot protection team working across primary and secondary care could reduce lengths of stay for foot ulcer admissions, and associated expenditure, as well as reducing major amputations.⁶⁷ Over a three year period, the median length of stay for foot ulcer admissions fell from 47 to 19 days. This produced a saving estimated at £1.3 million a year, even though hospital admissions related to diabetic foot problems increased from 118 to 174 a year. The abstract reported a 60% reduction in major amputations over three years, but an increase in minor amputations of 42%.

Ulcer management – cardiovascular risk reduction

103. The Specialist Diabetic Foot Clinic of the Royal Infirmary of Edinburgh introduced an aggressive cardiovascular risk policy in 2001.⁴⁴ Patients referred with new ulceration were screened for known cardiovascular risk factors including blood pressure and serum cholesterol. HbA1c, total cholesterol and serum creatinine results were taken from the year of ulceration. A cardiovascular risk score was derived and recommendations were made for anti-platelet therapy, statins, ACE inhibitors or angiotensin receptor blockers, and beta blockers, according to individual patient risk and taking account of contra-indications. Letters were sent to the primary care team for each patient setting out the recommended therapy changes (if any). Follow-up letters were sent in 2004 and 2005 to ensure that the first letter had been received and the recommended changes had been made.
104. In the first three years of this policy, 251 patients were screened and identified. The 5-year mortality for this group (cohort 2) was audited in 2008, and compared with rates for 404 diabetic foot ulcer patients who developed first ulceration between 1995 and 1999 (cohort 1). There were no significant differences in the available data for the two groups apart from total cholesterol (mean value 5.21 mmol/l in cohort 1 compared with 4.77 mmol/l in cohort 2). Blood pressure data were not available for cohort 1.
105. Five-year mortality was 48% in cohort 1 and 26.8% in cohort 2. Improvement in survival was seen for both neuro-ischaemic patients (5-year mortality of 58% in cohort 1 compared with 36% in cohort 2) and neuropathic patients (36% in cohort 1 and 19% in cohort 2).

Chapter 6. Cost Effectiveness of Diabetic Foot Interventions

106. A number of health economic studies have used simulation models to analyse the cost-effectiveness (i.e. the cost per quality-adjusted life year (QALY)) and the potential for cost saving of intensified prevention of diabetes-related foot ulcers and amputations. A 2001 study used a Markov model to analyse, for four different risk categories, the incremental cost-effectiveness of international recommendations⁶⁸ for foot ulcer prevention compared with current prevention in Sweden.⁶⁹ The risk categories and optimal prevention strategies modelled are shown in Table 3.
107. The model results suggested that an intensified prevention strategy was cost effective for all patients apart from those with no specific risk factors for foot ulceration, if foot ulcers and amputations could be reduced by 25%. The strategy produced increases in quality of life and was cost saving for seven of nine age cohorts in the three most severe risk groups. For the two age cohorts in those at-risk groups for whom the strategy was not cost saving, it did produce quality of life gains, with a cost per QALY of €4,000–5000 (1998 prices). The strategy was not cost saving nor cost effective for the low-risk patient group.

Table 3. Risk categories and optimal prevention strategies, (Ragnarson Tennvall et al.⁶⁹)

Risk category	Optimal prevention
1. Low risk - diabetic patients without any specific risk factors for developing foot ulcers	Education about foot care
2. Diabetic patients with sensory neuropathy alone	Professional foot care three times a year
3. Diabetic patients with sensory neuropathy and other risk factors such as peripheral vascular disease or foot deformity	Professional foot care six times a year, 50% receive shoes and 50% receive insoles each year
4. High risk – diabetic patients with at least one previous ulcer or amputation	Professional foot care six times a year, two pairs of protective or therapeutic shoes a year

108. An Austrian study based on the assumption that intensified prevention reduced the incidence of ulcer and amputation by 25–50% within 6 months produced similar results.⁷⁰ For higher-risk patients, intensive prevention increased quality of life and was cost saving. For low-risk patients the intervention increased costs and was not cost effective.
109. Clearly the costs associated with interventions will vary from country to country, and it is not possible to extrapolate directly from international studies. Strategies may be cost saving in some countries and not in others. The cost per QALY will also vary from country to country. The value of these studies, from the perspective of the NHS in England, is that they indicate the potential for increases in quality of life, for cost saving in certain circumstances, and also the categories of patient for whom health gain is likely to be maximised and savings are most likely to be realised.






Section III The Cost of Ulceration and Amputation in Diabetes

Introduction

110. This section will set out estimates of current NHS spending on diabetes-related foot problems in England. Robust estimates of the cost of diabetic foot care are difficult to produce owing to the lack of routine datasets outside the acute setting, and incomplete coding of diabetes in the acute sector. As a result, there is uncertainty as to resource use by people with diabetic foot ulcers in both community and acute settings.

111. Costs are modelled here using routine data sets, where available, supplemented by academic studies, local data, patient survey data and expert opinion, as appropriate. Estimates are compared with those from a 2003 cost of illness study. All costs are given in 2010–11 values.

112. Costs are estimated in the following categories:

-  primary, community and outpatient care for those with ulcers,
-  inpatient care for ulceration and amputation
-  post-amputation care

Chapter 7. Cost of Primary, Community and Outpatient Care for Ulceration

113. National datasets do not provide details of foot ulcer incidence, nor of resource use for patients with diabetic foot ulcers in the community setting. While overall activity data and unit costs are available for outpatient consultations, it is not possible discretely to identify patients with diabetic foot ulcers owing to the lack of detailed coding in outpatient datasets.
114. As shown in chapter 1, estimates of the prevalence of foot ulceration vary from 5% to 7% of the diabetes population, but these figures include patients with past as well as current ulcers.^{9,10,11} It is not known how many people with diabetes experience foot ulcers in a year. Recent data indicate that in Scotland 2.5% of the diagnosed diabetes population had current foot ulcers at the beginning of December 2010.¹³ Data from one English foot care clinic, Salford Royal NHS Foundation Trust, indicate that approximately 2.5% of the local diabetes population have foot ulcers at any given time.¹⁴
115. For modelling purposes, it has been assumed that 2.5% of the diagnosed diabetes population in England (61,400 people) have foot ulcers in any given week. The cost of primary, community and outpatient care is estimated on a weekly basis, and the weekly estimates are then multiplied by 61,400 x 52 to produce an estimate of annual expenditure for England.
116. Because of the uncertainty regarding use of primary, community and outpatient services by patients with diabetic foot ulcers, two approaches are used to estimate expenditure in this chapter. In part A, the results of an RCT are used, supplemented by data from two acute trusts. In part B, data from an NHS Diabetes/Diabetes UK patient survey are used. In part C, the cost estimates are compared.

A: Expenditure estimates based on RCT and acute trust data

117. In this section, the cost of community and outpatient care is estimated on a weekly basis for two patient groups; patients in the first group have no infection or relatively mild infection, and do not have conditions such as severe peripheral arterial disease, osteomyelitis or Charcot foot. Those in the second group have more severe infection, severe ischaemia, osteomyelitis, Charcot foot or a combination of these factors. Patients have been divided in this way as studies suggest that resource use is affected by factors such as the presence of bacterial infection and by comorbidities such as peripheral arterial disease.^{71,72,73}
118. The cost of care for the first group is estimated using data from a recent RCT. The cost of care for the second group is estimated using data provided by two acute providers, Imperial College Healthcare NHS Trust, and The North West London Hospitals NHS Trust.

Group 1: patients with less severe ulcers

119. An RCT of the use of dressing preparations estimated the average per patient cost of dressings management and professional time (apart from admitted patient care) in managing diabetic foot-related problems over a 24-week period.²² Costs for admissions and amputations were excluded.
120. Patients with ulcers extending to tendon, periosteum or bone, and those with infections of bone, soft tissue infections requiring systemic antibiotics, gangrene, critical renal disease, severe peripheral arterial disease and other complications at trial outset were excluded from the study.

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121. The average cost of dressings management, across the three dressings, was £172 (£185 in 2010–11 prices), and the average cost of professional time was £489 (£525 in 2010–11 prices). (Costs in this study were derived from 2005–07 publications. 2005–06 has been taken to be the average baseline price level).
122. The average weekly cost per patient for dressings and professional time is estimated at £44 (in 2010–11 prices) based on the assumption that care was provided to mean time to healing for those who healed during the trial and that care was provided for 24 weeks for those who did not heal during the trial. It should be noted, however, that nearly 70% of dressing changes for this patient group were performed by non-professionals such as family members or friends. No costs are counted for these dressing changes.
123. Secondary infection affected between 5.7% and 11.2% of unhealed ulcers at each of the clinic visits during the study. A total of 560 episodes of medication prescription for infection were reported during 24 weeks. Details are given in the trial report of all medications prescribed for infections. Costs for these have been estimated using the *British National Formulary*.⁷⁴ Of these prescriptions, 9% were for intravenous antibiotics. It is assumed that these were administered during a half hour district nurse home visit. Total expenditure on these medications and intravenous administration, (assuming average prescription duration of 14 days) is estimated at £77,358 for the study cohort. The mean weekly cost per patient is estimated at £19, calculated by dividing total expenditure by the number of ongoing patients at the mid-point of the study (169 at 12 weeks, allowing for 60 withdrawn and 88 healed).
124. The study also provides details of off-loading methods; 44% of patients had a casted device, 21% had bespoke shoes and/or insoles, 17% had a removable off-loading device, and 11% used another offloading method such as crutches. The average cost for these off-loading devices per patient during the trial period is estimated at £233, equivalent to £10 per patient per week. Costs for casted devices and removable off-loading devices are taken from a 2007 Italian study.⁷⁵ Costs for bespoke shoes and insoles were provided by Salford Royal NHS Foundation Trust.¹⁴ It is assumed that of those receiving shoes and/or insoles, 80% receive insoles and 20% receive bespoke shoes.
125. The mean weekly cost of all primary, community and outpatient care for patients in this group is estimated at £73.
126. As indicated above, patients with more serious ulcers or infections at baseline were excluded from the trial. Eighty eight patients (28%) withdrew from the trial. In at least 45% of these cases, the reason for withdrawal was ulcer deterioration, infection or amputation.

Group 2: patients with more severe ulcers

127. Costs for the care of patients with relatively severe ulcers are estimated from data on resource use supplied by two acute trusts, Imperial College Healthcare NHS Trust, and The North West London Hospitals NHS Trust.
128. Imperial College Healthcare NHS Trust provided details of care pathways for patients with severe ulceration, by type, indicating frequency of clinic attendance, and use of resources such as imaging and patient transport. The North West London Hospitals NHS Trust provided details of antibiotics prescribed for patients attending their multidisciplinary foot clinic over a 12- month period.

129. Data from The North West London Hospitals Trust indicate that mean disease duration for patients with osteomyelitis was approximately 35 weeks in 2010–11.⁷⁶ A Spanish study reported mean disease duration of 42 weeks for this patient group.⁷⁷ It will be assumed here that mean disease duration for patients with osteomyelitis is 35 weeks.
130. No studies have been identified showing mean ulcer duration for other severe ulcers. Median ulcer duration has been estimated as 31 weeks for patients with severe arteriopathy and as 29 weeks for patients with Charcot foot.⁷⁸ (These figures include approximately four weeks of ulceration before specialist assessment). For these patient groups, the study estimates of median duration will be taken as a proxy for the mean, although it is recognised that mean duration may be considerably longer than the median. More than one quarter of patients in both study groups had ongoing ulceration after a year of specialist care.
131. Care pathways provided by Imperial College Healthcare NHS Trust indicate that patients with osteomyelitis attend high-risk podiatry clinics on average 33 times in the first 35 weeks of care.⁷⁹ It is assumed that these consultations last 15 minutes. Patients have, on average, eight consultations with the multi-disciplinary team over 35 weeks, and three MRI scans. NHS transport is provided for 43% of attendances.
132. Data from The North West London Hospitals NHS Trust indicate that mean duration of antibiotic prescribing for patients with osteomyelitis was 30 weeks in 2010–11. The mean cost of prescribing was £2,608, equivalent to £75 a week averaged over the 35 weeks of ulcer duration. Medication costs are taken from the *British National Formulary*.⁷⁴
133. Attendance estimates for patients with Charcot foot and neuro-ischaemic lesions, derived from Imperial College pathways, are shown in Table 4. Staff unit costs for podiatry (assumed to be band 7) and plaster room staff (assumed to be band 3) are taken from the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2011.⁸⁰ Costs for MDT attendances and MRI scans are taken from 2010-11 Payment by Results (PbR) tariffs, adjusted for the average Market Forces Factor.⁸¹ No data were available on orthotic or dressing use. It has therefore been assumed that weekly costs in these areas are the same as for patients in Group 1. No data on antibiotic prescribing were available for patients with Charcot foot or neuro-ischaemic lesions. It has therefore been assumed that weekly costs for antibiotics for these patients are the same as for those in Group 1.
134. Mean weekly care costs for patients in Group 2 range from £82 to £189, as shown in Table 4. Estimated weekly costs for patients with osteomyelitis are more than twice those for Group 1 patients, while costs for those with neuro-ischaemia and Charcot foot are 13% and 30% higher, respectively.

Table 4. Estimated cost of community and outpatient care for patients with osteomyelitis, infected neuro-ischaemic ulcers, and Charcot foot with neuropathic ulcers

	Osteomyelitis		Infected neuro-ischaemic lesion		Charcot foot with neuropathic lesion	
	Attendances	Cost	Attendances	Cost	Attendances	Cost
High-risk podiatrist clinic	33	£1,064	32	£1,032	32	£1,032
MDT	8	£2,038	4	£599	7	£1,049
MRI	3	£677			1	£226
Plaster room (and podiatry attendance)					6	£254
Transport	18	£562	17	£548	5	£151
Total		£4,342		£2,179		£2,710
Weekly cost		£103		£52		£65
Weekly cost including antibiotics, orthotics and dressings		£189		£82		£95

135. In order to estimate national expenditure, it is necessary to estimate the proportion of patients in each group. The prevalence of osteomyelitis among patients with diabetic foot ulcers has been estimated at 12%⁸² to 15%⁸³ in US studies and at 23% in a UK study.⁸⁴ Of patients attending a multidisciplinary foot clinic in Nottingham over a 4-year period, 40.5% had peripheral arterial disease (defined as both pedal pulses missing), and a further 2.2% had Charcot foot.⁷⁸ The English arm of an international study using the six-element SINBAD classification system (based on ulcer site, area, and depth, and presence of ischaemia, neuropathy and bacterial infection) found that 41% of patients had ulcers with scores of 3 or more (associated with longer ulcer duration and reduced likelihood of healing).⁷¹

136. For modelling purposes it has been assumed that 60% of patients fall into Group 1 and 40% into Group 2. The prevalence of osteomyelitis is estimated at 18%, and that of Charcot foot at 2.2%. It is assumed that the remainder of patients in Group 2 have other complicating conditions such as severe ischaemia, bacterial infection, or a combination of these factors, and costs estimated above for patients with neuro-ischaemic ulcers with infection are used for these patients. Based on these assumptions, the total cost of community and inpatient care for people with diabetic foot ulcers is estimated at £307 million a year, as shown in Table 5.

Table 5. Estimated cost of community and outpatient care for diabetic foot ulceration

	Estimated patients	Weekly cost	Annual cost
Group 1			
Patients with less severe ulcers	36,839	£2,678,634	£139,288,951
Group 2			
Osteomyelitis	11,052	£2,089,473	£108,652,619
Charcot foot	1,351	£128,012	£6,656,624
Other severe ulcers	12,157	£998,284	£51,910,776
Total	61,398		£306,508,970

137. In this section, alternative cost estimates for community and outpatient care have been modelled using the findings of a 2010 NHS Diabetes and Diabetes UK patient survey on diabetic foot ulcer care. Fifty-nine patients responded to the survey, providing details of ulcer duration and health care use. In the previous 12 months, respondents had experienced ulceration, on average (mean), for 24 weeks. Of the respondents, 29% had had ulceration for 37–52 weeks, and 60% of those who answered the question (32/52) had ongoing ulcers.
138. Respondents reported on health care consultations related to foot ulceration. On average (mean), they reported 13 podiatrist visits during ulceration in the previous 12 months, five district nurse consultations, 2.8 GP practice nurse visits, 1.5 GP visits, and 13 outpatient consultations. (Five per cent of patients had also made at least one visit to accident and emergency departments.). Costs for these consultations have been estimated using PSSRU unit costs 2011⁸⁰ and PbR tariffs for 2010-11.⁸¹ The mean weekly cost per patient for these consultations is estimated at £90.
139. Respondents were also asked about medications, dressings and off-loading methods. Antibiotics for infections had been received by 74%, and among those who had received these medications, the average duration of medication was eight weeks. The costs of medications have been estimated using the *British National Formulary*.⁷⁴ The mean weekly cost of medications, across all patients, is estimated at £9.

140. On average, patients reported 33 dressing changes for their ulcers. The cost of dressings was taken from the RCT.22 Special insoles had been received by 75% and special shoes by 61%. The costs of insoles and shoes were provided by Salford Royal NHS Foundation Trust.14
141. The mean weekly cost of medications, dressings and off-loading is estimated at £34 per patient. The total weekly cost of consultations, medications, dressings and off-loading is estimated at £101.
142. The total cost of primary, community, and outpatient care is estimated at £324 million a year, based on the NHS Diabetes/Diabetes UK patient survey data, as shown in Table 6. The cost of accident and emergency care is estimated at £849,000.

Table 6. Estimated cost of primary, community, outpatient and accident and emergency care for ulceration in people with diabetes, based on NHS Diabetes/Diabetes UK Patient Survey, 2010

	Estimated weekly cost per patient	Estimated annual expenditure, England
GP and Practice Nurse	£4.12	£13,148,111
Podiatry	£17.96	£57,329,795
District nurse	£4.43	£14,149,398
Orthotist/Occupational Therapist	£0.09	£274,669
Outpatients	£63.01	£201,178,354
Medications	£8.50	£27,127,275
Off-loading	£3.35	£10,704,276
Total	£101.45	£323,911,879
Accident and Emergency	£0.27	£849,278
Total including Accident and Emergency		£324,761,157

C: Comparison of expenditure estimates

143. The estimate of total expenditure on primary, community and outpatient care derived in part B is 5% higher than that derived in part A. The weekly per patient estimates in part B are higher than for all patient sub-groups considered in part A, apart from those with osteomyelitis.
144. Patients who participated in the NHS Diabetes/Diabetes UK survey reported more health care consultations than recorded in the dressings RCT. Given the patient selection criteria used for the RCT, and the absence of data on resource use for those who withdrew, it may be that the RCT underestimates resource use for the 60% of patients with less severe ulcers. It is also noteworthy that 70% of dressing changes for patients in the RCT were carried out by non-professionals such as family members. It is not known whether this is typical practice for people with diabetic foot ulcers.
145. The range of activity covered in the survey was wider than that for Group 2 patients, covering GP, practice nurse, district nurse, and accident and emergency resource use as well as secondary care scheduled attendances.
146. It should be noted however, that the survey sample was small (59 patients) and it is not possible in such a survey to ensure a representative sample.

Chapter 8. Cost of Inpatient Care

147. In order to estimate expenditure on hospital admissions related to diabetic foot ulcers, Hospital Episode Statistics (HES) for 2010–11 were searched to identify admissions with a diabetes diagnosis code and diagnosis or procedure codes related to foot ulceration or amputation. Diabetes admissions were identified by means of International Classification of Diseases-10 (ICD-10) codes E10–14. Details of diagnosis and procedure codes used to identify foot problems are given in Appendix 1. Day-case admissions were excluded. Records with invalid Healthcare Resource Group (HRG) fields were also excluded.
148. Hospital Episode Statistics record 72,459 inpatient spells for 2010–11 in which diabetes and foot ulcer or amputation codes are recorded. This represents 8.8% of all ordinary admissions with a diabetes diagnosis code. (Ordinary admissions are those with at least one overnight stay).
149. Of these admissions, 5,917 included amputation procedure codes, 315 were for procedures on amputation stumps, and the remainder (66,227) included ulceration codes without amputation.
150. This section examines, first, admissions related to ulceration without amputation, and then amputation admissions and resource use.
151. PbR tariffs for 2010–11, adjusted for the average Market Forces Factor, are used to estimate costs for amputations and for admissions in foot care HRGs.⁸¹ It should be noted that while the tariff represents the cost of admissions to commissioners, and is derived from HRG-level Reference Costs submitted by acute providers, in some instances the mean cost to providers of care for sub-groups of patients may differ from the price paid by commissioners. This may occur, for example, if a sub-group of patients has significantly greater mean length of stay or requires more resource-intensive care than others whose care is grouped to a particular HRG. A recent patient-level costing study at Cambridge University Hospitals NHS Foundation Trust found that in 2006–07 the mean cost of care for inpatients with diabetes was 8.5% higher than tariff.⁸⁵
152. For admissions in non-foot care HRGs, costs are estimated for excess bed days, relative to admissions for people with diabetes who do not have foot ulceration.

Cost of inpatient care – ulceration

153. Some hospital admissions in people with diabetic foot ulcers occur as a direct result of ulceration. For example, patients may be admitted to hospital because of ulcer-related infection, for diagnostic procedures, or for debridement. In other cases, people with diabetic foot ulcers may be admitted to hospital for conditions unrelated to the ulcer, or ulceration may occur during an admission for an unrelated condition.
154. The impact of ulceration on the cost of a hospital admission is also likely to be variable. In some cases foot care will be the major cost-driver in an admission. In others, foot care may have a relatively small impact on overall cost.
155. In order to estimate inpatient expenditure attributable to foot ulceration, it is necessary to distinguish between these admission types. In situations where ulceration appears to be the main cost-driver in an admission, the whole cost of the admission will be counted here. In situations where ulceration does not appear to be the main cost driver, the marginal cost of ulceration will be estimated.

156. Inpatient activity is grouped to HRGs by means of an algorithm developed by the NHS Information Centre. A single HRG is chosen for each admission. The algorithm uses all procedure and diagnosis codes from the patient record, but generally gives particular weight to procedure codes and to relatively costly activity.
157. Admissions with diabetes and foot ulcer codes in 2010-11 were grouped to more than 500 HRGs. Clinical advice was sought in order to identify HRGs that relate to foot ulcer care. Approximately one fifth of these HRGs were considered to be foot care-related. Details of HRGs, and of the distribution of diabetic foot ulcer admissions, are provided in Appendix 2.
158. Of 66,227 admissions with diabetes and foot ulceration, 47% (31,391) were grouped to HRGs that were considered to be related to foot ulcer care. The allocation of activity to these HRGs is taken to indicate that foot ulcer care was likely to be the sole or most significant cost-driver during the admission. The cost of these admissions, based on 2010–11 PbR tariff payments, adjusted by the average Market Forces Factor, was £114 million.
159. The remainder of admissions with diabetes and foot ulceration (34,836) were grouped to HRGs in other clinical areas, indicating that non-foot-ulcer care was also provided during the admission, and was used to determine the HRG and tariff payment. For these admissions, the tariff paid by commissioners is unaffected by foot ulceration (unless length of stay is extended by ulceration to the point where additional payments are due). It is likely, however, that the cost to acute providers of these admissions is higher than if ulceration had not occurred. Care for patients with ulcers is likely in many cases to be more resource intensive than care for patients without ulcers, and lengths of stay may be longer (though often not sufficiently long to trigger additional payments). It is not possible to estimate the difference in the cost of a day of care for patients with and without foot ulcers. Length of stay has therefore been used here as a proxy for the marginal cost of ulceration in these admissions.
160. Multivariate regression analysis was carried out to estimate the impact of foot ulceration on length of hospital stay for patients with diabetes who are admitted in non-foot-ulcer-specific HRGs. HES data for 2009–10 were used. Finished admissions for people with diabetes were analysed. Day-case admissions were excluded, as were maternity admissions and non-emergency transfers between acute providers. Admissions with a diabetes diagnosis were identified by ICD-10 codes E10-E14. Foot ulcer admissions were identified by ICD-10 codes L97, L89, or R02, or by Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures-4.4 (OPCS-4.4) code S571 in combination with OPCS-4.4 codes Z504, Z505 or Z506. Foot ulcer and amputation-specific HRGs were excluded from the analysis, as costs for admissions in these HRGs are considered separately.
161. Generalised linear model regression was conducted. Covariates were selected through pairwise correlation using $p < 0.05$ as the benchmark. Covariates used in the regression were ulceration, patient age, gender, ethnicity, index of multiple deprivation score, admission method (elective or emergency), and specialty type (surgical or non- surgical).
162. Six model specifications were tested: normal, gamma and inverse Gaussian using both identity and log links. Candidate models were ranked according to their Akaike information criterion (AIC) values. The model with the lowest AIC value was the gamma identity link model. The gamma identity link model results were therefore used to estimate parameters.
163. The coefficient for ulceration in the gamma-link model was 12.71 (95% confidence interval 12.15 – 13.26). Based on this analysis, it is estimated that in 34,836 admissions coded to non-foot-ulcer-related HRGs, there were 417,804 excess bed days for patients with ulceration relative to people with diabetes who did not have ulceration.

164. The NHS Institute has estimated the cost of an inpatient bed day at £225.⁸⁶ Using this cost, expenditure on excess bed days in people with diabetic foot ulcers admitted to non-foot care HRGs is estimated at £100 million.
165. The annual cost of non-amputation inpatient care for diabetic foot ulcers is estimated at £213 million.

Cost of inpatient care - amputation

166. As indicated above, Hospital Episode Statistics for 2010–11 were searched to identify major and minor amputation admissions in people with diabetes. Major amputation admissions were identified by means of OPCS-4.4 codes X09 (amputation of leg) or X10 (amputation of foot). Minor amputation admissions were identified by means of OPCS-4.4 code X11 (amputation of toe). Trauma-related amputations (identified by ICD-10 codes S70–99, T00–35, or V01–Y09) were excluded from the analysis. Data without valid HRGs were also excluded.
167. HES data indicate that in 2010–11, there were 2,608 admissions for non-trauma-related major amputation in people with diabetes and 3,309 admissions for non-trauma related minor amputation. This is equivalent to an incidence rate of 0.11% of the diagnosed diabetes population for major amputations and 0.13% for minor amputations. These figures may be compared with those from the NDA for 2009–10, which showed incidence rates of 0.7% (major) and 0.13% (minor)¹⁸ and study data showing incidence rates of 0.10% (major) and 0.14% (minor) derived from 2008–09 HES data.⁸⁷ The overall amputation rate (0.24%) may be compared with that in a recent study of 2009–10 HES data, which found a rate of 0.25%.¹⁹
168. It should be noted that the NDA data measure the percentage of people with diabetes who have had at least one amputation in a given year. Our approach, and the other two studies cited, measure admissions in which a diabetes-related amputation occurs. The patient-to-amputation ratio was estimated at 0.88 in 2008–09.⁸⁷ It is to be expected, therefore, that the NDA incidence rate will be lower than the rate derived using admission-based approaches.
169. The majority of major amputations (61%) are grouped in HES to HRGs QZ11A and QZ11B (Amputation with and without complications and comorbidities, respectively). The remainder are grouped to other HRGs. The total cost of admissions involving non-traumatic major amputation in people with diabetes, in 2010–11, based on HRG tariff prices, was £25 million. Tariff prices are adjusted for the average Market Forces Factor.
170. The majority (60%) of minor amputations are grouped to HRG QZ12Z (Foot procedure for diabetes or arterial disease, and procedures to amputation stumps). The remainder are coded to other HRGs. The total cost of admissions involving non-traumatic minor amputation in people with diabetes, in 2010–11, based on HRG tariff prices, was £17 million.
171. It is noteworthy that some major amputations are grouped to non-amputation HRGs. This suggests that in those cases amputations were performed during admissions where other care was also provided. The mean tariff paid for major amputations grouped to amputation HRGs was £11,535, while the mean tariff paid for admissions in which a major amputation took place, but which were coded to other HRGs was £7,688. If all major amputations were grouped to amputation HRGs, the cost of major amputation admissions would rise to £30 million. The distribution of amputation activity and expenditure by HRG, for major and minor amputations, is shown in Appendix 3.

172. In addition, there were 315 admissions with OPCS 4.4 procedure X12 (Operations on amputation stump). Tariff payments for these admissions were £1.5 million.

173. Total expenditure on admitted patient care for foot ulceration and amputation in 2010–11 is estimated at £257 million, as shown in Table 7.

Table 7. Expenditure on admitted patient care for diabetic foot ulcers and amputation, 2010–11

	Admissions	Unit cost	Expenditure
Ulceration – foot-ulcer HRGs	31,391	£3,619	£113,608,050
Ulceration – non-foot-ulcer HRGs (excess length of stay)	34,836	£2,857	£99,543,866
Major amputation	2,608	£9,477	£24,716,787
Minor amputation	3,309	£5,244	£17,353,138
Procedures on amputation stumps	315	£4,689	£1,476,976
Total	72,459		£256,698,817

174. The foot care activity identified in HES may be compared with the findings of the 2010 Diabetes Inpatient Audit. As indicated above, the HES analysis found that 8.8% of admissions with a recorded diabetes diagnosis also had a record of foot ulceration or amputation. The Inpatient Audit reported that 10.7% of inpatients with diabetes had a foot complication. (9.4% of inpatients had a complication when admitted to hospital and a further 1.3% developed a foot complication during their hospital stay).⁴⁸

175. The Inpatient Audit also reported that 5% of inpatients with diabetes had been admitted specifically for foot disease. Amputation admissions and admissions in foot ulcer HRGs, in this chapter, together represent 4.6% of admissions with a recorded diabetes diagnosis.

176. It should be noted that the analysis in this paper focuses on the percentage of admissions, while the audit measured the percentage of patients on a single day. Given that lengths of stay are relatively long for people with ulcers, the percentage of patients with foot ulceration on any particular day is likely to be higher than the percentage of admissions involving foot ulceration.

Chapter 9. Cost of Post-Amputation Care

177. It is estimated that patients who have undergone major amputation receive, on average, 30 physiotherapy sessions in the year following amputation.⁸⁸ Unit costs for these consultations are taken from the PSSRU.⁸⁰ It is assumed that patients who have undergone minor amputation receive on average ten sessions of physiotherapy. Expenditure on physiotherapy is estimated at £1.9 million a year. It is not known what proportion of patients who have undergone amputation travel to physiotherapy sessions in NHS transport. If it is assumed that transport is provided for 50% of sessions, the annual cost is estimated at £1.8 million. Costs for patient transport are taken from NHS Reference Costs.⁸⁹
178. It is not known what percentage of amputees receive wheelchairs. If it is assumed that wheelchairs are provided for 50% of these patients, the annual cost is estimated at £1.1 million. Expenditure estimates are based on provision of the cheapest self or attendant propelled chairs. If power chairs or 'active user' chairs are provided, costs will be considerably higher. Wheelchair costs are taken from the PSSRU.⁸⁰
179. The National Amputee Statistical Database (NASDAB) provides data on the numbers of amputees referred to prosthetic services.⁹⁰ In 2006–07 (the most recent year for which figures are available) 3,701 patients in England were referred to prosthetic services after a lower limb amputation. For 1,185 of these cases, diabetes or diabetic neuropathy was recorded as the cause of amputation. (This is equivalent to approximately 86% of the major amputations in people with diabetes in that year). For approximately 1,000 other cases, the cause was given as either dysvascularity (with no further detail) or infection, and in 173 cases no cause was given. It is likely that some of these cases were also connected to diabetes.
180. The number of lower limb amputations in people with diabetes has increased by approximately 25% since 2006–07. (This estimate is derived from NDA amputation incidence data for 2006–07 and 2009–10, and QOF prevalence data for 2006–07 and 2009–10).
181. Costs are estimated here on the assumption that 86% of those undergoing major amputation are referred to prosthesis services. If, as suggested above, some of the referrals recorded as caused by dysvascularity or infection are in fact diabetes-related, costs are likely to be under-estimated. No costs are estimated here for prostheses for those who have had minor amputations.
182. The Royal National Orthopaedic Hospital NHS Trust estimates that prosthesis provision and associated care costs approximately £2,879 a year, on average. Median survival for diabetes patients who have had amputations is estimated at 4 years 3 months.⁹¹ Taking the median as a proxy for the mean, lifetime costs per patient are estimated at £12,237.
183. Annual expenditure on prosthesis services for people who have had diabetes-related amputations is estimated at £27 million. Total expenditure on amputations is estimated at £76 million, as shown in Table 8.

Table 8 Estimated annual expenditure on post-amputation care for people with diabetes

Risk category	
Acute care	£43,546,901
Physiotherapy	£3,721,431
Wheelchairs	£1,093,905
Prosthesis services	£27,445,186
Total	£75,807,423

Chapter 10. Summary of NHS Costs of Ulceration and Amputation

185. Overall expenditure on diabetes-related foot care and amputations is estimated at £639 million to £662 million, as shown in Table 9. This is equivalent to £2.6 million to £2.7 million per 10,000 people with diabetes.
186. There are believed to be substantial numbers of people with undiagnosed diabetes. The Association of Public Health Observatories estimated total diabetes prevalence, diagnosed and undiagnosed, in England at 3.16 million in 2011.¹⁶ These figures suggest that QOF registers capture only 78% of people with diabetes. It should be noted that there is, inevitably, considerable uncertainty around these figures. The estimate of 3.16 million implies a prevalence of 7.5%, but the lower and upper uncertainty limits for prevalence are 5.4% and 11% respectively. The expenditure figures estimated here do not include any ulcers in the undiagnosed diabetes population.

Table 10. Estimated annual expenditure on diabetic foot ulcers and amputation, England

	Lower Estimate	Upper Estimate
Primary, Community and Outpatient care	£306,508,970	£323,062,601
Accident and Emergency		£849,278
Inpatient care – ulceration	£213,151,916	£213,151,916
Inpatient care – amputation	£43,546,901	£48,896,735
Post-amputation care	£75,807,423	£75,807,423
Total	£639,015,210	£661,767,953

187. The estimates set out above may be compared with those from a 2003 York Health Economics Consortium (YHEC) study⁹². This study estimated total annual expenditure on neuropathic and neuro-ischaemic ulcers and resulting amputations in those with diabetes in the UK at £246 million, which is equivalent to £274 million a year for England in 2010–11 prices. These figures were based on a prevalence of diagnosed diabetes in the UK of 1.4 million. Adjustment to take account of current diagnosed prevalence produces an estimate of £574 million a year for England. The study assumed that 76% of all diabetic foot ulcers were neuropathic or neuro-ischaemic. If mean costs for other diabetic foot ulcers were assumed to be the same as those for neuropathic and neuro-ischaemic ulcers, the total annual cost for England in 2010–11 would be estimated at £755 million.
188. The 2003 study was based on the assumption that foot ulcer prevalence in those with diabetes was 5–7%. It was assumed that all patients with foot ulcers attended dermatology outpatient clinics for check ups and wound dressing, and that nearly half of all patients required nurse home visits to change dressings between clinic visits. Expert opinion suggests that many of the assumptions on resource use in the 2003 model do not reflect current clinical practice.

Section IV The Impact of Multidisciplinary Foot Care on Patient Outcomes and NHS Costs

Chapter 11. Cost, Savings and QALY Estimates: Multidisciplinary Diabetes Foot Care

189. The clinical and economic evidence reviewed in chapters 5 and 6 suggest that:

- it is possible to identify people with diabetes who are at risk of ulceration
- targeted preventive services can improve outcomes
- early access to multi-disciplinary specialist care for patients with ulcers can reduce ulcer duration, improve healing rates, reduce amputations and increase survival rates.

190. In this chapter, illustrative costs, savings and QALY gains from the introduction of specialist multidisciplinary care are presented, based on initiatives at South Tees Hospitals NHS Foundation Trust, Southampton University Hospitals NHS Trust, and Brent Teaching PCT. Staff costs are estimated in 2010–11 prices, using unit costs for salary, oncology, and management, estates, administrative and capital overheads from PSSRU 2011.⁸⁰ Savings are estimated using bed day cost estimates from the NHS Institute,⁸⁶ and NHS tariffs for 2010–11.⁸¹

191. QALY gains are estimated for amputations averted over a 5-year perspective for a 1-year cohort of patients. It is assumed that those who avert amputation experience ulcer healing. EQ-5D scores derived from a Swedish study²⁵ have been used. A mean index score of 0.44 was derived for patients with current foot ulcers (without previous amputation), 0.6 for those whose ulcers had healed without amputation, 0.61 for those who had undergone minor amputation and 0.31 for patients who had undergone major amputation. It has been assumed that 5 year mortality after ulceration is 44%,⁴² and that 2 year mortality after major amputation is 50%.³⁷ A re-ulceration rate of 3.5% a month is assumed, derived from study data.³² This is applied both to those whose ulcers have healed without amputation, and to those who have undergone amputation. QALYs are valued at £25,000 (the mid-point of the cost effectiveness range generally used by NICE).

Example 1: South Tees Hospitals NHS Foundation Trust (1995-2000)

192. As shown in chapter 5, the James Cook University Hospital in Middlesbrough established a multidisciplinary diabetic foot care team in 1995. The team was established in response to the Global Lower Extremity Amputation Study (GLEAS), which found that the South Tees area had by far the highest rate of diabetes-related lower limb amputations of four participating UK centres.⁶⁴ Care pathways and protocols were established for the management of diabetic foot ulcers, and educational events were organised to raise awareness of diabetic foot complications. The team established strong links with existing community chiropody services. Between 1995 and 2000, the diabetes related major amputation rate fell from 31.1 to 7.6, and the minor amputation rate from 25.4 to 10.0, per 10,000 people with diabetes.

193. The MDT ran a weekly 4 hour consultant-led clinic with a diabetes specialist nurse and two podiatrists.⁹³ The annual cost of the team is estimated at £33,000, as shown in Table 11. These expenditure estimates do not include set up costs, or the cost of educational events. No costs have been estimated for community chiropody as it is understood that inputs from this service for diabetic foot ulcers did not increase with the establishment of the team.

Table 11. Estimated annual cost of MDT at James Cook University Hospital, Middlesbrough

Staff	WTE*	Grade	Unit cost	Total cost
Podiatrist	0.21	7	£59,530	£12,700
Consultant	0.10		£180,845	£18,085
Diabetes Specialist Nurse	0.11	6	£50,667	£2,294
Total				£33,078

*WTE, whole-time equivalent

194. In 2000, the number of people with diabetes in the South Tees area was estimated at 6,254. Using this denominator, it is estimated that there were 24 fewer amputations in 2000 than if the rate had been maintained at the 1995 level. The saving to the NHS from these averted amputations, based on unit costs derived in chapter 8, is estimated at £249,000, as shown in Table 12. The estimated saving is more than seven times the cost of the team.

195. Monetised QALY gains (valued at £25,000 per QALY) over a 5-year perspective for a 1-year cohort of patients who avert major amputation are estimated at £151,000. No QALY gains are estimated for minor amputations averted, as studies suggest that long-term quality of life after minor amputation is not significantly different from that after ulcer healing.

Table 12. Estimated savings and monetised QALY gains, James Cook University Hospital, Middlesbrough

	Rate per 10,000 people with diabetes		Amputations averted	Savings	Value of QALY gain (at £25,000 per QALY)
Year	1995	2000	2000	2000	2000
Major amputations	31.05	7.58	15	£195,600	£151,412
Minor amputations	25.38	10.05	9	£53,859	
Total	56.43	17.63	24	£249,459	£151,412

Example 2: Southampton University Hospitals NHS Trust (2004-06)

196. A diabetic foot protection team was introduced at Southampton University Hospitals NHS Trust in 2004, and operated until 2007.⁶⁷ The service worked across primary and secondary care, providing a telephone advice and emergency access line for patients and clinical staff, weekly podiatry clinics at eight primary care locations, multi-disciplinary team outpatient clinics in secondary care, and multi-disciplinary inpatient care. The team covered a catchment area of approximately 17,000 people with diabetes, in Southampton City, Eastleigh and Test Valley, and New Forest PCTs. (Eastleigh and Test Valley and New Forest were incorporated into Hampshire PCT in 2006).
197. The foot protection team was composed of a team leader (senior podiatrist), two whole time equivalent (WTE) specialist podiatrists, one WTE diabetes specialist nurse and 0.2 WTE dietician.⁹⁴ The annual cost of the team is estimated at £180,000 in 2010-11 prices, as shown in Table 13.

Table 13. Estimated annual cost of MDT at Southampton University Hospitals NHS Trust

Staff	WTE	Grade	Unit cost	Total cost
Team Leader	1	8a	£69,823	£69,823
Podiatrist	2	7	£59,530	£119,060
Diabetes Specialist Nurse	1	6	£50,667	£50,667
Dietician	0.2	6	£50,667	£10,133
Total				£179,860

198. The team reported that mean length of stay for patients with diabetic foot ulcers fell from 50 days in the six months before the introduction of the foot care team to 19 days during the period from July 2004 to January 2006, a reduction of 31 days.⁹⁴ Over the study period the mean number of annual admissions with diabetic foot ulcer was 115.
199. The cost of a bed day was estimated locally at £300 in 2006 (approximately £331 in 2010–11 prices). However, in order to be consistent with the approach taken elsewhere in this paper, the NHS Institute's estimate of the cost of a bed day (£225)⁸⁶ is used here. It is recognised that this is likely to be an underestimate of the daily cost of care for people with diabetic foot ulcers.
200. The annual saving arising from a reduction in mean length of stay of 31 days for 115 admissions is estimated at £802,000. (If the local estimate of the cost of a bed day is used, the annual saving is estimated at £1.2 million).
201. HES data indicate that there were, on average, 16.7 non-traumatic major amputations a year in people with diabetes at Southampton University Hospitals NHS Trust in the three years before the introduction of the MDT (2001–02 to 2003–04 inclusive) and 10.3 in the three years after the introduction of the team (2004–05 to 2006–07). There were, on average, 16 minor amputations a year in the first period and 21.3 in the second period. Amputations for Isle of Wight residents are excluded from these figures as Southampton University Hospitals NHS Trust performs amputations for Isle of Wight residents but does not provide foot protection services for them. Amputations for non-UK residents are also excluded.
202. Applying the amputation costs from chapters 8 and 9, it is estimated that there was an annual saving of £55,000 from the shift from major to minor amputation. This saving is not adjusted for changes in diabetes prevalence.

203. Prevalence data from the QOF are available for PCTs in England from 2004–05. 2001–03 prevalence has been estimated for Southampton City, Eastleigh and Test Valley, and New Forest PCTs, using 2004–05 QOF data¹⁵ and the local annual rate of change in prevalence for 2009–10 from the Association of Public Health Observatories (APHO) diabetes prevalence model.¹⁶ Prevalence figures for 2004–07 have been taken from the QOF. It has been assumed that the diabetes populations of Eastleigh and Test Valley and New Forest comprised 25.7% of the diabetes population of the new Hampshire PCT, based on prevalence figures for 2005–06 (the year before reconfiguration). After adjustment for changes in diabetes prevalence, the saving from the shift from major to minor amputation is estimated at £87,000, as shown in Table 14.

204. Monetised five-year QALY gains (valued at £25,000 per QALY) for a 1-year cohort of patients who avoid major amputation are estimated at £65,000 to £83,000. The total annual financial saving to the NHS from the reduction in length of stay and the shift from major to minor amputation is estimated at £857,000–£889,000. This is almost five times the cost of the MDT.

Table 14. Estimated savings and monetised QALY gains, Southampton University Hospitals NHS Trust

	Average annual number				Value of QALY gain (at £25,000 per QALY)
	2001-04	2004-07	Unadjusted difference	Estimated saving	
Major amputations	16.67	10.33	-6.34	£84,442	
Minor amputations	16	21.33	5.33	-£29,661	
Total amputations	32.67	31.66	-1.01	£54,782	£65,146
Total including LOS* impact				£856,907	£65,146
	Annual rate per 10,000 people with diabetes				Value of QALY gain (at £25,000 per QALY)
	2001-04	2004-07	Adjusted difference	Estimated saving	
Major amputations	9.83	5.51	-8.1	£107,945	
Minor amputations	9.35	11.31	3.79	-£21,091	
Total amputations	19.19	16.82	-4.31	£86,854	£82,580
Total including LOS* impact				£888,979	£82,580

*LOS, Length of Stay

205. No data were available on ulcer incidence, ulcer duration, or rates of healing.

Example 3: Brent Teaching PCT and North West London Hospitals NHS Trust

206. Brent Teaching PCT and North West London Hospitals NHS Trust established a multidisciplinary specialist foot care team in 2004. The MDT operates two consultant-led clinics a week and an emergency service five days a week.⁷⁶ The annual cost of the MDT is estimated at £118,000, as shown in Table 15. Set-up costs for the MDT are not included as no data were available.

207. The MDT works closely with intermediate care services in Brent, which operate a Short Term Assessment, Rehabilitation and Reablement Service (STARRS), providing care to patients in their homes to avert admissions and facilitate rapid discharge. Local data indicate that during the 12 months from October 2009 to September 2010 the STARRS team provided care to 101 patients with diabetic foot problems. Of these, 81 received care (such as intravenous antibiotic administration) to avert hospital admission, and 20 patients received care to support early discharge. The mean duration of STARRS care was six days. The cost of this care is estimated at £31,185.⁷⁶

Table 15. Estimated annual cost of MDT and STARRS at Brent PCT and North West London Hospitals NHS Trust

Staff	WTE	Grade	Unit cost	Annual cost
Consultant Endocrinologist	0.40		£180,845	£72,338
Podiatrist	0.40	7	£59,530	£23,812
Diabetes Specialist Nurse	0.05	6	£50,667	£2,533
Consultant Radiologist	0.05		£180,845	£9,042
Consultant Vascular Surgeon	0.05		£180,845	£9,042
Plaster Technician	0.05	3	£28,678	£1,434
Total - MDT				£118,202
STARRS				£31,185
Total - MDT and STARRS				£149,387

208. The MDT forms part of an integrated diabetes service covering all aspects of diabetes care. It works closely with community podiatry teams, which operate three tiers of podiatry service: non-specialist (for those at risk of ulceration), intermediate diabetes care (for those with non-infected ulcers or ulcers with minor infection) and high-risk diabetes care (for those with more serious infection, or with ulcers of more than six weeks duration). The high-risk service is located in the acute trust to provide rapid access to the MDT.

209. No costs have been estimated for community chiropody as it is understood that while the establishment of the MDT and integrated diabetes service involved changes in the relationships between community and acute sector foot care services, the level of community podiatry resources devoted to diabetes foot care did not increase.

210. Members of the multidisciplinary and high-risk teams collaborate with GPs and non-diabetes-specialist podiatrists to build awareness of the diabetic foot and of referral guidelines.

211. Diabetes Health Intelligence analysis of foot care admissions and amputations in people with diabetes from April 2008 to March 2011 indicates that Brent Teaching PCT has one of the lowest rates in England for both indicators, as shown in Figures 13 and 14. Over the 3-year period, there were 100 admission episodes a year per 10,000 people with diabetes in Brent, compared with an average across all PCTs of 181. There were ten amputations (major and minor) a year per 10,000 people with diabetes in Brent, compared with an average across all PCTs of 27.⁴⁵

Figure 13. Annual foot care admission episodes per 10,000 people with diabetes by PCT, England, 2008–11 (Source: Diabetes Health Intelligence⁴⁵)

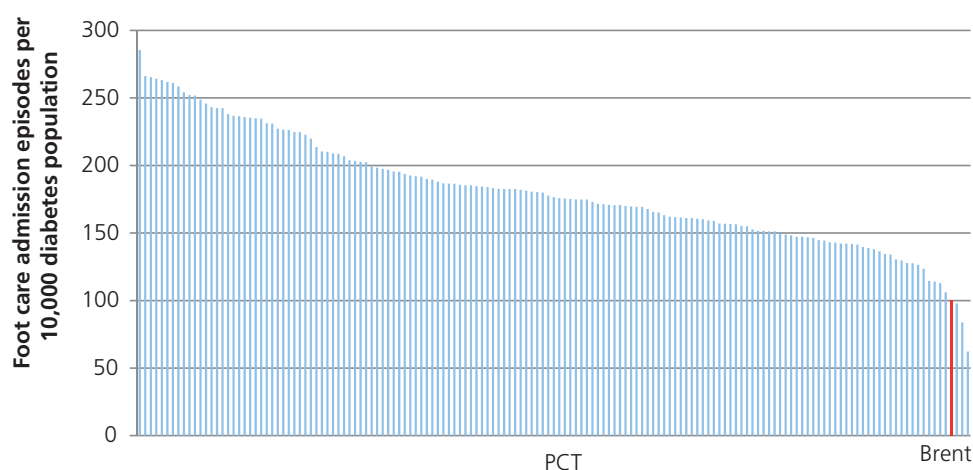
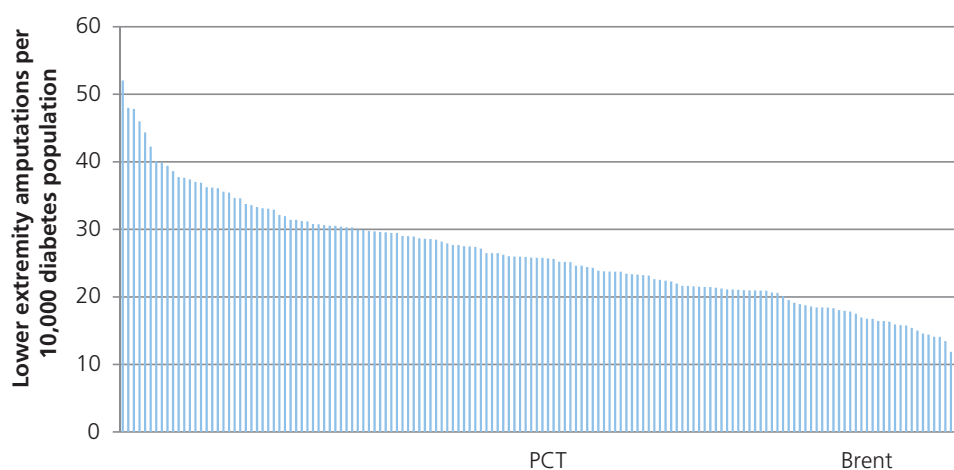


Figure 14 Annual lower extremity amputations (major and minor) per 10,000 people with diabetes by PCT, England, 2008–11 (Source: Diabetes Health Intelligence⁴⁵)



212. The risk of ulceration and amputation is related to factors such as age and ethnicity. YHPHO has developed the Diabetes Area Classification for PCTs, based on age distribution, ethnicity, deprivation, and obesity, at PCT-level.⁹⁵ This allows benchmarking and comparison against PCTs with similar risk factors.

213. Brent PCT belongs to the Indigo group, which has relatively young populations, a substantially higher than average proportion of the population from black and Asian ethnic groups, and higher than average deprivation. Indigo group foot care admission rates and amputation rates are considerably lower than the England average. The average foot care admission rate for the Indigo group PCTs was 129 per 10,000 people with diabetes, and the average amputation rate for the Indigo group was 16 per 10,000 people with diabetes. Brent PCT's amputation rate was the lowest in the Indigo group, and its foot care admission rate was the second lowest, as shown in Figures 15 and 16.

Figure 15. Annual amputations (major and minor) per 10,000 people with diabetes by PCT, Indigo Group, 2008–11 (Source: Diabetes Health Intelligence⁴⁵)

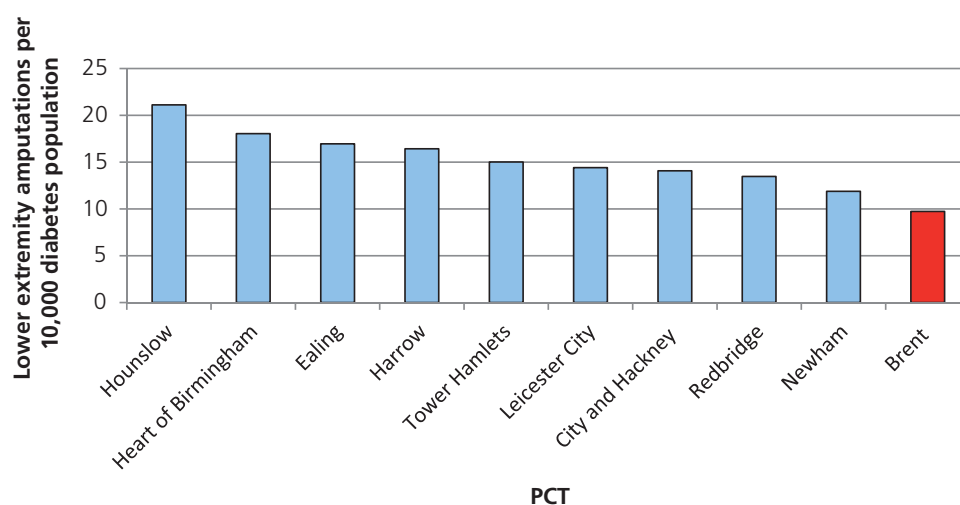
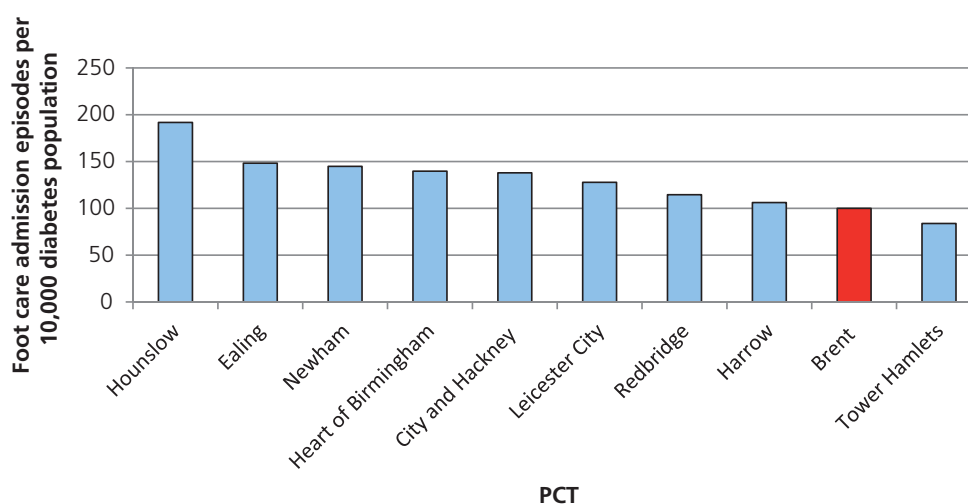


Figure 16. Annual foot care admission episodes per 10,000 people with diabetes by PCT, Indigo Group 2008–11 (Source: Diabetes Health Intelligence⁴⁵)



214. HES data for 2010–11 were examined to identify the distribution of foot care admissions in Brent across HRGs, applying the methodology used to estimate national expenditure in chapter 8. Admission rates per 10,000 people with diabetes were compared with those for other members of the Indigo group and expected admission numbers were estimated using the Indigo average. Amputation admissions were classified as major amputation, minor amputation, and procedures on amputation stumps. Admissions involving ulceration were divided into those in foot care HRGs and those in non-foot care HRGs. The costs of amputation and admissions in foot ulcer HRGs were estimated using mean tariffs in each category, and the attributable cost of ulceration in non-ulceration HRGs was estimated using the results of the regression analysis in chapter 8.
215. Rates for all amputation categories and for admissions in foot ulcer HRGs were lower in Brent than the average for the rest of the Indigo group, as shown in Table 15. The rate of admission involving foot ulceration in non-foot-care HRGs was higher in Brent. The estimated annual saving from lower admission rates, relative to the average for the rest of the Indigo group, was £201,000. This is approximately 1.3 times the cost of the MDT and STARRS for diabetic foot care. Monetised 5-year QALY gains from lower major amputation rates, relative to the Indigo average, are estimated at £65,000 for a 1-year patient cohort.

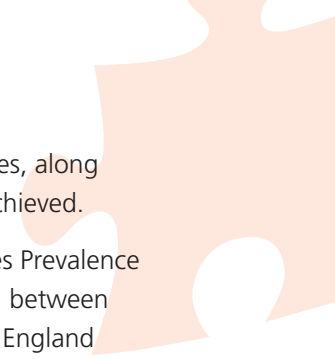
Table 15. Amputations and foot ulcer admissions, Brent, and estimated savings in relation to Indigo average

	Rate per 10,000 diabetes population		Admissions			Estimated savings
	Brent	Indigo (excluding Brent)	Expected	Actual	Difference	
Major amputations	4.57	7.84	15.42	9	6.42	£85,572
Minor amputations	4.57	5.34	10.51	9	1.51	£8,474
Procedures on amputation stumps	0.51	0.62	1.23	1	0.23	£1,070
Foot-ulcer HRGs	68.11	88.17	173.46	134	39.46	£142,801
Non-foot-ulcer HRGs	85.90	79.36	156.13	169	-12.87	-£36,819
Total						£201,098

216. A key aim of the integrated service is to reduce ulcer incidence and duration through early access to specialist care. If these aims are achieved, it is likely that there will be further savings. However, no data are currently available on ulcer incidence or duration.

Chapter 12. Discussion


217. The analysis presented in this paper suggests that expenditure on diabetic foot ulcers is substantial, around 0.6% to 0.7% of all NHS spending. Approximately £1 in every £150 the NHS in England spends each year is spent on diabetic foot ulcers.
218. Much of this activity is not pro-actively commissioned, or recognised by commissioners as spending related to diabetic foot disease. Much of the care is provided by non-specialist staff, and is not identified in local budgets as diabetic foot care.
219. The clinical and economic evidence reviewed in this paper suggest that targeted preventive services can identify those at risk of ulceration and improve outcomes, and that early access to multidisciplinary specialist care for patients with ulcers can reduce ulcer duration, improve healing rates, reduce amputations and increase survival rates.
220. The paper also presents cost, benefit and saving estimates from three services, which suggest that multidisciplinary foot teams with strong links to community services can generate QALY gains for patients, and financial savings for the NHS that substantially exceed the cost of the team. Savings are estimated in this paper arising from reductions in amputation rates, acute admissions, and length of hospital stay.
221. No savings or QALY gains are estimated here for reductions in ulcer duration as data were not available. However, given study evidence on the impact of early specialist assessment on ulcer duration, it is likely that multidisciplinary teams with strong links to community care and rapid access can generate additional NHS savings and QALY gains through faster healing.
222. It is believed that around one fifth of sites providing inpatient care for people with diabetes have no multidisciplinary foot team.⁴⁸ In many areas of the country there are no clear pathways for referral of increased risk or high risk patients to foot protection teams, or for rapid referral of patients with new ulcers, swelling or discolouration to MDTs, as recommended in NICE clinical guidelines.^{2,3,4}
223. Unlike current models of care, establishment of targeted specialist services requires proactive commissioning decisions. As in all areas of health care, decisions regarding the introduction of improved prevention and care services for foot problems in diabetes will need to be informed by local data on costs, savings and outcomes. The figures will vary depending on how services are currently delivered, and on the configuration of proposed new services. The potential for savings and benefits will also vary according to baseline standards of care.
224. The delivery of improved outcomes for patients and savings to the NHS is likely to require close collaboration between primary, community and acute care providers. Rapid access to specialist services requires understanding of the diabetic foot among non-specialist staff and clear referral protocols, as well as the availability of multidisciplinary teams. Avoidance of unnecessary admissions and early hospital discharge can only be achieved if appropriate services are available outside the acute setting.
225. The savings from improved care are likely to accrue both to commissioners and acute providers. The excess costs of extended lengths of stay are borne by acute providers, while the costs of amputations and extended ulcer duration are paid by commissioners. It will be important for commissioners and providers of care to consider the distribution of costs and savings arising from improved care, in order to ensure that improved services are appropriately incentivised.

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226. It will be important to audit new services using patient outcome and satisfaction measures, along with clinical and economic metrics, to ensure that gains in quality and productivity are achieved.
227. Diabetes prevalence is increasing. The Association of Public Health Observatories Diabetes Prevalence model predicts that the number of people with diabetes in England will increase by 23% between 2010 and 2020.¹⁶ The absolute number of type 2 diabetes-related major amputations in England increased by 43% between 1996 and 2005, even as rates per 10,000 people with diabetes were reduced.³⁸ Unless there is a significant increase in the quality and efficiency of diabetes foot care, it is likely that the cost of ulceration and amputation care for people with diabetes will rise substantially in the coming years, both in absolute terms and as a proportion of total NHS spending.
228. Provision of higher quality cost effective foot care for people with diabetes, and early intervention to avoid complications, are likely to play an important part in attempts to improve the overall quality and productivity of the NHS in the coming years.

Appendix 1

Codes for Identification of Inpatient Admissions related to Ulceration or Amputation in Diabetes

	Diagnosis code (ICD-10)	Procedure code (OPCS- 4)	Other ICD-10 code required	Other OPCS- 4 code required
Amputation				
Major amputation	At least one of E10, E11, E12, E13, E14	At least one of X09, X10		
Minor amputation	At least one of E10, E11, E12, E13, E14	X11		
Procedures on amputation stumps	At least one of E10, E11, E12, E13, E14	X12		
Ulceration				
Ulcer of the lower limb	L97		At least one of E10, E11, E12, E13, E14	
Decubitus ulcer	L89		At least one of E10, E11, E12, E13, E14	
Cellulitis	At least one of L03.0, L03.1		At least one of E10, E11, E12, E13, E14	
Osteomyelitis	M86		At least one of E10, E11, E12, E13, E14 AND at least one of L97, L89, L03.0, L03.1, R02	
Gangrene	R02		At least one of E10, E11, E12, E13, E14	
Atherosclerosis	I70.2		At least one of E10, E11, E12, E13, E14 AND at least one of L97, L89, L03.0, L03.1, R02	



Bacteraemia/ Septicaemia/ Septic shock/ Sepsis syndrome	At least one of A40, A41, A49.9		At least one of E10, E11, E12, E13, E14 AND at least one of L97, L89, L03.0, L03.1, R02	
Debridement of a foot/Leg wound	At least one of E10, E11, E12, E13, E14	S57.1		At least one of Z50.4, Z50.5, Z50.6
Diabetes mellitus with peripheral circulatory complications	At least one of E10.5, E11.5, E12.5, E13.5.E14.5			

Appendix 2

Foot-ulcer-related HRGs, and admissions for people with diabetes by HRG, England 2010-11

HRG 4	HRG description	Admissions
JD03A	Intermediate skin disorders with major CC	5657
JD03B	Intermediate skin disorders with intermediate CC	3754
KB03B	Diabetes with lower limb complications without major CC	3407
JD01A	Major skin disorders category 2 with major CC	2192
QZ16A	Diagnostic vascular radiology and other transluminal procedures with major CC	1784
JC03A	Major skin procedures category 1 with major CC	1557
KB03A	Diabetes with lower limb complications with major CC	1357
WA03X	Septicaemia with intermediate CC	697
QZ17A	Non-surgical peripheral vascular disease with major CC	638
QZ03Z	Bypasses to tibial arteries	633
HD25A	Infections of bones or joints with major CC	620
JD01B	Major skin disorders category 2 with intermediate CC	561
QZ15B	Therapeutic endovascular procedures with intermediate CC	532
JD04A	Minor skin disorders category 3 with major CC	512
AB06Z	Minor pain procedures	505
WA18X	Admission for unexplained symptoms with intermediate CC	486
JC06A	Minor skin procedures category 2 with major CC	473
JC01A	Major multiple skin procedures with major CC	402
HD21A	Soft tissue disorders with major CC	380
HD31A	Sprains, strains, or minor open wounds with major CC	374
QZ11B	Amputations without major CC	269
JC03B	Major skin procedures category 1 with intermediate CC	262
JD04B	Minor skin disorders category 3 with intermediate CC	260
HD24A	Non-inflammatory bone or joint disorders with major CC	237
QZ16B	Diagnostic vascular radiology and other transluminal procedures with intermediate CC	232
WA04S	Acute febrile illness length of stay 4 days or less with major CC	222

WA19W	Abnormal findings without diagnosis with CC	201
QZ17B	Non-surgical peripheral vascular disease with intermediate CC	200
QZ12Z	Foot procedures for diabetes or arterial disease, and procedures to amputation stumps	189
HD26A	Musculoskeletal signs and symptoms with major CC	182
HB24B	Minor knee procedures for non trauma category 2 with CC	175
HB33B	Intermediate foot procedures for non-trauma category 1 with CC	169
HB34B	Minor foot procedures for non-trauma category 2 with CC	136
JC04A	Intermediate skin procedures with major CC	129
HD23A	Inflammatory spine, joint or connective tissue disorders with major CC	126
HB21A	Major knee procedures for non trauma category 2 with major CC	113
WA20W	Examination, follow up and special screening with CC	95
HB99Z	Other procedures for non-trauma	88
HB32Z	Intermediate foot procedures for non-trauma category 2	81
HB35B	Minor foot procedures for non-trauma category 1 with CC	80
JC07Z	Minor skin procedures category 1	78
HA92Z	Knee trauma diagnosis without procedure	74
JC06B	Minor skin procedures category 2 with intermediate CC	68
HA93Z	Foot trauma diagnosis without procedure	65
HB23B	Intermediate knee procedures for non trauma with CC	65
JC15Z	Skin therapies level 3	58
JC01B	Major multiple skin procedures with intermediate CC	56
QZ02A	Lower limb arterial surgery with CC	56
HD36A	Pathological fractures or malignancy of bone and connective tissue with major CC	49
JC04B	Intermediate skin procedures with intermediate CC	48
HA21B	Major knee procedures category 2 for trauma with CC	46
HB31Z	Major foot procedures for non-trauma	45
HB25A	Minor knee procedures for non-trauma category 1 with major CC	43
QZ15A	Therapeutic endovascular procedures with major CC	42
JD02A	Major skin disorders category 1 with major CC	41
JD06A	Minor skin disorders category 1 with CC	40
HA22B	Major knee procedures category 1 for trauma with CC	35

JC02A	Major skin procedures category 2 with major CC	34
JD05A	Minor skin disorders category 2 with major CC	33
WA21W	Other procedures and health care problems with CC	31
HA23B	Intermediate knee procedures category 2 for trauma with CC	30
JC05B	Minor skin procedures category 3 with intermediate CC	29
JC05A	Minor skin procedures category 3 with major CC	28
HA34Z	Minor foot procedures for trauma category 2	20
WA06W	Other viral illness with CC	20
HA26B	Minor knee procedures category 1 for trauma with CC	19
PA17B	Intermediate infections without CC	19
HA31B	Major foot procedures for trauma with CC	17
JC27Z	Nursing procedures & dressings 1	16
AB03Z	Complex pain procedures	15
HA25B	Minor knee procedures category 2 for trauma with CC	15
HA35Z	Minor foot procedures for trauma category 1	15
HA33Z	Intermediate foot procedures for trauma category 1	13
WA04T	Acute febrile illness length of stay 4 days or less with intermediate CC	11
HB22B	Major knee procedures for non trauma category 1 with CC	10
AB04Z	Major pain procedures	9
JD05B	Minor skin disorders category 2 with intermediate CC	9
WA18V	Admission for unexplained symptoms with major CC	9
JC02B	Major skin procedures category 2 with intermediate CC	8
JD03C	Intermediate skin disorders without CC	8
HB25B	Minor knee procedures for non trauma category 1 with CC	7
HA24Z	Intermediate knee procedures category 1 for trauma	6
HA32Z	Intermediate foot procedures for trauma category 2	6
HA96Z	Multiple trauma diagnoses without procedure	6
JC16Z	Skin therapies level 4	6
JD01C	Major skin disorders category 2 without CC	6
HD23B	Inflammatory spine, joint or connective tissue disorders with CC	5
JD02B	Major skin disorders category 1 with intermediate CC	5
AB05Z	Intermediate pain procedures	4

HB21B	Major knee procedures for non trauma category 2 with CC	4
JC17Z	Skin therapies level 5	4
QZ11A	Amputations with major CC	4
QZ19Z	Blood vessel injury with no significant procedure	4
WA22V	Other specified admissions and counselling with major CC	4
HD31B	Sprains, strains, or minor open wounds with CC	3
HD32A	Major cranial, visceral or blood vessel injury with major CC	3
JC14Z	Skin therapies level 2	3
HB91Z	Other non trauma diagnosis without procedure	2
HD21B	Soft tissue disorders with CC	2
HD25B	Infections of bones or joints with CC	2
WA09W	Other non-viral infection with CC	2
AB02Z	Complex major pain procedures	1
HD24B	Non-inflammatory bone or joint disorders with CC	1
HD35A	Other wounds or injuries with major CC	1
JC03C	Major skin procedures category 1 without CC	1
NZ09Z	Admission with full investigation	1
PA17A	Intermediate infections with CC	1
PA35A	Skin disorders with CC	1
PA37Z	Diabetes mellitus	1
WA03V	Septicaemia with major CC	1

CC, complications and comorbidities

Appendix 3

Table A3.1 Major amputation admissions and associated tariffs, 2010-11, by HRG, England

HRG	HRG description	Admissions with major amputation	% of major amputations	Mean tariff	Expenditure
QZ11B	Amputations without major CC	964	37%	£9,297	£8,961,966
QZ11A	Amputations with major CC	627	24%	£14,960	£9,380,056
QZ12Z	Foot procedures for diabetes or arterial disease, and procedures to amputation stumps	412	16%	£5,031	£2,072,661
QZ02A	Lower limb arterial surgery with CC	141	5%	£9,410	£1,326,867
QZ15B	Therapeutic endovascular procedures with intermediate CC	109	4%	£4,286	£467,211
QZ15A	Therapeutic endovascular procedures with major CC	84	3%	£9,377	£787,692
QZ03Z	Bypasses to tibial arteries	43	2%	£10,799	£464,371
HB32Z	Intermediate foot procedures for non-trauma category 2	33	1%	£3,153	£104,058
QZ16A	Diagnostic vascular radiology and other transluminal procedures with major CC	24	1%	£9,853	£236,465
QZ16B	Diagnostic vascular radiology and other transluminal procedures with intermediate CC	24	1%	£3,317	£79,612
HB21A	Major knee procedures for non-trauma category 2 with major CC	21	1%	£7,711	£161,933
	Other	126	5%		£673,895
Total		2,608			£24,716,787

CC, complications and comorbidities

Table A3.2 Minor amputation Admissions and associated tariffs, 2010-11, by HRG, England


HRG	HRG description	Admissions with major amputation	% of major amputations	Mean tariff	Expenditure
QZ12Z	Foot procedures for diabetes or arterial disease, and procedures to amputation stumps	1,969	60%	£4,873	£9,595,195
QZ15B	Therapeutic endovascular procedures with intermediate CC	269	8%	£4,545	£1,222,582
HB34B	Minor foot procedures for non-trauma category 2 with CC	189	6%	£1,462	£276,339
JC03A	Major skin procedures category 1 with major CC	178	5%	£6,406	£1,140,266
QZ15A	Therapeutic endovascular procedures with major CC	155	5%	£9,533	£1,477,608
QZ02A	Lower limb arterial surgery with CC	138	4%	£8,957	£1,236,084
QZ16B	Diagnostic vascular radiology and other transluminal procedures with intermediate CC	55	2%	£3,435	£188,940
QZ03Z	Bypasses to tibial arteries	52	2%	£11,307	£587,989
HB33B	Intermediate foot procedures for non-trauma category 1 with CC	46	1%	£2,346	£107,901
JC01A	Major multiple skin procedures with major CC	42	1%	£10,543	£442,806
QZ16A	Diagnostic vascular radiology and other transluminal procedures with major CC	34	1%	£9,853	£334,992
	Other	182	6%	£4,079	£742,434
	Total	3,309			£17,353,138

CC, complications and comorbidities

References

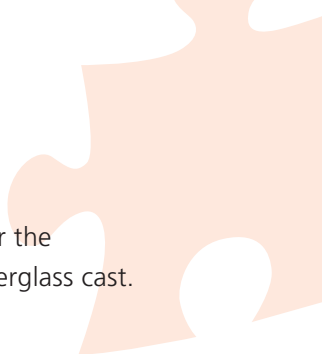
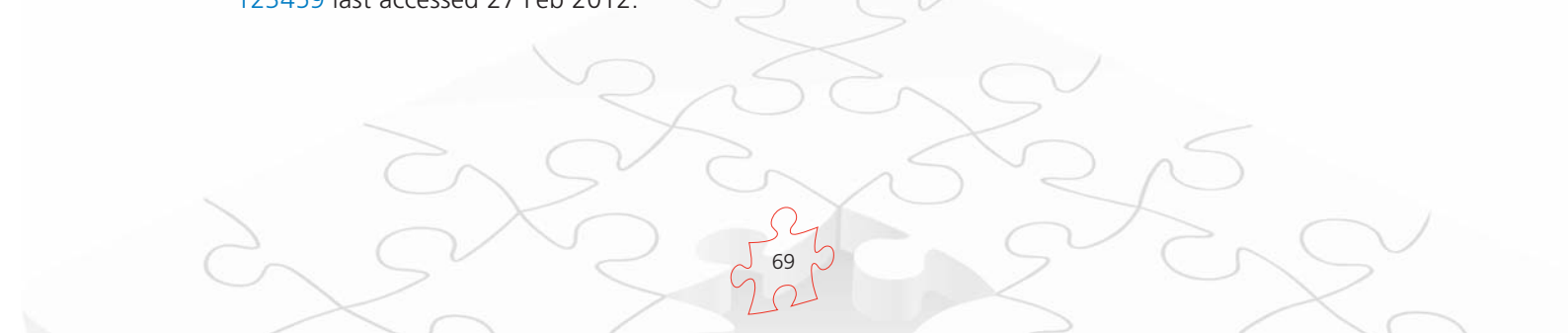
- 1 Game FL, Hinchliffe RJ, Apelqvist J et al. A systematic review of interventions to enhance the healing of chronic ulcers of the foot in diabetes. *Diabetes Metab Res Rev* 2012;28(Suppl 1):119–41.
- 2 National Institute for Health and Clinical Excellence. *Type 2 Diabetes Prevention and Management of Foot Problems. Clinical Guideline 10*. London: National Institute for Health and Clinical Excellence, 2004. Available from <http://publications.nice.org.uk/type-2-diabetes-foot-problems-cg10>, last accessed 28 Feb 2012.
- 3 National Institute for Health and Clinical Excellence. *Type 1 Diabetes in Children, Young People and Adults. Clinical Guideline 15*. London: National Institute for Health and Clinical Excellence, 2004, last modified 2011. Available from <http://publications.nice.org.uk/type-1-diabetes-cg15>, last accessed 28 Feb 2012.
- 4 National Institute for Health and Clinical Excellence. *Diabetic Foot Problems: Inpatient Management of Diabetic Foot Problems. Clinical Guideline 119*. London: National Institute for Health and Clinical Excellence, 2011. Available from <http://publications.nice.org.uk/diabetic-foot-problems-cg119>, last accessed 28 Feb 2012.
- 5 National Institute for Health and Clinical Excellence. *Diabetes in Adults Quality Standard*. London: National Institute for Health and Clinical Excellence, 2011. Available from www.nice.org.uk/guidance/qualitystandards/diabetesinadults/diabetesinadultsqualitystandard.jsp, last accessed 28 Feb 2012.
- 6 *Putting Feet First: National Minimum Skills Framework*. Joint initiative from Diabetes UK, Foot in Diabetes UK, NHS Diabetes, the Association of British Clinical Diabetologists, the Primary Care Diabetes Society, the Society of Chiropodists and Podiatrists. London: Diabetes UK, 2011. Available from www.diabetes.org.uk/Documents/Professionals/Education%20and%20skills/NMSF_16Feb2011.pdf, last accessed 27 Feb 2012.
- 7 *Putting Feet First: Commissioning Specialist Services for the Management and Prevention of Diabetic Foot Disease in Hospitals*. London: Diabetes UK, 2009. Available from www.diabetes.org.uk/Documents/Reports/Putting_Feet_First_010709.pdf, last accessed 27 Feb 2012.
- 8 *Commissioning Diabetes Foot Care Services*. London: NHS Diabetes, 2011. Available from www.diabetes.nhs.uk/document.php?o=23, last accessed 27 Feb 2012.
- 9 Kumar S, Ashe HA, Parnell LN et al. The prevalence of foot ulceration and its correlates in type 2 diabetic patients: a population-based study. *Diabet Med* 1994;11:480–4.
- 10 Walters DP, Gatling W, Mullee MA, Hill RD. The distribution and severity of diabetic foot disease: a community study with comparison to a non-diabetic group. *Diabet Med* 1992;9:354–8.


- 11 Neil HA, Thompson AV, Thorogood M et al. Diabetes in the elderly: the Oxford Community Diabetes Study. *Diabet Med* 1989;6:608–13.
- 12 Abbott CA, Carrington AL, Ashe H et al. The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort. *Diabet Med* 2002;19:377–84.
- 13 Leese GP, Stang D, McKnight JA and Scottish Diabetes Foot Action Group A national strategic approach to diabetic foot disease in Scotland: changing a culture. *The British Journal of Diabetes & Vascular Disease* 2011; 11: 69-73
- 14 Personal communication, Paul Chadwick, Principal Podiatrist, Salford Royal NHS Foundation Trust
- 15 <http://www.ic.nhs.uk/qof> last accessed 27 Feb 2012.
- 16 APHO Diabetes Prevalence model for England, <http://www.yhpho.org.uk/resource/view.aspx?RID=81090> last accessed 27 Feb 2012.
- 17 Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. *Lancet* 2005;366:1719–24.
- 18 National Diabetes Audit Executive Summary 2009-10 *The NHS Information Centre* 2011
- 19 Holman N, Young RJ, Jeffcoate WJ. Variation in the incidence of amputation of the lower limb in England *Diabetologia* 2012
- 20 Krans HM, Porta M, Keen H. Diabetes care and research in Europe: the St. Vincent Declaration action programme 1992. Copenhagen: World Health Organization; 1992. WHO Regional Office, document no. EUR/IGP/OR 055/3
- 21 Price P. The Diabetic Foot: Quality of Life *Clinical Infectious Diseases* 2004;39 (Suppl.2) S129-131
- 22 Jeffcoate WJ, Price PE, Phillips CJ et al. Randomised controlled trial of the use of three dressing preparations in the management of chronic ulceration of the foot in diabetes. *Health Technol Assess* 2009;13:1–86, iii–iv.
- 23 Brazier J, Roberts J, Tsuchiya A, Busschbach J. A comparison of the EQ-5D and SF-6D across seven patient groups. *Health Econ* 2004;13:873–84.
- 24 Davison SN, Jhangri GS, Feeny DH. Comparing the Health Utilities Index Mark 3 (HUI3) with the Short Form-36 preference-based SF-6D in chronic kidney disease. *Value Health* 2009;12:340–5.
- 25 Ragnarson Tennvall G, Apelqvist J. Health-related quality of life in patients with diabetes mellitus and foot ulcers. *J Diabetes Complications* 2000;14:235–41.
- 26 Guide to the Methods of Technology Appraisal NICE 2008
- 27 Wasserfallen JB, Halabi G, Saudan P et al. Quality of life on chronic dialysis: comparison between haemodialysis and peritoneal dialysis. *Nephrol Dial Transplant* 2004;19:1594–9.

- 
- 28 U.K. Prospective Diabetes Study Group Quality of Life in Type 2 Diabetic Patients Is Affected by Complications But Not by Intensive Policies to Improve Blood Glucose or Blood Pressure Control (UKPDS 37) *Diabetes Care* 22: 7 July 1999
- 29 Willrich A, Pinzur M, McNeil M et al. Health related quality of life, cognitive function, and depression in diabetic patients with foot ulcer or amputation. A preliminary study. *Foot Ankle Int* 2005;26:128–34.
- 30 Eckman MH, Greenfield S, Mackey WC et al. Foot infections in diabetic patients. Decision and cost-effectiveness analyses. *JAMA* 1995;273:712–20.
- 31 Jeffcoate WJ, Chipchase SY, Ince P, Game FL. Assessing the outcome of the management of diabetic foot ulcers using ulcer-related and person-related measures. *Diabetes Care* 2006;29:1784–7.
- 32 Apelqvist J, Larsson J, Agardh CD. Long-term prognosis for diabetic patients with foot ulcers. *J Intern Med* 1993;233:485–91
- 33 Pound N, Chipchase S, Treece K et al. Ulcer-free survival following management of foot ulcers in diabetes. *Diabet Med* 2005;22:1306–9.
- 34 Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system. The contribution of depth, infection, and ischemia to risk of amputation. *Diabetes Care* 1998;21:855–9.
- 35 Lincoln NB, Radford KA, Game FL, Jeffcoate WJ. Education for secondary prevention of foot ulcers in people with diabetes: a randomised controlled trial. *Diabetologia* 2008;51:1954–61.
- 36 Ghanassia E, Villon L, Thuan Dit Dieudonne JF et al. Long-term outcome and disability of diabetic patients hospitalized for diabetic foot ulcers: a 6.5-year follow-up study. *Diabetes Care* 2008;31:1288–92.
- 37 Waugh NR. Amputations in diabetic patients—a review of rates, relative risks and resource use. *Community Med* 1988;10:279–88.
- 38 Vamos EP, Bottle A, Majeed A, Millett C. Trends in lower extremity amputations in people with and without diabetes in England, 1996-2005. *Diabetes Res Clin Pract* 2010;87:275–82.
- 39 Icks A, Scheer M, Morbach S et al. Time-dependent impact of diabetes on mortality in patients after major lower extremity amputation: survival in a population-based 5-year cohort in Germany. *Diabetes Care* 2011 34:1350-4
- 40 Ikonen TS, Sund R, Venermo M, et al. Fewer major amputations among individuals with diabetes in Finland in 1997-2007: a population-based study. *Diabetes Care* 2010; 33:2598-603
- 41 Resnick HE, Carter EA, Lindsay R et al. Relation of lower-extremity amputation to all-cause and cardiovascular disease mortality in American Indians: the Strong Heart Study. *Diabetes Care* 2004;27:1286–93.
- 42 Moulik PK, Mtonga R, Gill GV. Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology. *Diabetes Care* 2003;26:491–4.

- 43 Cancer survival in England: one-year and five-year survival for 21 common cancers, by sex and age ONS 2010
- 44 Young MJ, McCardle JE, Randall LE, Barclay JL. Improved survival of diabetic foot ulcer patients 1995-2008: possible impact of aggressive cardiovascular risk management. *Diabetes Care* 2008;31:2143-7.
- 45 <http://www.yhpho.org.uk/default.aspx?RID=116836> last accessed 27 Feb 2012.
- 46 Jeffcoate WJ, van Houtum WH. Amputation as a marker of the quality of foot care in diabetes. *Diabetologia* 2004;47:2051-8.
- 47 Wrobel JS, Robbins J, Armstrong DG. The high-low amputation ratio: a deeper insight into diabetic foot care? *J Foot Ankle Surg* 2006;45:375-9.
- 48 National Diabetes Inpatient Audit 2010 NHS Diabetes
http://www.diabetes.nhs.uk/information_and_data/diabetes_audits/national_diabetes_inpatient_audit/ last accessed 27 Feb 2012.
- 49 Diabetes UK survey of people with diabetes and access to healthcare services 2009
http://www.diabetes.org.uk/Documents/Reports/Members'_survey_report_22.01.2010.pdf last accessed 27 Feb 2012.
- 50 Management of diabetes A national clinical guideline *Scottish Intercollegiate Guidelines Network* 2010
- 51 Crawford F, Inkster M, Kleijnen J, Fahey T. Predicting foot ulcers in patients with diabetes: a systematic review and meta-analysis. *QJM* 2007;100:65-86.
- 52 Adler AI, Erqou S, Lima TA, Robinson AH. Association between glycated haemoglobin and the risk of lower extremity amputation in patients with diabetes mellitus-review and meta-analysis. *Diabetologia* 2010;53:840-9.
- 53 Leese GP, Reid F, Green V et al. Stratification of foot ulcer risk in patients with diabetes: a population-based study. *Int J Clin Pract* 2006;60:541-5.
- 54 McCabe CJ, Stevenson RC, Dolan AM. Evaluation of a diabetic foot screening and protection programme. *Diabet Med* 1998;15:80-4.
- 55 Plank J, Haas W, Rakovac I et al. Evaluation of the impact of chiropodist care in the secondary prevention of foot ulcerations in diabetic subjects. *Diabetes Care* 2003;26:1691-5.
- 56 McMurray SD, Johnson G, Davis S, McDougall K. Diabetes education and care management significantly improve patient outcomes in the dialysis unit. *Am J Kidney Dis* 2002;40:566-75.
- 57 Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005;293:217-28.
- 58 Dorresteyn JA, Kriegsman DM, Assendelft WJ, Valk GD. Patient education for preventing diabetic foot ulceration. *Cochrane Database Syst Rev* 2010:CD001488.

- 
- 59 Ince P, Game FL, Jeffcoate WJ. Rate of healing of neuropathic ulcers of the foot in diabetes and its relationship to ulcer duration and ulcer area. *Diabetes Care* 2007;30:660–3.
- 60 Margolis DJ, Kantor J, Santanna J et al. Risk factors for delayed healing of neuropathic diabetic foot ulcers: a pooled analysis. *Arch Dermatol* 2000;136:1531–5.
- 61 Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Healing diabetic neuropathic foot ulcers: are we getting better? *Diabet Med* 2005;22:172–6.
- 62 Oyibo SO, Jude EB, Tarawneh I et al. The effects of ulcer size and site, patient's age, sex and type and duration of diabetes on the outcome of diabetic foot ulcers. *Diabet Med* 2001;18:133–8.
- 63 Krishnan S, Nash F, Baker N et al. Reduction in diabetic amputations over 11 years in a defined U.K. population: benefits of multidisciplinary team work and continuous prospective audit. *Diabetes Care* 2008;31:99–101.
- 64 Canavan RJ, Unwin NC, Kelly WF, Connolly VM. Diabetes- and nondiabetes-related lower extremity amputation incidence before and after the introduction of better organized diabetes foot care: continuous longitudinal monitoring using a standard method. *Diabetes Care* 2008;31:459–63.
- 65 Larsson J, Apelqvist J, Agardh CD, Stenstrom A. Decreasing incidence of major amputation in diabetic patients: a consequence of a multidisciplinary foot care team approach? *Diabet Med* 1995;12:770–6.
- 66 Rates calculated from unpublished data provided by South Devon Healthcare NHS Foundation Trust
- 67 Bowen G. et al. The impact of a diabetic foot protection team (DFPT) on outcomes for patients with diabetic vascular disease *British Journal of Surgery* 2008; 95(S1): 4-5
- 68 International Consensus on the diabetic foot. The International Working Group on the Diabetic Foot, Amsterdam 1990
- 69 Ragnarson Tennvall G, Apelqvist J. Prevention of diabetes-related foot ulcers and amputations: a cost-utility analysis based on Markov model simulations. *Diabetologia* 2001;44:2077–87.
- 70 Rauner M. et al. Using a Markov model to evaluate the cost-effectiveness of diabetic foot prevention strategies in Austria (2004) *Proceedings of the Western Multiconference, International conference on Health Sciences Simulation*, January 18-22 2004 San Diego, California, USA
- 71 Ince P, Abbas ZG, Lutale JK et al. Use of the SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. *Diabetes Care* 2008;31:964–7.
- 72 Oyibo SO, Jude EB, Tarawneh I et al. A comparison of two diabetic foot ulcer classification systems: the Wagner and the University of Texas wound classification systems. *Diabetes Care* 2001;24:84–8.
- 73 Leese G, Nathwani D, Young M. et al. Use of antibiotics in people with diabetic foot disease: A consensus statement *The Diabetic Foot Journal* 2009;12: 2

- 
- 74 British National Formulary 62 <http://bnf.org/bnf/bnf/current/> last accessed on 10/02/12
- 75 Piaggese A, Macchiarini S, Rizzo L et al. An off-the-shelf instant contact casting device for the management of diabetic foot ulcers: a randomized prospective trial versus traditional fiberglass cast. *Diabetes Care* 2007;30:586–90.
- 76 Personal communication, Wing May Kong, Consultant Endocrinologist, The North West London Hospitals NHS Trust
- 77 Morales Lozano R, Gonzalez Fernandez ML, Martinez Hernandez D et al. Validating the probe-to-bone test and other tests for diagnosing chronic osteomyelitis in the diabetic foot. *Diabetes Care* 2010;33:2140–5.
- 78 Ince P, Kendrick D, Game F, Jeffcoate W. The association between baseline characteristics and the outcome of foot lesions in a UK population with diabetes. *Diabet Med* 2007;24:977–81.
- 79 Personal communication, Jonathan Valabhji, Consultant Diabetologist, Imperial College Healthcare NHS Trust
- 80 Curtis L. Unit Costs of Health and Social Care 2011 PSSRU
- 81 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112284 last accessed 27 Feb 2012.
- 82 Lavery La, Armstrong DG, Peters EJG. Probe-to-Bone Test for Diagnosing Diabetic Foot Osteomyelitis Reliable or relic? *Diabetes Care* February 2007 vol. 30 no. 2 270-274
- 83 Ramsey SD, Newton K, Blough D. et al. Incidence, Outcomes, and Cost of Foot Ulcers in Patients with Diabetes *Diabetes Care* 22:382–387, 1999
- 84 Shone A, Burnside J, Chipchase S. et al. Probing the Validity of the Probe-to-Bone Test in the Diagnosis of Osteomyelitis of the Foot in Diabetes *Diabetes Care* April 2006 vol. 29 no. 4 945
- 85 Simmons D, Wenzel H. Diabetes inpatients: a case of lose, lose, lose. Is it time to use a 'diabetes-attributable hospitalization cost' to assess the impact of diabetes? *Diabet Med* 2011;28:1123–30.
- 86 http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/length_of_stay.html last accessed 27 Feb 2012.
- 87 Vamos EP, Bottle A, Edmonds ME. et al. Changes in the incidence of lower extremity amputations in people with and without diabetes in England between 2004 and 2008 *Diabetes Care*. 2010 Dec;33(12):2592-7
- 88 Estimates provided by the Royal National Orthopaedic Hospital, Stanmore
- 89 NHS Reference Costs 2009-10
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_123459 last accessed 27 Feb 2012.
- 

- 
- 90 The Amputee Statistical Database for the United Kingdom 2006/07 *Information Services Division, NHS Scotland on behalf of National Amputee Statistical Database (NASDAB) 2009*
- 91 Stewart CP, Jain AS, Ogston SA. Lower limb amputee survival. *Prosthet Orthot Int* 1992;16:11–18.
- 92 Gordois A, Scuffham P, Shearer A et al. The health care costs of diabetic peripheral neuropathy in the US. *Diabetes Care* 2003;26:1790–5.
- 93 Personal communication, Simon Ashwell, Consultant Endocrinologist, The James Cook University Hospital
- 94 Personal communication, Graham Bowen, Clinical Lead for Diabetes , Southampton City PCT, 2004-07
- 95 <http://www.yhpho.org.uk/resource/item.aspx?RID=9950> last accessed 27 Feb 2012

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