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**Impact of case-mix adjustment on observed variation in the healing of diabetic foot ulcers at 12 weeks using data from the National Diabetes Foot Care Audit of England and Wales: a cohort study**

**Running title: Variation in healing of diabetic foot ulcers: a cohort study**

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Diabetic foot, foot ulcer, healing, audit variation, case-mix adjustment, care delivery

## **Abbreviations**

BMI	Body mass index
DFU	Diabetic foot ulcer
FEA	First expert assessment
ICD-10	International Classification of Diseases
IHP	Independent health providers
NDFA	National Diabetes Foot Care Audit of England and Wales
NDA	National Diabetes Audit
NHS	National Health Service
OPCS-4	OPCS Classification of interventions and procedures
RRT	Renal replacement therapy
SINBAD	Ulcer classification based on Site, Ischaemia, Neuropathy, Bacterial infection, Area, Depth

## **ABSTRACT**

### **Aim**

This cohort study investigates the extent to which variation in ulcer healing between services can be explained by demographic and clinical characteristics.

### **Methods**

The National Diabetes Foot Care Audit (NDFCA) collated data on people with diabetic foot ulcers presenting to specialist services in England and Wales between July 2014 and March 2018. Logistic regression models were created to describe associations between risk factors and a person being alive and ulcer-free 12 weeks from presentation, and to investigate whether variation between 120 participating services persisted after risk factor adjustment.

### **Results**

Of 27,030 people with valid outcome data, 12,925 (47.8%) were alive and ulcer-free at 12 weeks, 13,745 (50.9%) had an unhealed ulcer and 360 had died (1.3%). Factors associated with worse outcome were male sex, more severe ulcers, history of cardiac or renal disease and a longer time between first presentation to a non-specialist healthcare professional and first expert assessment. After adjustment for these factors, four services (3.3%) were more than 3SD above and seven services (5.8%) were more than 3SD below the national mean for proportions that were alive and ulcer-free at follow-up.

### **Conclusions/interpretations**

Variation in the healing of diabetic foot ulcers between specialist services in England and Wales persisted after adjusting for demographic characteristics, ulcer severity, smoking, body mass index and co-morbidities. We conclude that other factors contribute to variation in healing of diabetic foot ulcers and include the time to specialist assessment.

(239 words)

## INTRODUCTION

There is evidence of wide variation between countries, regions and communities in the outcomes of diabetic foot disease. The incidence of major amputation has been reported to be as much as 200 times higher in some countries than in others (1). Within countries, the incidence of major amputation has also been shown to vary 7-10 fold between populations with diabetes in both the USA (2,3) and the UK (4,5). There are many factors which may contribute to such differences including socio-demographic factors (eg ethnicity, social deprivation, age) and clinical risk factors (smoking status, co-morbidities, the presence of peripheral artery disease (PAD) and distal neuropathy) and their interactions. Other potential contributing factors include the structure of health care delivery and the quality of specialist care (6).

Major amputation has limitations as a measure of the outcome of foot disease in diabetes (7) and ulcer healing has been chosen as a preferable outcome for the National Diabetes Foot Care Audit of England and Wales (NDFCA) because it reflects the principal aims of care: return to usual function and limb salvage rather than limb sacrifice. By contrast with amputations, however, there have been relatively few studies of diabetic foot ulcers in which healing has been used as an outcome. Of these, some have compared healing in clinical sub-groups – such as those with and without evidence of PAD (7,8). Others have compared the incidence of healing associated with different degrees of ulcer severity using clinical scores based mainly on the presence of ulcer depth, area and infection and the presence of either neuropathy or PAD (9). One multinational study used multivariate analysis to demonstrate that several patient and ulcer characteristics were independently associated with healing: age, sex, history of heart failure, end stage renal failure, PAD, neuropathy, infection and ulcer area, depth and position on the foot (10).

The NDFCA was established in 2014 and its data provide the opportunity to extend knowledge of diabetic foot ulcer outcomes (11,12). The aim of the present study was to describe patient and ulcer characteristics that are associated with healing and assess whether these factors help explain variation in ulcer healing between multi-disciplinary foot care teams.

## **METHODS**

### **Data sources**

The NDFA collates data on people with diabetes presenting with a foot ulcer to multi-disciplinary foot care teams in England and Wales. It is part of the National Diabetes Audit (NDA) programme. Data collected comprise the unique NHS number, date of birth, time from first presentation with the ulcer to any health care professional and its first expert assessment (FEA) by a member of a specialist foot care team in either the community or hospital, severity of the index foot ulcer at first expert assessment using the SINBAD classification (12) and whether there is associated Charcot disease. The specialist team also records the following defined healing outcomes: whether the person was both alive and ulcer-free at 12 weeks after first expert assessment (whether or not they had undergone any form of surgery, including amputation), or whether they were alive at 12 weeks but with an unhealed ulcer or surgical wound. As this was a study using data recorded in clinical practice and the status of each ulcer was not determined at exactly 12 weeks from first expert assessment, healing status was defined at any point between 10 and 14 weeks (70-98 days).

Further data on demographic characteristics (sex, ethnicity, social deprivation) and clinical characteristics (type of diabetes, HbA1c, systolic blood pressure, total cholesterol, history of kidney disease) were obtained from the core NDA data (13) The occurrence of major amputation (Classification of Interventions and Procedures (OPCS-4) codes X093-99) within 6 months of first expert assessment, hospital admission for myocardial infarction (ICD-10 codes I21-2), stroke (ICD-10 codes I61, I63, I64, I679) and heart failure (ICD-10 code I50) were obtained from Hospital Episode Statistics for England and Patient Episode Database for Wales, which routinely document hospital activity in England and Wales respectively.

### **Ethics statement**

The NDA programme is commissioned by NHS England and the Welsh government and managed by the Healthcare Quality Improvement Partnership. The NDFA is delivered by NHS Digital (13) in partnership with Diabetes UK. Initially, the legal basis for the NDFA data collection in both England and Wales was informed patient consent. In May 2017 a new

legal basis for data collection was provided in the form of a Direction from NHS England under Section 254 of the Health and Social Care Act 2012, which meant that patient consent was no longer required in England. In Wales, the legal basis for the collection of data remained patient consent for the duration of this analysis. All patients are provided with standard written information about the NDA. All counts of people taken from the NDA are rounded to the nearest five to protect confidentiality.

### **Study population**

31,440 individuals aged 18 years or older were registered by the NDA after presenting to one of 140 specialist foot care services between 14<sup>th</sup> July 2014 and 31<sup>st</sup> March 2018. If an individual had more than one ulcer episode registered by the NDA, only the first was selected for analysis. 4,410 (14.0%) were excluded from the cohort due to missing follow-up data and this left a study population of 27,030. Entry into the cohort, or index date, was defined as the date of first expert assessment (FEA) by a member of a multi-disciplinary footcare service.

### **Follow-up and outcome**

The outcome was that of being alive and ulcer-free at approximately 12 weeks from FEA. To allow for the fact that clinical appointments did not always occur exactly 12 weeks after FEA, outcomes reported between 10 to 14 weeks from FEA were included in the analysis. In the primary analysis people who had undergone an amputation but had a healed surgical wound and no further ulcers were classed as being ulcer-free. A sensitivity analysis re-classifying all people who had undergone an amputation at this time as not being ulcer-free was also undertaken.

### **Classification variables**

Age and duration of diabetes derived from the NDA was calculated at the time of presentation to the specialist service. Ethnicity was defined as White, Asian, Black, or other. Deprivation scores were derived from home postcode and defined by the Indices of Multiple Deprivation 2015 (England) and 2014 (Wales). To enable cross-border comparisons, a

combined England and Wales score was created using the Employment and Income domain (14,15). For the purpose of analysis these scores were divided into quintiles.

Ulcer severity was measured using the SINBAD classification (12). A binary outcome was recorded for each of six aspects – site of the ulcer (on the hind foot or elsewhere), evidence of ischaemia, evidence of neuropathy, the presence of bacterial infection, the ulcer being greater than 1cm<sup>2</sup> in area and reaching to muscle, tendon or deeper. The existence of either active or previous Charcot arthropathy was also noted in this study. The interval between first presentation to any health care professional and FEA was taken from the NDFA and grouped as: self-presenting, ≤2 days, 3-13 days, 14 days-2 months and >2 months.

The latest HbA1c, systolic blood pressure, total cholesterol, body mass index and smoking status recorded in the core NDA within the audit data collection occurring in the same year or one year prior to the initial presentation to the multi-disciplinary team were identified. To account for non-linear associations between these factors and ulcer healing the variables were split into categorical variables which included a category for missing data. Smoking status was defined as current smoker, ex-smoker and never smoked.

Kidney disease was defined as an eGFR of <60 mL/min/1.73 m<sup>2</sup>, a hospital admission with an ICD-10 codes of N185, Z490, Z491, Z492, Z992 or evidence of renal transplant or dialysis (OPCS-4 codes M01 or X40). Any history of a hospital admission for myocardial infarction (ICD-10 codes I21-22), stroke (ICD-10 codes I61, I63-4, I679) and heart failure (ICD-10 code I50) in the year prior to or one month after the first expert assessment prior to the first expert assessment of the ulcer was identified.

### **Statistical analysis**

Univariable logistic regression models were run for each of the classification variables to establish baseline univariable associations with the outcome. A multivariable logistic regression model was run where all demographic and clinical characteristics were potentially included. Variables were selected for inclusion in the model using an iterative step-wise backward elimination procedure where variables were added in order of the largest p value until all those with an association at 95% significance were included. Using the same approach, a further model was constructed that included time from first presentation of the



ulcer to a healthcare professional to first expert assessment. This information was used to identify factors that may confound the association between service (the key exposure of interest) and outcome.

Two healing ratios were created for each of the 120 (out of 140) services with 20 or more patients included in the study. Firstly, an unadjusted healing ratio was calculated. This was calculated as the proportion of people being treated at that centre who were alive and ulcer-free at 12 weeks, multiplied by the proportion of people alive and ulcer-free in the whole cohort, multiplied by 100. An unadjusted healing ratio of 100 indicates that the proportion of people alive and ulcer-free at 12 weeks treated by that service is exactly the same as the proportion found across the whole of cohort of people included in this analysis. A value below 100 indicates fewer people treated at that service were alive and ulcer-free than in the total cohort across England and Wales whilst a value above 100 shows that a greater proportion of people treated at that service were alive and ulcer-free than the proportion for the whole of England and Wales.

Secondly, in order to take account of the differing patient and ulcer characteristics across services an adjusted healing ratio was calculated. This took the odds of being alive and ulcer-free after adjustment for risk factors from the logistic regression model to calculate the probability of each individual being alive and ulcer-free at 12 weeks based on their demographic and ulcer characteristics. For each service the sum of these probabilities provided the expected number of people who would be alive and ulcer-free at 12 weeks if each individual had the same healing rate as found across the whole cohort in England and Wales for those with the same demographic and ulcer characteristics. The observed, or actual, number of people alive and ulcer-free at 12 weeks for each service was divided by the expected number in each service and was multiplied by 100 to give the standardised healing ratio. An adjusted standardised healing ratio below 100 indicates that after adjustment for patient and ulcer characteristics, fewer people being treated by that centre were alive and ulcer-free at 12 weeks than would be expected based on the outcomes of the whole cohort across England and Wales. Conversely, an adjusted standardised healing ratio greater than 100 indicates that a greater proportion of people treated at that centre were alive and ulcer-free at 12 weeks than would be expected based on the outcomes of the whole cohort across England and Wales. Services with a healing ratio more than three standard deviations above

or below the mean for the whole cohort were considered to have a healing rate outside that which could be reasonably explained by variation in case-mix.

## RESULTS

Between 14<sup>th</sup> July 2014 and 31<sup>st</sup> March 2018 31,400 people presented to one of the 140 specialist units providing data to the NDFA with a new active foot ulcer to a specialist team, of whom 27,030 (86.0%) had a valid outcome recorded. After a median of 12 weeks follow up from first expert assessment 12,925 (47.8%) were alive and ulcer-free, 13,745 (50.9%) had an unhealed ulcer whilst 360 had died (1.3%) A total of 1,425 people (5.7%) had one or more major or minor amputations in the 12 week follow up period with 375 (26.2% of these) having a healed surgical wound.

### Univariable models

Univariable logistic regression models showed associations between ulcer-free survival and male sex (OR 0.83 95% CI 0.79-0.88 compared to female), and smoking status: OR 0.82, 95% CI 0.76-0.88 (current smoker) and 0.78, 95% CI 0.66-0.92 (missing smoking status) compared to never smokers.

Having an ulcer on the hind foot (OR 0.62, 95% CI 0.58-0.66), evidence of ischaemia (OR 0.44, 95% CI 0.42-0.46), evidence of neuropathy (OR 0.70, 95% CI 0.66-0.74) or bacterial infection (OR 0.57, 95% CI 0.54-0.60) were associated with reduced odds of being alive and ulcer-free. Ulcers that were 1cm<sup>2</sup> or greater in area (OR 0.42 95% CI 0.40-0.45) or that involved the muscle, tendon or were deeper (OR 0.43, 95% CI 0.40-0.46) were also less likely to heal.

Compared to those with a HbA1c of 48-53 mmol/mol those with a HbA1c of 59-74 mmol/mol (OR 0.91, 95% CI 0.84-0.98), 75-85 mmol/mol (OR 0.87, 95% CI 0.79-0.96) and  $\geq 86$  mmol/mol (OR 0.88, 95% CI 0.76-0.95) had lower odds of being alive and ulcer-free. Those with a body mass index of less than 20 kg/m<sup>2</sup> (OR 0.79, 95% CI 0.67-0.92) and an unknown body mass index (OR 0.73, 95% CI 0.63-0.85) had lower odds of being alive and ulcer-free than people with a body mass index of 25-29.9 kg/m<sup>2</sup>. A history of renal disease, myocardial infarction, stroke or heart failure were associated with lower odds of being alive and ulcer-free. No association was found between outcome and type of diabetes, ethnicity or deprivation (see Table 2).

### **Multivariable model**

The primary logistic regression model to assess associations with ulcer-free survival included sex, age, deprivation, smoking status, body mass index, duration of diagnosed diabetes, all elements of the SINBAD classification and evidence of Charcot arthropathy. Variables indicating co-morbidity with kidney disease, myocardial infarction and heart failure (but not stroke) were also included in the model (see Table 2). Adding the time from first presentation to a healthcare professional to FEA of the ulcer resulted in age and smoking status no longer being included in the model but ethnicity becoming a statistically significant explanatory variable.

Categorising everyone who underwent an amputation as having an unhealed ulcer irrespective of the state of the surgical wound resulted in a model that did not include age or deprivation as explanatory variables but did include ethnicity (see Table 2).

Across all models the strongest predictors of ulcer non-healing as measured by the beta coefficient were evidence of ischaemia, having an ulcer of 1cm<sup>2</sup> or greater, having an ulcer involving the muscle, tendon or deeper, and being male (see Table 2).

### **Variation persisting after risk-adjustment**

Figure 1 shows a funnel plot of the non-standardised healing ratios for the 120 participating care providers with 20 or more cases registered. It highlights the variation in crude rates of being alive and ulcer-free by care provider. There were seven (5.8%) care providers that had ulcer healing rates more than three standard deviations (3SD) above the mean for the whole cohort and 11 (9.2%) more than three standard deviations below the mean for the whole cohort (in contrast to the expected total of 0.3% outside 3 SD either side of the mean for the standard normal distribution). If the definition of acceptable variation is reduced to two standard deviations from the mean 24 (20.0%) of care providers fell below and 14 (11.7%) were above this limit (in contrast to the expected total of 5% outside 2 SD either of the mean for the standard normal distribution). Figure 2 shows the funnel plot for the same 120 participating care providers after standardising the healing ratios. It indicates that even after risk-adjustment there were four (3.3%) care providers with an ulcer healing ratio more than three standard deviations above and seven (5.8%) with an ulcer healing ratio more than three standard deviations below the mean for the whole cohort. For two standard deviation

thresholds the risk-adjusted healing ratios for 18 services (15.0%) were below and 12 services (10.0%) above.

## **DISCUSSION**

This study of 27,030 people with new diabetic foot ulcers presenting to specialist teams shows that just under half were alive and ulcer-free between 10 and 14 (median 12) weeks following first expert assessment. The strongest associations with ulcer healing were the severity of the ulcer as measured by the SINBAD score, as well as sex and the presence of Charcot arthropathy. Time to the first expert assessment was also a strong predictor of outcome. After adjustment for case-mix the percentage of care providers with a healing ratio outside three standard deviations from the cohort average fell from 15.0% to 9.2%. This suggests that whilst the demographic and clinical characteristics included in the case-mix adjustment explain some of the variation in ulcer healing by care provider, there are factors not included in the analysis that contribute to a greater extent. These are likely to be at service level and potentially include differences in the organisation and delivery of foot care in different settings.

Few other studies of factors associated with better or worse outcome have used ulcer healing as the outcome of interest. A single multinational prospective study exploring factors associated with healing by 12 months reported significant associations between healing and ulcer area, PAD, neuropathy and clinical co-morbidities in 1,088 people with foot ulcers and used them as the basis for calculating a 'risk scoring rule' (16). Other studies exploring factors associated with ulcer healing have nearly all been based on systematic reviews; significant associations were reported between measures of PAD and healing time (17-19). In addition, a single large, retrospective study used data held by the US Wound Registry on 6,440 individuals and reported associations between ulcer healing and multiple factors including wound duration, number of ulcers, infection, patient age, PAD and other co-morbidities from which a 'wound healing index' was devised and reported to be predictive of healing (20).

### Strengths and limitations

One of the strengths of this analysis is the large cohort size drawn from routine practice across specialist care providers throughout England and Wales. Not all care providers

participate in the NDFA and participating services do not necessarily register all newly presenting ulcers. Previous community surveillance has suggested that foot ulcers occur in approximately 2% per year of all people with diabetes in UK (21), of which less than half are likely to be referred for expert assessment in specialist services (22). Using annual caseload estimates provided by NDFA submitters as the denominator, the population coverage of the NDFA for the study period is estimated at 13.3% varying from 8.1% to 23.4% across the regions of England and Wales even though the data presented here are derived from the early years of the audit and participation has increased steadily over time. Those referred to specialist services will have tended to have either more severe ulcers or those which have proved resistant to earlier interventions. On the other hand, it is possible that a percentage of those with more overt PAD may have been referred directly to specialist vascular services.

The binary nature of some ulcer severity variables may have limited the statistical explanatory power of the analysis. For example, the SINBAD scores for ischaemia and neuropathy are not graduated for severity. Nevertheless, this study shows that differences between care providers in England and Wales in healing of diabetic foot ulcers persist after case-mix adjustment. These observations suggest that factors other than those measured in the study are likely to be significant contributors to variation in provider level outcomes. It is noteworthy that repeated studies conducted over the last 25 years have reported that alterations to the structure and process of health care delivery have resulted in very marked improvements, albeit using incidence of major amputation rates as the primary outcome (23-26). It is therefore possible that differences in the structure and delivery of diabetic foot ulcer care are also major contributors to the observed variation in ulcer healing by 12 weeks.

These data confirm that audit is an important part of routine clinical management and can provide evidence of variation in outcome between different specialist services which can be used as the basis of improving quality of care and outcomes. The identification of modifiable factors that contribute to such variation and of effective interventions is also required. The present observations confirm the importance of certain socio-demographic and clinical risk factors but also suggest that a significant contribution might be made by aspects of the delivery of specialist care. Further research is needed into the relationship between the organisation and accessibility of care, staff education and training and outcomes in people with diabetic foot ulcers.



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## **NOVELTY STATEMENT**

- The outcome of diabetic foot disease varies widely between centres.
- In order to explore potential causes of variation, it is necessary to adjust data for case-mix using data on the multiple patient-centred factors which may influence the rate of healing.
- This study was prospective and conducted in a very large population of people newly presenting with diabetic foot ulcers in England and Wales.
- The main conclusion of the study is that significant variation in healing was observed between clinical services even after making allowance for case-mix. Residual variation may be explained by aspects of the organisation and delivery of care.

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## **AUTHOR RELATIONSHIPS**

None of the authors has any relationship which could be regarded as a conflict of interest with regard to this work.

## **AUTHOR CONTRIBUTIONS**

All authors were closely involved in the conduct of this study. WJ is Clinical Lead of the NDFFA and BY is the Clinical Lead of the parent National Diabetes Audit. AY, CM, PK, JM, SW and NH conducted all aspects of data handling and analyses. AY, PK, WJ, BY, SW and NH drafted the report. All authors contributed to and approved the final version of the manuscript.



**Table 1: Baseline characteristics of people presenting to specialist services in England and Wales in 2014-2018 with a diabetic foot ulcer by outcome at approximately 12 weeks**

	All		Alive and ulcer-free		With unhealed ulcer		Died		Lost to follow up	
	N	%	N	%	N	%	N	%	N	%
Number	31,440		12,925		13,745		360		4,410	
Sex										
Female	9,175	29.2%	4,015	31.1%	4,015	29.2%	125	34.7%	1,305	29.6%
Male	21,820	69.4%	8,740	67.6%	8,740	63.6%	225	62.5%	3,030	68.7%
Unknown	450	1.4%	170	1.3%	170	1.2%	10	2.8%	75	1.7%
Age										
<40 years	835	2.7%	370	2.9%	305	2.2%	-	0.0%	155	3.5%
40-49 years	2,370	7.5%	1,005	7.8%	1,030	7.5%	10	2.8%	325	7.4%
50-59 years	5,690	18.1%	2,350	18.2%	2,475	18.0%	20	5.6%	845	19.2%
60-69 years	7,395	23.5%	3,110	24.1%	3,250	23.6%	40	11.1%	995	22.6%
70-79 years	8,160	26.0%	3,365	26.0%	3,625	26.4%	100	27.8%	1,070	24.3%
80+ years	6,970	22.2%	2,715	21.0%	3,045	22.2%	190	52.8%	1,020	23.1%
Mean (SD)	67.7 (13.7)		67.3 (13.7)		67.9 (13.5)		78.2 (11.6)		67.2 (14.3)	
Median (IQR)										
Type of diabetes										
Type 1	3,965	12.6%	1,635	12.6%	1,730	12.6%	35	9.7%	565	12.8%
Type 2 and other	26,975	85.8%	11,100	85.9%	11,795	85.8%	315	87.5%	3,760	85.3%
Unknown	505	1.6%	190	1.5%	220	1.6%	10	2.8%	85	1.9%
Duration of diabetes diagnosis										
0-9 years	9,355	29.8%	3,775	29.2%	4,150	30.2%	80	22.2%	1,350	30.6%
10-19 years	12,825	40.8%	5,620	43.5%	5,260	38.3%	145	40.3%	1,795	40.7%
20+ years	8,505	27.1%	4,005	31.0%	3,235	23.5%	110	30.6%	1,155	26.2%
Unknown	755	2.4%	340	2.6%	280	2.0%	20	5.6%	110	2.5%
Mean (SD)	15.3 (10.8)		15.9 (11)		14.7 (10.5)		16.7 (10.7)		15.2 (10.7)	
Median (IQR)										
Ethnicity										
White	24,810	78.9%	10,175	78.7%	10,830	78.8%	285	79.2%	3,515	79.7%
Asian	1,140	3.6%	480	3.7%	480	3.5%	10	2.8%	175	4.0%
Black	785	2.5%	300	2.3%	355	2.6%	5	1.4%	125	2.8%
Other	555	1.8%	210	1.6%	260	1.9%	5	1.4%	80	1.8%
Missing	4,150	13.2%	1,760	13.6%	1,825	13.3%	55	15.3%	510	11.6%
Deprivation										
Most deprived	7,975	25.4%	3,235	25.0%	3,455	25.1%	75	20.8%	1,210	27.4%
2nd most deprived	6,600	21.0%	2,635	20.4%	2,930	21.3%	85	23.6%	945	21.4%
3rd most deprived	6,340	20.2%	2,625	20.3%	2,840	20.7%	60	16.7%	815	18.5%
2nd least deprived	5,450	17.3%	2,285	17.7%	2,360	17.2%	75	20.8%	725	16.4%
Least deprived	4,170	13.3%	1,790	13.8%	1,775	12.9%	50	13.9%	560	12.7%
Unknown	910	2.9%	355	2.7%	390	2.8%	10	2.8%	155	3.5%
Smoking										
Current smoker	4,290	13.6%	1,585	12.3%	1,985	14.4%	30	8.3%	690	15.6%
Ex-smoker	13,125	41.7%	5,480	42.4%	5,750	41.8%	185	51.4%	1,710	38.8%
Never smoked	13,345	42.4%	5,610	43.4%	5,700	41.5%	125	34.7%	1,905	43.2%
Unknown	680	2.2%	245	1.9%	310	2.3%	15	4.2%	105	2.4%
SINBAD score										
Site - on hindfoot	5,580	17.7%	1,825	14.1%	2,835	20.6%	135	37.5%	790	17.9%
Ischaemia present	10,920	34.7%	3,270	25.3%	5,925	43.1%	220	61.1%	1,505	34.1%
Neuropathy present	25,150	80.0%	10,035	77.6%	11,475	83.5%	275	76.4%	3,365	76.3%
Bacterial infection present	13,590	43.2%	4,705	36.4%	6,930	50.4%	140	38.9%	1,820	41.3%
Area greater than 1cm <sup>2</sup>	15,595	49.6%	5,000	38.7%	8,200	59.7%	225	62.5%	2,170	49.2%
Depth to muscle, tendon	6,005	19.1%	1,635	12.6%	3,495	25.4%	75	20.8%	805	18.3%
Charcot										
Present	385	1.2%	150	1.2%	185	1.3%	-	0.0%	45	1.0%
Possible	530	1.7%	205	1.6%	235	1.7%	-	0.0%	85	1.9%
Inactive	1,165	3.7%	430	3.3%	595	4.3%	5	1.4%	135	3.1%

Not present	24,685	78.5%	10,310	79.8%	10,740	78.1%	305	84.7%	3,330	75.5%
Unknown	4,680	14.9%	1,830	14.2%	1,990	14.5%	45	12.5%	810	18.4%
<b>Time to first assessment</b>										
Self presenting	7,760	24.7%	3,650	28.2%	3,045	22.2%	70	19.4%	1,000	22.7%
<= 2 days	4,655	14.8%	1,925	14.9%	2,020	14.7%	60	16.7%	655	14.9%
3-13 days	9,575	30.5%	4,040	31.3%	4,145	30.2%	110	30.6%	1,280	29.0%
14 days - 2 months	6,545	20.8%	2,475	19.1%	2,995	21.8%	80	22.2%	990	22.4%
> 2 months	2,905	9.2%	835	6.5%	1,540	11.2%	40	11.1%	490	11.1%
<b>HbA1c (mmol/mol)</b>										
<48	5,615	17.9%	2,375	18.4%	2,370	17.2%	95	26.4%	780	17.7%
48-53	4,360	13.9%	1,860	14.4%	1,830	13.3%	40	11.1%	625	14.2%
54-58	3,405	10.8%	1,420	11.0%	1,470	10.7%	45	12.5%	470	10.7%
59-74	7,890	25.1%	3,225	25.0%	3,495	25.4%	95	26.4%	1,075	24.4%
75-85	3,620	11.5%	1,450	11.2%	1,650	12.0%	30	8.3%	495	11.2%
86+	5,680	18.1%	2,255	17.4%	2,555	18.6%	40	11.1%	825	18.7%
Unknown	875	2.8%	345	2.7%	375	2.7%	15	4.2%	140	3.2%
Mean (SD)	66.6 (22)		66 (21.4)		67.2 (22.3)		61.4 (20.1)		67.3 (23)	
Median (IQR)										
<b>Body mass index (kg/m<sup>2</sup>)</b>										
<20	865	2.8%	405	3.1%	305	2.2%	20	5.6%	140	3.2%
20-24.9	5,195	16.5%	2,300	17.8%	2,060	15.0%	75	20.8%	755	17.1%
25-29.9	9,390	29.9%	4,130	32.0%	3,880	28.2%	95	26.4%	1,280	29.0%
30-34.9	8,160	26.0%	3,500	27.1%	3,405	24.8%	90	25.0%	1,170	26.5%
35-39.9	4,175	13.3%	1,805	14.0%	1,790	13.0%	35	9.7%	545	12.4%
40+	2,700	8.6%	1,140	8.8%	1,160	8.4%	20	5.6%	375	8.5%
Unknown	960	3.1%	465	3.6%	325	2.4%	20	5.6%	150	3.4%
Mean (SD)	30.6 (6.8)		30.5 (6.8)		30.8 (6.7)		29.2 (6.7)		30.4 (6.8)	
Median (IQR)										
<b>Systolic blood pressure (mmHg)</b>										
<120	5,465	17.4%	2,080	16.1%	2,500	18.2%	90	25.0%	785	17.8%
120-129	6,330	20.1%	2,610	20.2%	2,715	19.8%	70	19.4%	935	21.2%
130-139	8,920	28.4%	3,805	29.4%	3,825	27.8%	80	22.2%	1,210	27.4%
140+	9,870	31.4%	4,090	31.6%	4,320	31.4%	105	29.2%	1,350	30.6%
Unknown	860	2.7%	335	2.6%	380	2.8%	15	4.2%	130	2.9%
Mean (SD)	132.6 (17)		132.9 (17)		132.5 (17)		129 (18.9)		132.4 (17)	
Median (IQR)										
<b>Cholesterol (mol/l)</b>										
<5	23,775	75.6%	9,825	76.0%	10,365	75.4%	280	77.8%	3,305	74.9%
5+	6,690	21.3%	2,720	21.0%	2,950	21.5%	65	18.1%	950	21.5%
Unknown	980	3.1%	380	2.9%	430	3.1%	15	4.2%	150	3.4%
Mean (SD)	4.2 (1.2)		4.2 (1.2)		4.2 (1.2)		4 (1.2)		4.2 (1.2)	
Median (IQR)										
<b>Co-morbidities</b>										
Kidney disease	2,115	6.7%	685	5.3%	1,055	7.7%	65	18.1%	310	7.0%
MI	720	2.3%	190	1.5%	400	2.9%	25	6.9%	110	2.5%
Stroke	765	2.4%	265	2.1%	345	2.5%	30	8.3%	130	2.9%
Heart failure	3,190	10.1%	960	7.4%	1,605	11.7%	125	34.7%	500	11.3%

**Table 2: Odds ratios for ulcer-free survival at approximately 12 weeks follow-up derived from logistic regression models**

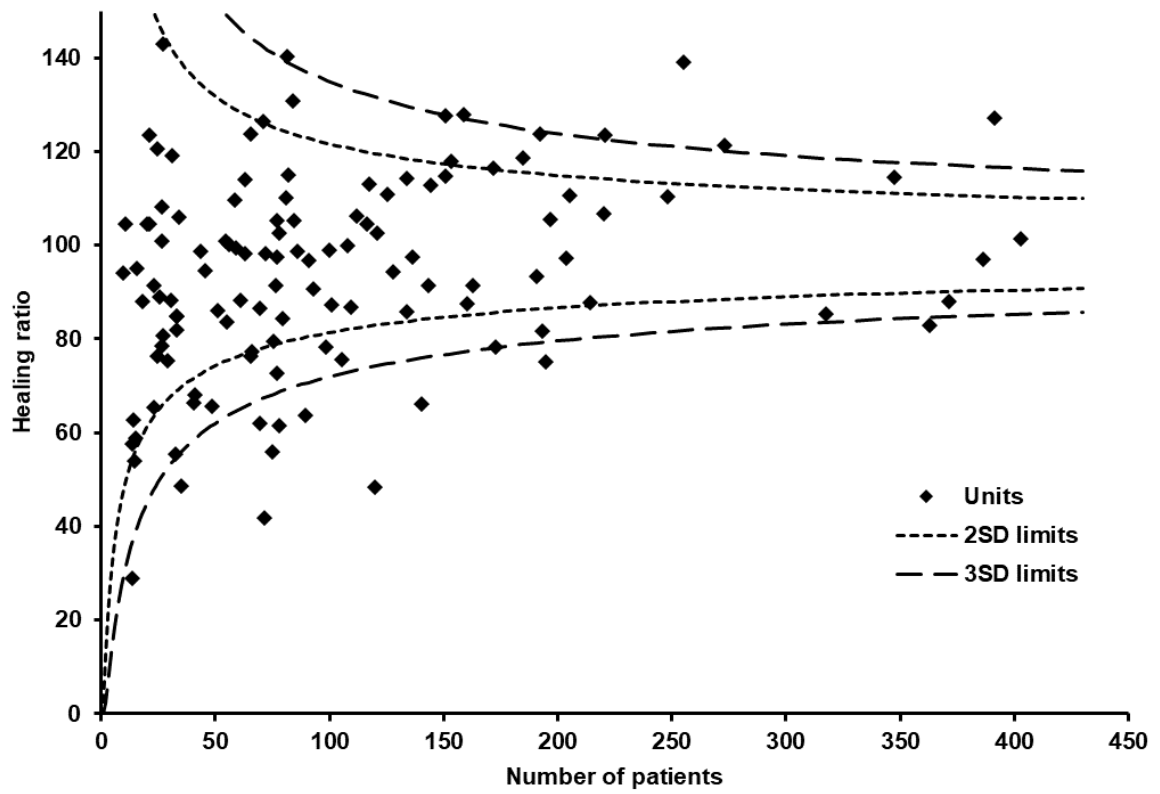
	Univariable	Main model		Multivariable Including time to assessment		All people who underwent amputation classed as unhealed	
	OR (95% CI)	OR (95% CI)	$\beta$ co-efficient	OR (95% CI)	$\beta$ co-efficient	OR (95% CI)	$\beta$ co-efficient
<b>Sex</b>							
Female	1.00	1.00	-	1.00	-	1.00	-
Male	0.83 (0.79-0.88)	0.88 (0.83-0.93)	-0.093	0.88 (0.84-0.94)	-0.068	0.88 (0.83-0.93)	-0.055
Unknown	0.80 (0.65-0.98)	1.35 (0.87-2.11)	0.064	1.18 (0.79-1.77)	0.040	1.07 (0.54-2.10)	0.023
<b>Age</b>							
<40 years	1.27 (1.08-1.49)	1.19 (1.00-1.41)	0.041				
40-49 years	1.03 (0.93-1.14)	0.96 (0.86-1.07)	-0.011				
50-59 years	1.00	1.00	-				
60-69 years	1.00 (0.93-1.08)	1.03 (0.95-1.11)	0.010	Not included in model		Not included in model	
70-79 years	0.96 (0.89-1.03)	0.97 (0.90-1.05)	-0.010				
80+ years	0.89 (0.83-0.96)	0.91 (0.83-0.99)	-0.035				
Unknown	1.06 (0.42-2.68)	0.97 (0.36-2.59)	-0.007				
<b>Type of diabetes</b>							
Type 1	1.12 (0.92-1.35)					0.64 (0.32-1.28)	-0.047
Type 2 and other	1.00	Not included in model		Not included in model		1.00	-
Unknown	1.13 (0.92-1.39)					0.58 (0.29-1.17)	0.011
<b>Duration of diabetes diagnosis</b>							
0-9 years	1.00	1.00	-	1.00	-	1.00	-
10-19 years	0.85 (0.80-0.90)	0.88 (0.82-0.93)	-0.011	0.88 (0.82-0.93)	-0.008	0.87 (0.82-0.93)	-0.007
20+ years	0.73 (0.69-0.78)	0.81 (0.76-0.87)	-0.043	0.81 (0.75-0.87)	-0.041	0.79 (0.74-0.85)	-0.049
Unknown	0.73 (0.62-0.86)	0.91 (0.70-1.20)	0.005	0.89 (0.68-1.16)	0.000	0.90 (0.68-1.19)	0.004
<b>Ethnicity</b>							
White	1.00			1.00	-	1.00	-
Asian	1.08 (0.95-1.23)			1.20 (1.04-1.38)	0.041	1.24 (1.08-1.43)	0.049
Black	0.91 (0.78-1.07)	Not included in model		1.10 (0.93-1.29)	0.015	1.09 (0.92-1.29)	0.011
Other	0.87 (0.73-1.05)			0.88 (0.73-1.07)	-0.040	0.90 (0.74-1.09)	-0.038
Unknown	1.02 (0.95-1.10)			1.02 (0.95-1.11)	-0.005	1.02 (0.94-1.11)	-0.009

Deprivation							
Most deprived	1.00	1.00	-	1.00	-		
2nd most deprived	0.95 (0.89-1.02)	0.96 (0.89-1.03)	-0.034	0.96 (0.89-1.04)	-0.036		
3rd most deprived	0.99 (0.92-1.06)	1.00 (0.92-1.07)	-0.020	1.00 (0.93-1.08)	-0.020		
2nd least deprived	1.02 (0.95-1.10)	1.03 (0.95-1.11)	-0.008	1.05 (0.97-1.13)	-0.005		Not included in model
Least deprived	1.07 (0.99-1.16)	1.11 (1.02-1.21)	0.018	1.13 (1.03-1.23)	0.021		
Unknown	0.96 (0.83-1.12)	1.24 (0.98-1.57)	0.043	1.24 (0.98-1.57)	0.042		
Smoking							
Current smoker	0.82 (0.76-0.88)	0.87 (0.80-0.94)	-0.023			0.89 (0.82-0.96)	-0.015
Ex-smoker	0.96 (0.91-1.01)	1.02 (0.97-1.08)	0.053	Not included in model		1.04 (0.98-1.10)	0.062
Never smoked	1.00	1.00	-			1	-
Unknown	0.78 (0.66-0.92)	0.81 (0.58-1.13)	-0.037			0.78 (0.55-1.11)	-0.049
SINBAD score							
Site - on hindfoot	0.62 (0.66-0.58)	0.73 (0.68-0.78)	-0.067	0.74 (0.69-0.79)	-0.064	0.74 (0.69-0.79)	-0.064
Ischaemia present	0.44 (0.46-0.42)	0.48 (0.45-0.51)	-0.192	0.48 (0.45-0.51)	-0.194	0.46 (0.44-0.49)	-0.204
Neuropathy present	0.70 (0.74-0.66)	0.77 (0.72-0.82)	-0.057	0.77 (0.72-0.82)	-0.057	0.76 (0.71-0.81)	-0.060
Bacterial infection present	0.57 (0.60-0.54)	0.78 (0.74-0.83)	-0.067	0.78 (0.74-0.83)	-0.067	0.76 (0.72-0.81)	-0.075
Area greater than 1cm <sup>2</sup>	0.42 (0.45-0.40)	0.52 (0.49-0.55)	-0.111	0.53 (0.50-0.56)	-0.104	0.51 (0.48-0.53)	-0.145
Involving muscle, tendon or deeper	0.43 (0.46-0.40)	0.60 (0.56-0.64)	-0.180	0.62 (0.58-0.67)	-0.177	0.51 (0.48-0.55)	-0.189
Charcot							
Present	0.87 (0.70-1.08)	0.83 (0.66-1.05)	-0.018	0.85 (0.68-1.07)	-0.015	0.86 (0.68-1.08)	-0.018
Possible	0.92 (0.76-1.11)	0.95 (0.78-1.16)	0.016	0.98 (0.80-1.19)	0.020	1.02 (0.83-1.24)	0.025
Inactive	0.77 (0.68-0.87)	0.73 (0.63-0.83)	-0.059	0.72 (0.63-0.82)	-0.065	0.74 (0.65-0.85)	-0.059
Not present	1.00	1.00	-	1.00	-	1.00	-
Unknown	0.96 (0.90-1.03)	1.00 (0.93-1.07)	0.042	1.00 (0.93-1.08)	0.041	1.01 (0.94-1.09)	0.038
Time to first assessment							
Self presenting	1.24 (1.16-1.32)			1.09 (1.02-1.17)	-0.015		
<= 2 days	0.98 (0.90-1.05)			0.98 (0.90-1.06)	0.020		
3-13 days	1.00	Not included as potential variable		1.00	-		Not included as potential variable
14 days - 2 months	0.85 (0.79-0.91)			0.87 (0.81-0.93)	-0.065		
> 2 months	0.56 (0.51-0.61)			0.62 (0.56-0.69)	0.041		
HbA1c (mmol/mol)							
<48	0.97 (0.89-1.06)	Not included in model		Not included in model		Not included in model	
48-53	1.00						

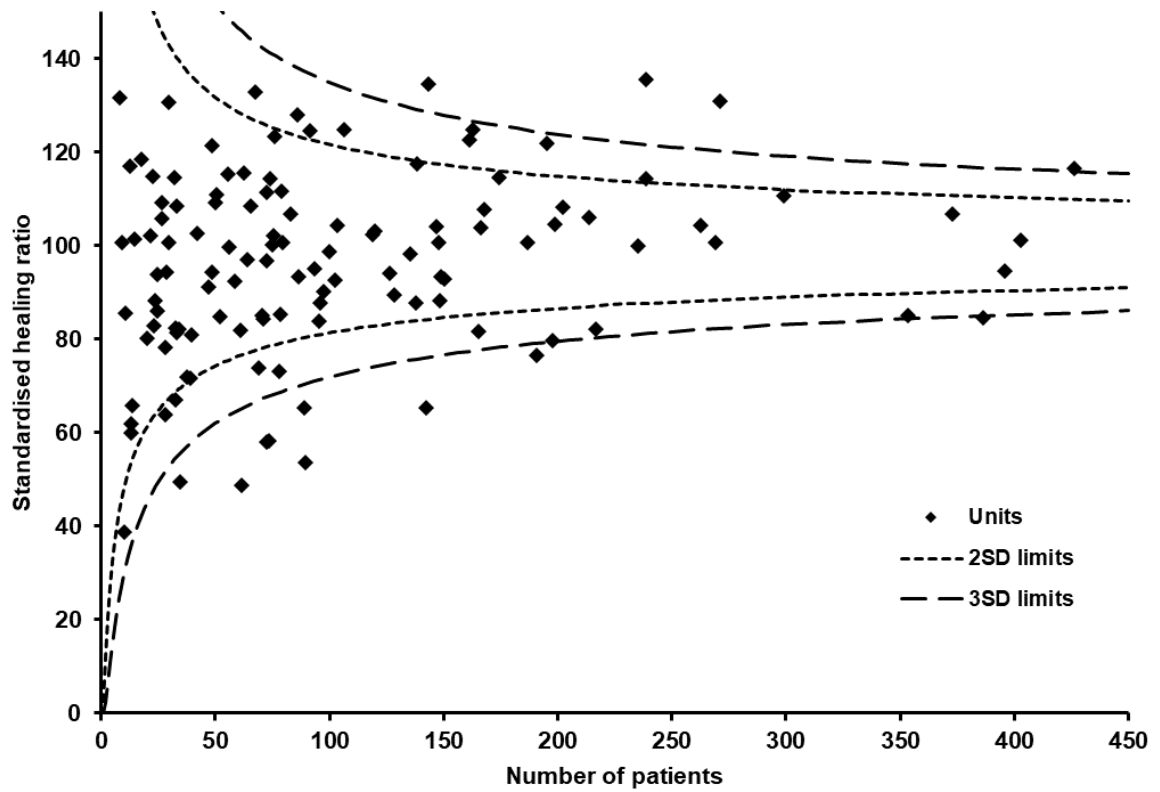
54-58	0.94 (0.86-1.04)							
59-74	0.91 (0.84-0.98)							
75-85	0.87 (0.79-0.96)							
86+	0.88 (0.80-0.95)							
Unknown	0.89 (0.76-1.05)							
Body mass index (kg/m <sup>2</sup> )								
<20	0.79 (0.67-0.92)	0.86 (0.73-1.01)	-0.018	0.84 (0.71-0.99)	-0.025	0.86 (0.73-1.01)	-0.022	
20-24.9	0.95 (0.88-1.02)	0.98 (0.91-1.06)	0.025	0.97 (0.89-1.04)	0.020	0.96 (0.89-1.04)	0.014	
25-29.9	1.00	1.00	-	1.00	-	1.00	-	
30-34.9	1.03 (0.97-1.10)	1.01 (0.94-1.08)	0.040	1.02 (0.96-1.10)	0.046	1.03 (0.96-1.10)	0.042	
35-39.9	1.06 (0.98-1.15)	1.00 (0.92-1.09)	0.031	1.03 (0.95-1.12)	0.042	1.04 (0.96-1.13)	0.041	
40+	1.09 (0.99-1.19)	0.99 (0.90-1.10)	0.026	1.03 (0.93-1.13)	0.037	1.04 (0.94-1.15)	0.037	
Unknown	0.73 (0.63-0.85)	0.64 (0.50-0.81)	-0.101	0.61 (0.49-0.77)	-0.113	0.64 (0.50-0.81)	-0.104	
Systolic blood pressure (mmHg)								
<120	1.00							
120-129	1.17 (1.08-1.26)							
130-139	1.21 (1.13-1.31)	Not included in model		Not included in model		Not included in model		
140+	1.15 (1.07-1.24)							
Unknown	1.06 (0.91-1.24)							
Cholesterol (mol/l)								
<5	1.00							
5+	0.98 (0.92-1.04)	Not included in model		Not included in model		Not included in model		
Unknown	0.92 (0.80-1.06)							
Co-morbidities								
Kidney disease	0.63 (0.57-0.69)	0.87 (0.78-0.98)	-0.036	0.86 (0.77-0.97)	-0.039	0.85 (0.76-0.96)	-0.040	
MI	0.47 (0.40-0.56)	0.72 (0.59-0.86)	-0.028	0.72 (0.60-0.87)	-0.027	0.70 (0.58-0.85)	-0.029	
Stroke	0.77 (0.65-0.90)	Not included in model		Not included in model		Not included in model		
Heart failure	0.58 (0.53-0.62)	0.74 (0.68-0.81)	-0.050	0.74 (0.67-0.81)	-0.051	0.73 (0.66-0.80)	-0.053	
Model fit								
c-statistic		0.686		0.690		0.698		
Nagelkerke-R2		0.139		0.145		0.158		



Figure 1: Funnel plot of unadjusted ratio of people alive and ulcer-free



**Figure 2: Funnel plot of standardised ratio people alive and ulcer-free adjusted for case-mix**



Adjusted for sex, age, ethnicity, smoking status, duration of diagnosed diabetes, SINBAD score, presence of Charcot