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Final Project Report

Budget Impact Analysis of Introducing Diabetic Neuropathy Screening in England with Corneal Confocal Microscopy

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Glossary

Term	Description
Base Case	The case of a system being analysed for which no inputs are changed from their initial values.
Budget Impact Analysis	A form of economic analysis to estimate the financial consequences of adopting a new intervention.
Corneal Confocal Microscopy (CCM)	A clinical ophthalmic technique for in vivo imaging of the living cornea and its cellular structure.
Cost Effectiveness Analysis	A form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action.
Diabetic Eye Screening (DES) Programme	Regional programmes that are part of the national programme for diabetic retinopathy screening.
Diabetic Neuropathy	Nerve damage that can occur in people with diabetes. There are different types of diabetic neuropathies including small fibre neuropathy, large fibre neuropathy, autonomic neuropathy, peripheral neuropathy etc.
Diabetic Retinopathy	A disease of the retina which results in impairment or loss of vision in patients with diabetes.
Direct Costs	Direct costs are expenses which can be linked directly to a specific item or treatment.
Discounting	Multiplying costs in the future by a discount rate to find their present value.
Model Parameters	Inputs for an economic model.
Monofilament test	A test to diagnose diabetic neuropathy. Sensitivity to touch is tested using a soft nylon fibre called a monofilament.
Optometrist	Primary health care specialists trained to examine the eyes to detect defects in vision, signs of injury, ocular diseases or abnormality and problems with general eye health.
Roving vans	Vans which contain the necessary medical equipment and staff to perform scans in different geographical locations.
Sensitivity Analysis	A set of analyses in which different inputs are used to assess their impact on the main outcome.
Tomocap	A disposable thin plastic cap which is placed over the CCM microscope lens

1. Background

Diabetic Neuropathy (DN) is nerve damage that commonly occurs in people with diabetes. Currently, diagnosis relies on clinical examination and tests like the monofilament test. These methods can only detect advanced DN, such that foot ulceration and amputation rates remain high. Previous research has indicated that Corneal Confocal Microscopy (CCM) can detect DN at an earlier stage and in a less invasive manner than current assessment methods (Tavakoli et al. 2008).

It has been proposed that annual screening for DN using CCM could be implemented nationally alongside current Diabetic Retinopathy (DR) screening within the NHS Diabetic Eye Screening Programme. The aim of this study was to determine the budget impact of such an approach.

2. Methods

A Budget Impact Analysis (BIA) using a cost-calculator approach was undertaken in line with best-practice guidelines (Sullivan et al. 2014). It was not possible to conduct a full cost-effectiveness analysis in this case, as there were no data on the effectiveness of DN screening. The BIA was constructed in Excel.

2.1 Scope of the analysis

The population of interest were diabetic patients attending DR screening as part of the NHS Diabetic Eye Screening Programme. Two separate models were constructed to assess the budget impact of screening using 1) fixed cameras in community optometry practices (Model 1), and 2) mobile cameras deployed in roving vans (Model 2). For both models, annual DN screening using CCM incorporated alongside DR screening was compared to DR screening alone. The base case analysis considered a short-term time horizon of five years, in order to capture effects beyond those of the first year (for which costs are significantly different) without extending too far into the future (which would introduce more uncertainty). This is a common time horizon for BIAs (Sullivan et al. 2014).

2.2 Data collection

Four sets of model parameters were identified: patient parameters, policy parameters, screening output parameters, and unit costs.

- **Patient parameters** (including prevalence, incidence, and annual DR screening figures) were obtained from published sources (Public Health England 2016; HSCIC 2015; Public Health England 2015; Abbott et al. 2011).
- **Policy parameters** were established as a result of discussion among ENA project team members.
- **Screening output parameters** were primarily taken from the final project report for: "Implementation of Corneal Confocal Microscopy in Primary Care Optometry Practices for Screening and Early Assessment of Diabetic Neuropathy (ENA): a Feasibility Study"
- **Unit costs** of equipment were identified from the ENA study budget and full prices were used. The cost of a van for mobile screening purposes was taken from a cost-effectiveness study on Mobile Mammography (Carkaci et al. 2013). Staff pay bands were identified from current job advertisements and unit costs were chosen as the mid-points from NHS Agenda for Change figures (NHS 2015). The annual cost of treating DN and its complications was taken from Gordois et al. (2003). Unit costs associated with training were estimated from costs incurred during the feasibility study and venue cost information provided by the Wellcome Trust (Wellcome Trust 2016).

A comprehensive list of model parameters and their sources is available upon request.

2.3 Assumptions

Information was not readily available for all parameters (e.g. the total number of patients screened for DR was known, but the numbers of patients treated by optometry practices, specialist hospitals, and mobile units in current practice were unknown). Therefore some assumptions were made.

- Model 1 assumed that all screening in England would be conducted in optometry practices.
- Model 2 assumed that all screening in England would be conducted in mobile units.
- Data collected from regional Diabetic Eye Screening Programme (DESP) websites suggested that most screening for DR in England is conducted at static screening locations. Therefore, results in this report show budget impact for both models compared to DR screening in optometry practices.
- Based on the ENA feasibility study, training sessions were assumed to last ten hours spanning over two days; and host an average of ten optometrists.

2.4 Calculating budget impact

Costs used in the analysis were adjusted to 2015 GBP using the Hospital & Community Health Services (HCHS) pay and prices index (Curtis & Burns 2015). In adherence with best-practice guidelines, discounting was not applied (Sullivan et al. 2014).

For ease of interpretation, results were calculated as total costs for four different cost categories.

- **Cost of staff time**: The cost of an optometrist's time was identified from Band 7 of NHS Agenda for Change. NHS pay bands were identified from current job advertisements; this salary may be a conservative estimate for some practitioners. The unit cost was multiplied by the number of screening appointments and their duration. For the roving vans model (Model 2), the cost of a Retinopathy Screener was used instead (Band 5) because mobile units for DR screening are typically staffed by a dedicated team of screeners, as opposed to community optometrists. The cost of an image analyst's time was also identified as Band 5 as this is the norm for similar current roles for Diabetic Eye Screeners/Graders. This unit cost was multiplied by the number of usable images and analysis duration.
- **Cost of equipment:** The cost (to perform CCM) is incurred for each practice (or mobile unit) in year one. Unit costs for anaesthetics, eye gel and TomoCaps are incurred for each DN screening appointment.
- **Cost of training:** Training costs are incurred in year one. For the optometry practice model (Model 1), it was assumed that optometrists would attend training sessions provided for groups of practices. At training sessions, optometrists learn how to use CCM, interpret images, and apply the theory to paid participants. Venue costs and participant costs are shared by the groups of practices attending the training sessions. Each practice incurs costs for in-practice supervision for three hours (for their first patients) and for ongoing support in the first year. The cost of staff time while training is also included in this category as the cost is associated with training. For the roving vans model (Model 2), the training sessions are assumed to be the same and costs are calculated per mobile unit and for retinopathy screeners instead of optometrists.
- **Cost of treating DN**: The cost of treating DN and its complications was identified by Gordois et al. (2003). In the base case analysis, the total cost to the NHS of treating DN was assumed to be unaffected by screening outcomes because of a lack of data to suggest otherwise.

It is possible to identify further costs which are expected to contribute equally to both diabetic neuropathy and diabetic retinopathy screening under comparison (e.g. building costs). These costs are typically indirect costs and can be excluded as they result in no change in budget impact.

2.5 Sensitivity Analysis

Sensitivity analysis involves changing values for uncertain inputs to other feasible values, to test their overall impact on the outcome. Sensitivity analysis was performed around the main areas of uncertainty, including:

- The time spent on image selection and uploading in DN screening.
- The final average salary of an optometrist.
- The cost of the training venue.
- The number of practices or mobile units where DN screening would be introduced.
- The impact of early detection of DN on disease progression and the potential for a resultant decrease in the need for treatment.*
- The sensitivity of CCM to detect DN. This will only cause budget impact if there is potential for positive results to lead to a change in treatment costs.

*Some evidence suggests that improved diabetic management shows potential to halt progression of DN for type 1 diabetes patients (Albers et al. 2010). Type 1 patients make up 10% of the diabetic population in England (Diabetes UK 2015). In sensitivity analysis, we assumed that 10% of type 1 diabetes patients (1% of all diabetes patients) with positive DN screening results would change their behaviour sufficiently to offset the progression of DN and avoid DN treatment costs.

Sensitivity analysis was conducted as a series of one-way sensitivity analyses. This meant that one input was changed at a time, while other inputs were kept at the level indicated in the main analysis.

3. Results

The budget impact of introducing DN screening alongside current DR screening in the NHS Diabetic Eye Screening Programme was calculated as the cost of screening for both conditions less the cost of screening for DR alone. The main results of the BIA are presented in Table 1.

Table 1. Budget impact of DN Screening (Base case analysis)

Budget Component	DR Screening (Optometry Practices)	DR + DN Screening (Optometry Practices)	DR + DN Screening (Mobile Units)
Staff Time	£127,191,533.25	£209,275,889.71	£163,693,325.15
Equipment	£0.00*	£129,407,901.48	£116,411,808.08
Training	£0.00*	£548,756.76	£277,499.14
Treating DN	£2,591,484,794.11	£2,591,484,794.11	£2,591,484,794.11
Total Cost	£2,718,676,327.36	£2,930,717,342.07	£2,871,867,426.49
Total Cost Per Person Per Year	£259.45 (£12.14 excluding Treating DN)	£279.69 (£32.37 excluding Treating DN)	£274.07 (£26.76 excluding Treating DN)
Total Difference		£212,041,014.70	£153,191,099.13
Total Difference Per Person Per Year		£20.24	£14.62

*These figures are zero because the equipment and training components included training and equipment associated with DN Screening. Equipment and training costs for DR would be the same for all interventions, so did not need to be included.

The analysis shows that the projected budget impact of introducing DN screening in optometry practices is £212,041,014 over five years, which equates to a difference of £20 per person per year. The budget impact of using mobile units is estimated as £153,191,099 over five years, which is an

additional cost of £15 per person per year. In England there is currently a mix of fixed and mobile screening for DR, but the composition of the system was not known.

3.1 Sensitivity Analysis

The results of sensitivity analyses are presented in Tables 2 and 3. Table 2 shows budget impact as the difference per person per year. The time horizon was varied to illustrate how a larger proportion of costs are incurred in the first year (primarily training and equipment costs). Overall, costs remained stable to the changes used in the analysis. Due to the high prevalence of diabetes, total budget impact for different parameter values is also provided (see Table 3).

Table 2. Effect on costs of varying parameters used in the analysis (per person per year)

Items varied in sensitivity analysis	DR + DN Screening (Optometry Practices)	DR + DN Screening (Mobile Units)
Budget impact for the base case analysis (per person per year)	**£20.24**	**£14.62**
If the image selection and upload time was 1 minute	£19.08	£13.84
If the image selection and upload time was 10 minutes	£21.68	£15.59
If the average annual salary of the optometrists was £40,000 (as opposed to midpoint of Band 7 – £35,891)	£20.75	£13.62
If the average annual salary of the optometrists was £45,000 (as opposed to midpoint of Band 7 – £35,891)	£21.37	£12.41
If the cost of the training venue was £1000	£20.23	£14.62
If the cost of the training venue was £5000	£20.28	£14.65
If the time horizon was 1 year	£46.13	£34.59
If the time horizon was 10 years	£16.29	£11.63
If the number of optometry practices was 1000	£18.88	£14.62
If the number of optometry practices was 1500	£21.00	£14.62
If the number of mobile units was 700	£20.24	£13.97
If the number of mobile units was 1000	£20.24	£15.55
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 77%)	£19.85	£14.23
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 65%)	£19.91	£14.29
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 85%)	£19.81	£14.19

Table 3. Effect on costs of varying parameters used in the analysis (total budget impact)

Items varied in sensitivity analysis	DR + DN Screening (Optometry Practices)	DR + DN Screening (Mobile Units)
Budget impact for the base case analysis	**£212,041,014.70**	**£153,191,099.13**
If the image selection and upload time was 1 minute	£199,934,167.74	£145,073,708.82
If the image selection and upload time was 10 minutes	£227,174,573.41	£163,337,837.01
If the average annual salary of the optometrists was £40,000 (as opposed to midpoint of Band 7 – £35,891)	£217,386,432.75	£142,753,879.22
If the average annual salary of the optometrists was £45,000 (as opposed to midpoint of Band 7 – £35,891)	£223,923,409.58	£129,990,075.89
If the cost of the training venue was £1000	£211,975,064.70	£153,149,949.13
If the cost of the training venue was £5000	£212,502,664.70	£153,479,149.13
If the time horizon was 1 year	£87,779,830.01	£65,830,129.71
If the time horizon was 10 years	£385,203,254.51	£274,931,618.28
If the number of optometry practices was 1000	£197,882,617.59	£153,191,099.13
If the number of optometry practices was 1500	£220,074,462.59	£153,191,099.13
If the number of mobile units was 700	£212,041,014.70	£146,424,644.04
If the number of mobile units was 1000	£212,041,014.70	£162,928,193.04
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 77%)	£208,003,235.20	£149,153,319.63
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 65%)	£208,632,499.54	£149,782,583.96
If 1% of positive results for DN change behaviour sufficiently to incur no treatment costs (CCM sensitivity 85%)	£207,583,725.65	£148,733,810.07

4. Discussion

Given a time horizon of 5 years, the estimated budget impact of introducing DN screening alongside DN screening in optometry practices in England is £212,041,014. To account for uncertainty, sensitivity analysis of parameter values suggests that the estimated impact lies between £197,882,617 and £227,174,573. If the policy were to use mobile units with designated screeners (paid at Band 5), the estimated budget impact would be lower at £153,191,099 (between £142,753,879 and £163,337,837). The changes which had the most impact on overall cost were: using a lower number of optometry practices and increasing image selection/upload time.

Assuming that screening is conducted by optometrists paid at the mid-point of Band 7, DR screening was estimated to cost £12 per person screened per year (excluding DN treatment costs). This budget impact analysis predicts that the introduction of DN screening would cost an additional £20 per person per year in optometry practices, or an additional £15 per person per year to deliver both services in mobile units.

In reality, DR screening services are provided by a range of staff with different wages, in a range of settings with different cost structures. Furthermore, extra transitional costs are likely to exist that occur when making significant changes to current practice, but these are too difficult to quantify.

This budget impact analysis was produced under very tight time constraints. The study attempted to overcome data limitations on the composition of fixed and mobile screening services through the use of assumptions and sensitivity analysis, to provide the best estimate of budget impact given these limitations.

More evidence around the benefits of screening for DN is required before a screening programme can be recommended for a national roll-out.

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