Predicted costs and outcomes of reduced vibration detection in the UK

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1 Diabetic peripheral neuropathy (DPN) is common among people with diabetes.

2 Vibration detection has been shown to be a good predictor of the long-term complications of DPN.

3 The average individual with reduced vibration detection incurs higher costs and yields lower quantity and quality of life than the average individual with normal vibration detection modelled over 10 years.

4 Concentrating preventive footcare on people with reduced vibration detection could save the NHS valuable resources and improve health outcomes.

KEY WORDS

- **Amputation**
- **Foot ulcer**
- **Diabetic peripheral neuropathy**
- **Costs**
- **Markov model**

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Introduction

The ability to perceive vibration has been shown to be a good predictor of the long-term complications of diabetic peripheral neuropathy. This study estimated the predicted costs and complications to the NHS associated with reduced compared with normal vibration detection, using a quantitative sensory testing device. It concludes that identifying people with reduced vibration detection would enable preventive care to be targeted at those patients, potentially saving the NHS valuable resources and improving health outcomes.

Foot ulceration is a common reason for hospital admission of diabetic patients in the UK (Currie et al, 1996). People with diabetes are 15 times more likely to have an amputation than those without (Bild et al, 1989). Diabetic foot ulceration and amputations cost the NHS £244m in 2001 (Gordois et al, 2003). If at-risk groups could be identified and measures taken to prevent these complications, potentially large cost savings and improvements in health-related quality of life could result.

Diabetic peripheral neuropathy (DPN) increases the risk of foot ulcers and lower extremity amputation as people with DPN have an increased tendency to sustain unrecognised damage through trauma and pressure. Reduced vibration detection is one of the first signs of polyneuropathy (Grunert et al, 1990) and studies have shown it to be a good predictor of long-term complications of DPN (Young et al, 1994; Abbott et al, 1998; Coppini et al, 1998).

Vibration detection can be quantified using an electronic tuning fork that allows vibration to be adjusted, depending upon the voltage applied. The vibration-perception threshold (VPT) is defined as the lowest voltage at which vibration can be detected.

VPT has been shown to be a more accurate predictor of ulceration and amputation than three common clinical tests: foot sensation (using cotton wool), ankle reflexes, and vibration sensation (using a 128 Hz tuning fork), with test sensitivity and specificity of 70% and 72% respectively (Coppini et al, 1998). Moreover, VPT has been reported to have a higher positive predictive value than both neuropathy disability score and Semmes-Weinstein monofilaments (Pham et al, 2000). However, sensory nerve fibre dysfunction is only one of many potential risk factors for diabetic foot ulcers.

The aim of this study was to estimate the predicted costs and complications to the NHS for people with reduced compared with normal vibration detection.

Research methods

We constructed a Markov model of DPN progression in the UK (*Figure 1*). The Markov model is an incidence-based approach to

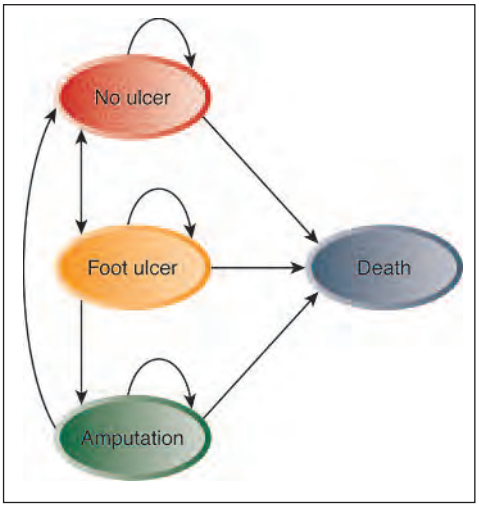

Figure 1: Markov model of diabetic peripheral neuropathy progression in the UK.

estimating resource use and associated costs and outcomes.

People with diabetes begin with no ulceration and some remain ulcer free. Others progress to ulceration and remain in that state until healed or progress to amputation. Amputation is modelled as an acute event and patients return to the equivalent of 'healed' after amputation. Patients can die from all causes at any stage in the model. Mortality is dependent on age and DPN state.

Moving from one health state to another is dependent on transition probabilities. We estimated the proportion of patients with diabetes proceeding to each health state and identified the health service contacts and treatments provided at each stage.

The outcomes of the model are costs, number of ulcers and amputations, duration of ulceration, life-years and quality-adjusted life-years (QALYs) by vibration detection level.

Outcomes, rates and transition probabilities

Rates of foot ulceration and amputation, the probability of healing and health state utility scores were identified from a focused literature search on MEDLINE and EMBASE from 1992 onwards. The transitional probabilities used in the model, and their sources, are summarised in *Table 1*.

Progression to ulceration is dependent on the level of vibration detection. Reduced vibration detection was defined as a VPT test score of ≥25V (Young et al, 1994; Abbott et al, 1998). The rate of progression to ulceration was taken from data presented in Young et al (1994) since this study had the longest follow-up period of the published evidence. In their 4-year prospective study of 469 diabetic patients with no history of foot ulceration, less than 4% of patients with a VPT <25V developed new ulcers compared with almost 20% of

Table 1. Base case transitional parameter values and distributions

Event	Base case value	Mean	SD	Min	Max	Source
Annual rate of first foot ulceration for VPT≥25V	0.0495	0.491	0.020	0	0.099	Young et al, 1994
Annual rate of recurrent foot ulceration for VPT≥25V	0.1875	0.1874	0.077	0	0.375	Young et al, 1994
Annual rate of first and recurrent foot ulceration for VPT<25V	0.0077 +0.0025* year	0.0288	0.014	0	0.065	Young et al, 1994
Annual rate of amputation given ulceration	0.0417	0.0416	0.017	0	0.0834	Department of Health, 2002
Proportion of foot ulcers healed within 12 months	0.694	0.693	0.124	0.388	1	Allenet et al, 2000
Utility with amputation	0.7	0.7	0.021	0.65	0.75	Carrington et al, 1996
Utility with foot ulceration	0.6	0.6	0.020	0.55	0.65	Carrington et al, 1996
Utility with good health	0.8	0.8	0.020	0.75	0.85	Carrington et al, 1996
Age-specific mortality rates*	**Age**	**Type 1**		**Type 2**		Rossing et al, 1996 and Evans et al, 2002
	<50	0.013406		0.008503		
	55	0.044855		0.016987		
	65	0.101843		0.036692		
	>69	0.192797		0.076074		

* Linear interpolation was used to calculate age-specific rates between the ages given. VPT = vibration perception threshold

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1 We used an initial annual foot ulceration rate of 0.77% in the cohort of diabetic patients with normal vibration detection (VPT<25V).

2 We used annual rates of 4.95% and 18.75% for first and recurrent foot ulceration in the cohort of patients with reduced vibration detection (VPT≥25V).

3 The duration of foot ulceration was modelled as the residual of the probabilities of healing, amputation and death.

4 Mortality for the model was calculated using age-specific all-cause mortality rates for people with diabetes.

those with a VPT ≥25V. Moreover, no recurrent ulceration was reported in the group of patients with VPT <25V, whereas 30 recurrent ulcers were reported in the group with VPT ≥25V.

Foot ulceration rates: Based on these data, we used an initial annual foot ulceration rate of 0.77% in the cohort of diabetic patients with normal vibration detection (VPT<25V). To control for differences in the duration of diabetes between groups, this rate was increased by 0.25% per annum.

In the absence of data on recurrent ulcers for this group, we conservatively assumed that the probability of recurrent ulcers was identical to that for first ulcer. Additionally, we used annual rates of 4.95% and 18.75% for first and recurrent foot ulceration in the cohort of patients with reduced vibration detection (Young et al, 1994). These figures are conservative compared with those of Abbott et al (1998) who reported a 7.2% incidence of first foot ulceration within one year for a sample of 1035 patients with a VPT of at least 25V.

Duration of foot ulceration: We modelled the duration of foot ulceration as the residual of the probabilities of healing, amputation and death. The probability of a foot ulcer healing and the patient returning to a state of no ulceration is taken from Allenet et al (2000), who estimated that 69.4% of patients receiving standard treatment for first ulceration were healed within 52 weeks. Duration of ulceration is assumed to be independent of VPT score.

Amputation rates: Hospital Episode Statistics (Department of Health, 2002) report an annual amputation incidence of 0.25% among people with diabetes. The prevalence of foot ulceration among people with diabetes in the UK has been estimated at 6% (Scottish Intercollegiate Guidelines Network, 2001). Using these data, we estimated a rate of 4.17% for progression from ulceration to amputation. This figure is close to that reported in a UK community-based cohort study (Abbott et al, 2002). Once patients have foot ulcers, they are equally likely to experience an amputation, regardless of their VPT score.

Mortality rates: Mortality for the model was calculated using age-specific all-cause mortality rates for people with diabetes. All-cause mortality rates for adults with type 1 and type 2 diabetes are based on Rossing et al (1996) and Evans et al (2002) (*Table 1*).

Our model calculated the weighted average age-specific mortality rates based on proportions of diabetes type used in the model, with 59.1% of the cohort being type 2 and the remaining 40.9% type 1 (Young et al, 1994).

Foot ulceration and amputation have been shown to be associated with an increased risk of mortality among people with diabetes. Following results presented by Apelqvist et al (1993) and Boyko et al (1996), we assumed that the risk of death doubled after ulceration and quadrupled post amputation.

Utility scores and QALYs: Utility scores were taken from Carrington et al (1996) (*Table 1*). The study used a visual quality of life ladder to estimate the impact of diabetic foot ulceration and amputation on utility. Foot ulceration and amputation resulted in reported utility scores of 0.6 and 0.7 respectively. The diabetic control group returned a utility score of 0.8. Utility scores were multiplied by life-years to provide QALYs.

Costs used in the model

The cost data used in the model were estimated in a concurrent cost of illness study (Gordois et al, 2003). We calculated the weighted average monthly cost of foot ulceration in the UK based on estimated costs and proportions of foot ulcers without infection, with superficial infection (e.g. cellulitis), and with deep infection (e.g. osteomyelitis). Similarly, we calculated the weighted average cost of amputation in the UK, based on unit costs and proportions of toe, foot and leg amputations (*Table 2*).

In order to reflect a positive rate of time preference, costs and benefits were discounted to present values. Discount rates of 6% and 1.5% were applied to costs and benefits respectively to reflect the UK guidelines (National Institute for Clinical Excellence, 2001).

Estimation

The model was run over a 10-year time horizon with monthly cycles. We modelled

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1 The predicted costs and outcomes for both normal and reduced vibration detection cohorts were modelled using Monte Carlo simulations.

2 This allowed us to analyse the distributions of the costs and consequences and to define confidence intervals.

3 The average individual with reduced vibration detection incurs 3.35 times more costs, yields 0.19 fewer QALYs, and lives for approximately 2 months less than an average individual with normal vibration detection, discounted over 10 years.

the predicted costs and outcomes for both normal and reduced vibration detection cohorts using Monte Carlo simulations.

The Monte Carlo approach simulates a random sample of patients with different rates of events (probabilities) drawn from predetermined distributions. This enabled us to account for uncertainties surrounding health state transition probabilities and utility scores. The main advantage of Monte Carlo simulation, over a basic expected value analysis, is that it allowed us to analyse the distributions of the costs and consequences and to define confidence intervals.

The health state utility scores and transition probabilities were all characterised as symmetric triangular distributions (*Table 1*). This was appropriate for two reasons: minimum and maximum values are fixed, and the most likely value (mode) falls equally between the minimum and maximum.

Sensitivity analysis

Sensitivity analysis tests various components of the model to identify those where changes in input parameter values bring about the greatest change in the results.

We undertook one-way sensitivity analyses by varying each parameter by 20% above and below its 'base case' expected value. In order to isolate the impact of varying the parameter from the inherent white noise of simulation, we used the same set of sample values for each distribution.

Table 2. Healthcare costs used in the model

	2001 (£)	Proportion
Foot ulceration		
No deep infection	£253.50	0.939
With cellulitis	£616.89	0.0195
With osteomyelitis	£1143.87	0.0415
Weighted average monthly cost	**£298**	
Amputation		
Toe	£3443.48	0.535
Foot	£7786.01	0.08
Leg	£10978.78	0.385
Weighted average unit cost	**£6692**	

Source: Gordois et al (2003)

Results

From the 10 000 Monte Carlo simulations, the reduced vibration detection cohort experienced approximately three times more foot ulcers than the normal vibration cohort (*Table 3*). This is explained by the higher probability of ulcers in the reduced vibration cohort. There is a greater relative share of recurrent ulcers (33%) in the cohort with reduced vibration detection than in the normal cohort (5%), explained by the higher probability of recurrent ulcers.

The reduced vibration cohort experienced approximately three times more amputations than the normal vibration cohort. This is expected given that the probability of amputation is dependent on foot ulceration.

The mean time to first ulcer in the reduced vibration cohort was approximately 15 months earlier than in the normal vibration cohort, and the mean duration for recurrent ulcers was significantly lower than for first ulcers in both cohorts.

This is surprising given that the probability of a foot ulcer healing is equal for first and recurrent ulcers. However, this is partly the result of censoring within the simulation. Recurrent ulcers occur after first ulcers, and are therefore more likely to be censored after 10 years of simulation, i.e. some might be in a state of ulceration at the end of the 10-year period, and thus the time in the ulcerated state is ended in the final period of the model rather than when the ulcer is healed.

Similarly, the mean duration of ulcers in the normal vibration cohort was significantly lower than that in the reduced vibration cohort. Individuals were more likely to experience foot ulcers toward the end of the 10-year simulation since the probability of foot ulceration increases with time in the normal vibration cohort. This censoring will underestimate the true mean duration (and costs) of ulcers in the normal vibration cohort.

The average individual with reduced vibration detection incurs 3.35 times more costs for foot ulcers and amputations, yields 0.19 fewer QALYs, and lives for approximately 2 months less than an average individual with normal vibration detection, discounted over 10 years. These differences were significant at the 1% level ($P<0.0001$).

The 10% highest-cost subgroups have a shorter time to first ulcer, remain in ulceration for longer, incur higher costs, and yield more QALYs and life-years than their full cohort counterparts. The main driver of these results is increased survival. An increase in average life-years results in additional QALYs and longer ulcer duration, resulting in higher costs.

When comparing the differences between the two highest-cost subgroups with the differences between the full cohorts, the absolute difference in costs and QALYs was greater between the subgroups than between the full cohorts. The reduced vibration subgroup yields 0.4 fewer QALYs ($P<0.0001$) on average per person than the normal subgroup. This is a result of relatively longer ulcer duration in the reduced vibration subgroup as time spent in ulceration yields lower utility scores.

The difference in life-years between the subgroups was smaller than the difference between the full cohorts because the subgroups we selected were those with higher costs, which are associated with longevity and ulceration.

Sensitivity analysis

Sensitivity analysis was performed varying each parameter by 20% above and below its 'base case' expected value. The key drivers of costs in the reduced vibration detection cohort are the probability of first foot ulceration and the probability of healing (*Table 4*). The probability of recurrent ulceration has little effect on costs. However, recurrent ulceration can only follow first ulceration and the duration of recurrent ulceration is censored.

The probability of first foot ulceration is the largest driver of QALYs and life-years since transition to foot ulceration triggers a fall in the utility component of QALYs and

Table 3. Ulceration and amputation, and discounted mean costs and outcomes per person over 10 years

	Full cohort		10% highest-cost subgroups	
Outcome	**Normal vibration (VPT<25V)**	**Reduced vibration (VPT≥25V)**	**Normal vibration (VPT<25V)**	**Reduced vibration (VPT≥25V)**
Total foot ulcers	1623	5008	1072	1897
First ulcers (% of total)	1537 (95%)	3369 (67%)	1000 (93%)	1000 (53%)
Recurrent ulcers (% of total)	86 (5%)	1639 (33%)	72 (7%)	897 (47%)
Mean time to first ulcer (years)	5.46 (5.32-5.60)	4.31 (4.22-4.41)	4.89 (4.73-5.05)	2.64 (2.52-2.75)
Mean duration of first ulcer years)	1.03 (0.98-1.08)	1.13 (1.09-1.17)	1.44 (1.37-1.50)	2.04 (1.95-2.13)
Mean duration of recurrent ulcer (years)	0.78 (0.62-0.94)	1.02 (0.97-1.07)	0.91 (0.74-1.09)	1.45 (1.36-1.53)
Total amputations	80	226	80	186
Mean cost per person	£457 (£426-£487)	£1531 (£1470-£1593)	£4225 (£4048-£4401)	£9544 (£9345-£9743)
Mean QALYs per person	6.21 (6.17-6.25)	6.02 (5.98-6.06)	6.31 (6.23-6.40)	5.93 (5.85-6.01)
Mean life-years per person	7.80 (7.75-7.85)	7.65 (7.60-7.70)	8.26 (8.15-8.37)	8.22 (8.11-8.33)

95% confidence intervals in parentheses. QALYs = quality-adjusted life-years; VPT = vibration perception threshold

Table 4. Sensitivity analysis on reduced vibration cohort; discounted mean costs and outcomes per person over 10 years

		Cost	QALYs	Life-years
Base model		£1531	6.02	7.65
Annual rate of first foot ulceration	+20%	£1793 (17.1%)	5.98 (-0.7%)	7.63 (-0.3%)
	-20%	£1256 (-18.0%)	6.07 (0.8%)	7.69 (0.5%)
Annual rate of recurrent foot ulceration	+20%	£1603 (4.7%)	6.01 (-0.2%)	7.65 (0.0%)
	-20%	£1460 (-4.6%)	6.02 (0.0%)	7.65 (0.0%)
Proportion of foot ulcers healed within 12 months	+20%	£1386 (-9.5%)	6.03 (0.2%)	7.65 (0.0%)
	-20%	£1743 (13.8%)	6.00 (-0.3%)	7.65 (0.0%)
Prevalence of type 1 diabetes mellitus	12%	£1586 (3.6%)	6.32 (4.9%)	8.04 (5.1%)
Discount rate	0%	£2096 (36.9%)	6.43 (6.8%)	8.18 (6.9%)

Percentage change from the base model in parentheses. QALYs = quality-adjusted life-years

doubles the risk of death.

The second largest driver of QALYs and life-years is the duration of ulceration through the probability of healing. This is because time spent in ulceration has a negative impact on the utility component of QALYs. Analysis with proportion of the cohort with type 1 diabetes set at 12%, representative of the UK (DARTS, 2001), influences both costs and outcomes. This is because mortality rates are higher for the type 1 variant. All results were sensitive to changes in the discount rate.

Conclusions

We estimated that the average individual with reduced vibration detection incurs 3.35 times more foot ulcer and amputation costs, yields 0.19 fewer QALYs, and lives for approximately 2 months shorter than an average individual with normal vibration detection, discounted over 10 years.

In a concurrent cost of illness study (Gordois et al, 2003), we estimated that there are 433 674 people in the UK with diabetes who have DPN. Assuming that there is the same proportion of people with reduced vibration detection in the UK as reported by Young et al (1994), then there are approximately 190 800 people with diabetes and reduced vibration detection. Multiplying this by the average cost per person (£1531), we estimated that the long-term complications of DPN experienced by the population with reduced vibration detection will cost the NHS approximately £292 m (discounted) over the next 10 years.

The treatment of diabetic foot ulceration and amputation is time-consuming and expensive. If appropriate at-risk groups could be identified by the use of VPT, resources could be concentrated on those patients. This could potentially save the NHS valuable resources and improve health outcomes. A recent study has showed that compliance with a preventive foot care programme reduced the incidence of foot ulceration in individuals with reduced vibration detection (Calle-Pascual et al, 2002).

If all individuals with reduced vibration detection were identified and their risk of ulceration and amputation reduced to levels experienced by those with normal vibration detection, this could save the NHS approximately £204 m, and save 29 000 life-years and 36 000 QALYs (discounted) over the next 10 years.

The costs of the instrumentation and the quantitative assessment of VPT are relatively small in this context. Moreover, the cost of instrumentation would be spread across many patients and over several years.

This study is not without limitations. It is estimated that type 1 diabetes accounts for 12% of all cases of diabetes in the UK

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2 The costs of the instrumentation and quantitative assessment of VPT are relatively small, and would be spread across many patients and over several years.

(DARTS, 2001). However, the risk of foot ulceration for a given VPT level was drawn from a sample containing 40.9% of people with type 1 diabetes. Thus, people with type 1 diabetes are overrepresented in the model.

This has implications for mortality, and consequently for both costs and QALYs, since mortality rates for people with type 1 diabetes are higher than for people with type 2 diabetes. In the absence of separate studies of the predictive value of the VPT in type 1 and type 2 diabetic populations, it is not possible to overcome this limitation.

Similarly, the model uses an initial age of 54 years because the existing evidence on the predictive value of the VPT is not adjusted for age.

Finally, the published evidence has a maximum follow-up period of only 4 years (Young et al, 1994); we have projected future incidence of ulceration, assuming that the rates remain constant for 10 years.

We undertook a subgroup analysis of the 10% of individuals incurring the highest costs. Those in the reduced vibration cohort remained in ulceration for longer, had shorter time to first ulceration, incurred higher costs and yielded fewer QALYs than those in the normal vibration cohort.

We can speculate that, given the probability of foot ulceration increasing with VPT score, those individuals incurring the highest costs may have higher VPT scores.

Future research is needed on the costs and health consequences of individuals with extreme VPT scores. A future study might be designed to collect a minimum of individual level data on VPT scores, foot ulcers and amputations, and associated economic costs and health state utility scores over a long period (10 years) in patients with diabetes. ■

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1 This study has several limitations.

2 People with type 1 diabetes are over-represented because the risk of foot ulceration for a given VPT was drawn from a sample containing 40.9% of people with type 1 diabetes.

3 Since mortality rates for people with type 1 diabetes are higher than for people with type 2 diabetes, this has implications for mortality, and hence for both costs and QALYs

4 The model uses an initial age of 54 years because existing evidence on the predictive value of the VPT is not adjusted for age.

5 Published evidence has a maximum follow-up of 4 years, so we have projected future incidence of ulceration, assuming that rates remain constant for 10 years.