ScotPHN report

Updating the Scottish Needs Assessment Programme Report on Type 2 Diabetes: Screening and Prevention

Part D: Cost-effectiveness and budget impact analysis of screening for Type 2 Diabetes

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1 Introduction

This note examines the issues surrounding the cost effectiveness of screening for Type 2 diabetes. Interest in population based screening for diabetes has increased in many countries in response to a recognised public health challenge. Endorsement of screening needs to follow a sequence of evaluation and evidence synthesis designed to assess whether it would represent a cost effective use of resources.

Cost-effectiveness alone while necessary is not sufficient for decision-makers who should also be concerned with the financial or budgetary implications of screening. It also discusses how a budget impact analysis of diabetes screening could be developed and illustrates the scale of resources that may be required if a national programme of population based screening was introduced in Scotland. A formal definitive analysis of resource implications could follow a decision about the precise structure and organisation of the screening programme and how this might be introduced, integrated and co-ordinated alongside existing screening and prevention initiatives targeting cardiovascular health in Scotland.

2 Cost-effectiveness analysis

The updated Scottish Needs Assessment Programme report on Type 2 diabetes considers screening for diabetes in the context of a vascular risk profiling programme. However, the lack of research evidence on this approach means that this section of the note considers the evidence base for the cost-effectiveness of diabetes screening alone.

2.1 Randomised trials

Reliable estimates of the effectiveness and cost-effectiveness of an integrated diabetes prevention and treatment programme remain elusive. Evidence is particularly sparse at the population level. High quality trial evidence is available for some preventive and lifestyle interventions and selected treatment options for persons with pre-diabetes or diabetes. The costs and benefits of alternative management strategies for complications associated with diabetes have been more extensively studied. What is missing is direct clinical trial evidence on the treatment effects arising from screen-detected versus clinically detected diabetes. No large scale screening trials designed to establish precise and reliable estimates of comparative health effects measured over a reasonably long time horizon have been conducted. The ongoing Anglo-Danish–Dutch Study of Intensive Treatment In People with Screen Detected Diabetes in Primary Care (ADDITION-Cambridge) trial of screening and intervention for type 2 diabetes is the first UK trial with a protocol for evaluating cost effectiveness.[1] However, the ADDITION-Cambridge trial runs the risk of generating little in the way of precise evidence on population level effects given its

relatively small size and focus on high-risk individuals. A recent study suggested that a trial with 650,000 people randomised and followed up for several decades would be unlikely to show significant differences between alternative screening strategies for diabetes.[2]

2.2 Modelling studies

Evidence on the effectiveness and cost-effectiveness of screening for Type 2 diabetes is based on modelling of simulated screening programmes. A long-term model for diabetes screening requires appropriate specification of mathematical structure and assumptions, careful estimation and robust validation of the model's predictions. Typical components of the models include characteristics of the individuals, groups or populations that will be targeted for screening and the choices surrounding screening and treatment regimes. Model outputs encompass the expected distribution of cost and health outcomes conditional on the distribution of key parameters reflecting screening compliance, risk factors, health events, resource utilisation and cost. Evidence based information can be used to calibrate some parameters but assumptions and simplifications are inevitable when information is limited.

The design, sophistication and realism of screening models varies greatly. Over the past decade or so diabetes screening models have increasingly focused on capturing uncertainty and isolating those parameters which tend to have a material effect on cost-effectiveness. Having generated an expected distribution of costs and effects the outstanding challenge for all models is establishing their validity when applied to

a specific population. When trial information is used for some elements of the screening programme a narrow validation is simply a check of model predictions against the observed trajectories of costs and effects reported in the trials. This is necessary but by no means sufficient when the target population for screening is not comparable with individuals or groups recruited to trials. Likewise, risk predictions may be imported from epidemiological studies that may be less relevant for a specific population group that may be offered screening. More general validation is problematic for models that aim to estimate the longer run impact of screening when the effects of current and future treatment regimes are difficult to ascertain with any reasonable degree of certainty.

2.3 Recent analyses of screening cost-effectiveness

A review of modelling studies of the cost-effectiveness of screening to detect type 2 diabetes reveals a range of different model structures, calibrated using different sets of assumptions with corresponding differences in cost effectiveness. A recent HTA review[3] considered models reported up to 2005 and constructed a model of screening and early treatment that suggested that from a NHS perspective screening was cost effective for people aged 40 to 70.

Two subsequent models using European populations and data report cost effectiveness estimates with different time horizons and health outcomes. A Danish model[4] of short run costs and CHD events (up to 5 years) reported median incremental cost effectiveness ratios (ICER), narrowly defined as the cost per CHD event prevented which ranged from £40,300 to £69,500 depending on compliance,

treatment risk reduction and cost model. Corresponding 95% prediction limits of the median ICERs were [£25,400 – £80,200] and [£37,800 – £198,400]. The ICERs were not sensitive to decisions about which groups to target for screening or to the costs of screening or treatment. The most important factor that explained much of the uncertainty in the ICER estimates was the assumption about the risk reduction from multifactorial therapy offered to people with screen detected diabetes.

Gillies *et* al[5] compared a range of screening strategies against no screening using a hybrid decision tree and Markov model with careful allowance for uncertainty in model parameters. The distribution of costs and health outcomes was estimated over a time horizon of 50 years. An NHS perspective was adopted for the measurement and valuation of the direct screening and treatment costs with health-related quality of life measured by EQ-5D utility values estimated for different health states associated with the duration of diabetes and associated complications. The cost per quality-adjusted life year (QALY) gained of £14,150 for screening for type 2 diabetes alone. When screening for diabetes and impaired glucose tolerance is combined with lifestyle interventions or pharmacological interventions the cost per QALY was £6,242 and £7,023 respectively. If the threshold for willingness-to-pay for each QALY gained is at least £20,000 the probability that screening for diabetes and impaired glucose tolerance is cost effective is very close to one.

Screening for diabetes alone is less likely to be cost effective. The findings were generally robust to variation in the key model parameters including the prevalence of impaired glucose tolerance and diabetes, sensitivities of screening tests, costs of

screening and treatment and targeted screening of different ethnic groups with a higher expected prevalence of type 2 diabetes. The results are also conditioned by the time horizon which needs to be at least 30 years before the screening and intervention strategies achieve conventional levels of cost effectiveness. Although no sensitivity analysis of variation in the effectiveness of interventions for people with screen-detected diabetes was reported but it could be assumed that this factor will have a crucial influence on whether cost-effectiveness might be realised in practice.

A surprising characteristic and limitation of many models of the cost effectiveness of screening for type 2 diabetes is their reliance on modelling state transitions for cohorts using Markov type models with one-off as opposed to sequential screening. A recent study using the Archimedes individual level simulation model within a USA population setting addressed these weaknesses.[2] Allowing for the timing and cumulative effect of health outcomes over a very long time-horizon (up to 50 years), Kahn et al reported a four-fold difference in cost per quality-adjusted life year (QALY) of $US 10,500 to $US 40,778 depending on the screening strategy (target age group and screening frequency). The findings suggest that screening for type-2 diabetes in a USA setting is most cost effective if it is initiated between the ages of 30 and 45 with screening repeated every 3-5 years. The summary measure of cost-effectiveness or cost per QALY was not very sensitive to variation in the costs of screening or treatment. Probabilistic sensitivity analysis was not conducted making it difficult to draw inferences about the precision of the array of point estimates that are generated by the Archimedes model. Questions also remain regarding the generalisability of the model. Some of the underlying physiological and risk models might prove to be common components of screening simulation models that could be

cautiously applied to populations with different inherent risks of diabetes. However, translating the findings to health-care systems with different patterns of health service use and cost is not easily accomplished as the model would have to be re-calibrated and estimated using a different set of parameters and then carefully validated by comparing simulated and observed screening, treatment and population health outcomes.

2.4 Cost effectiveness analysis conclusions

Several models suggest that screening for diabetes may be cost effective. The degree of uncertainty and the difficulty of easily transferring results from studies in different population settings raise questions over whether these findings are robust and directly relevant to NHSScotland. The Scottish population will share some features of the stylised or simulated populations studied in the cost-effectiveness models. Compared to a UK or USA population, the higher cardiovascular and diabetes risk profile of the Scottish population may manifest itself in a greater absolute gain in potential health outcomes and on balance enhance the cost-effectiveness of earlier detection and effective management.

The lack of reliable evidence on long term programme effectiveness for screen-detected people with pre-diabetes or diabetes limits the usefulness of the existing models. The projection of very long term costs and effects over 30, 40 or 50 years is a key feature of many of the simulated models but there is no actual data which can be used to assess the accuracy of these projections which nevertheless remain the principal drivers of cost-effectiveness.

It is also difficult to separate the incremental health gain of earlier detection and management of diabetes from the effects of cardiovascular screening followed by effective interventions that alter the profile of future cardiovascular events. In practice, if screening for diabetes is integrated within a more general screening initiative like the Scottish Keep Well/Well North anticipatory care programmes the distribution of costs and effects due to diabetes screening is likely to change. Some initial costs of screening and therapy will be shared. Screen detected hypertension and dyslipidaemia coupled with effective management will influence both cardiovascular risk profiles and the costs of managing diabetes and associated complications over the medium to long term.

Finally, the existing cost-effectiveness evidence is missing on some key components of a screening programme for diabetes. As noted above, the updated Scottish Needs Assessment Programme report recommends that screening specific subgroups of the population for Type 2 diabetes should be implemented as part of NHS vascular risk management programmes, a recommendation which is inline with that of the UK National Screening Committee. However, there is uncertainty about the cost effectiveness of diagnostic pathways involving different blood glucose tests making analyses problematic. Another area where cost-effectiveness evidence needs to be strengthened is the timing and intensity of life-style or therapeutic interventions offered to people with pre-diabetes and the contemporary impact of intensive multifactorial treatment and management using novel therapeutic strategies.

3 Budget impact analysis

3.1 The evidence base

Assessment of cost effectiveness is often combined with budget impact analyses (BIAs) which have become a routine feature of many economic evaluations and health technology assessments. The objective of a BIA is to estimate the potential financial consequences of adoption and diffusion over time of a new health programme or intervention compared with a reference scenario based on current patterns of care and treatment. The perspective is usually that of the budget holder or payer (at local, regional or national level) who is interested in comparing the overall budget impact when individual level incremental costs are applied to a group or population. BIAs have tended to focus on single health technologies. A recent survey of published BIAs revealed that about half were for new pharmaceuticals where BIAs are integral to drug approval, coverage and reimbursement decisions.

Few screening programmes have been subjected to formal BIAs. There are no published BIAs of population screening for diabetes. Nor have there been any BIAs for diabetic screening in the context of a vascular risk programme.

A small scale BIA[6] examined the short run (up to 3 year) net costs of opportunistic screening for pre-diabetes and diabetes with 1 259 adult volunteers recruited from the Screening for Impaired Glucose Tolerance (SIGT) study. The aim of the study was to assess net costs of different screening tests (random plasma or capillary glucose, glucose challenge test (GCT) or HbA1C) followed by preventive

management (following the Diabetes Prevention Program) compared to the costs of not screening. From a US health system fee-for-service perspective (Medicare) and a single payer perspective (Veterans Administration) screening appeared to be cost-saving, reducing budget costs by between 16% to 21% depending on the type of test employed. The absolute value of the cost savings per person screened was around US$ 30 or US$ 10 per year in 2007 prices.

3.2 Considerations for Scotland

Replacing the current mix of *ad-hoc* and opportunistic models in Scotland with a systematic population screening programme for diabetes could have substantial budgetary and organisational implications. Ideally a BIS would compare resource use and costs for existing screening activities across the Diabetes Managed Clinical Networks in Scotland with a new national screening programme. Although it is feasible to estimate the costs of a new population based programme with agreed and well defined characteristics it is much more difficult to identify, measure and cost the resources that are used in the diverse range of existing activities, many of which are embedded in routine care or more general initiatives like Keep Well.

However, when considering a new national screening programme which has a significant impact on the numbers of screen detected people with pre-diabetes and diabetes it is helpful to place an upper bound on the budgetary implications. One approach is to select a screening protocol and then estimate expected resource use at each stage of the screening programme from initial identification of potential participants (perhaps using a pre-defined risk threshold), invitation, uptake, testing

and subsequent management. The gross budget impact of the new screening programme could then be calculated and considered against what might in practice be a very low baseline of screening activity and corresponding resource use.

An indirect measure of the annual "efficiency" of the current mix of screening activities in Scotland is the number of individuals with diabetes who are newly diagnosed and recorded over a one year period. These incident cases will be much lower than the estimated prevalence of undiagnosed pre-diabetes and diabetes in the target population.

The most recent information for Scotland based on 2007 data suggests an overall annual incidence rate of 3.096 per 1 000 (personal communication Dr Jeremy Walker). For women and men aged 40 to 69 the incidence rate in 2007 was 5.178 per 1 000. When age and sex specific incidence rates are applied to the estimated population by age and sex in Scotland for 2009 this would correspond to approximately 10 611 individuals aged 40 to 69 who were newly diagnosed with type 2 diabetes. This group represents around two thirds of the total number of newly diagnosed cases calculated across all age groups.

The incident cases that emerge annually in Scotland can be compared with the numbers expected given the prevalence of undiagnosed pre-diabetes and diabetes. Based on the distribution of glycated haemoglobin (HbA1c) recorded for people who participated in the Scottish Health Survey for 2008/09, around 21.7% of respondents aged 40 or older had HbA1c levels ≥ 6.0% (personal communication Dr Sarah Wild).

The corresponding percentage for this age group with HbA1c ≥ 6.5% was 3.8%. If the recommended threshold of HbA1c ≥ 6.5% for the detection of prevalent diabetes (or prediction of subsequent risk of diabetes) is used, this would suggest that around 77,870 persons aged 40 to 69 in Scotland would be identified, representing what could be regarded as the true overall prevalence of diabetes. The difference of around 67,000 between the overall prevalence and the persons diagnosed/registered with diabetes could reflect the upper limit of the gap between screen-detected cases using an ideal population based screening programme and the present mix of screening activities in Scotland.

Screening will be somewhat less comprehensive as it is unlikely that all people in a specific age group would be eligible for screening. Screening programmes for diabetes are likely to target people who fall within the upper quartile of a diabetic or cardiovascular risk score. If the experience of the ADDITION-Cambridge screening study is applied to people aged 40 to 69 in Scotland this would entail inviting around 501,693 (512,314 less 10,611 newly diagnosed cases) of which around 74% or 371,253 would be expected to attend for an initial screen. Of these 25,615 would be eligible for a further OGTT, 21,788 would attend for an OGTT and eventually 12,969 people would be diagnosed with Type 2 diabetes, representing around 2.6% of the original high risk group invited to participate in the screening programme.

The sheer magnitude of this flow of people through the different stages of screening provides an indication of the material effect that this screening protocol could have on NHS budgets. Using very conservative estimates of the direct NHS costs for the

resources required to deliver this pattern of one-off systematic screening, the gross budget impact in Scotland would be at least £10.5m or around £21 per person who received an initial invitation to participate in the screening programme. When the additional costs of follow-up of non-attenders are added, allowance is made for adapting the programme so that eligible but harder to reach, socially deprived[7,8] and/or ethnic[9], groups become more willing to participate and adequate resources are allocated to support management and administration the overall programme costs would rise. When expressed per person screened many of these costs might appear trivial but the aggregate budget impact of a well designed and effective national screening programme for the Scottish population could be significant. Over time as the prevalent cases were detected the costs would probably decline as the screening programme would presumably concentrate on detecting incident cases of pre-diabetes and diabetes.

Attempts to justify the costs of systematic screening by suggesting that many of these costs are already incurred in the current mix of screening activities are not persuasive. Assuming that costs could be easily passed on to or somehow absorbed within existing primary care budgets is both naive and unrealistic. The current yield of these opportunistic screens is very low in relation to what could be achieved with a more systematic approach that would inevitably have to be substantially scaled up.

The difference in scale can be appreciated by comparing the half million or so people that could be invited to the above programme with the eligible population for Keep Well of 139,192 people of whom only 67,712 had received a health check by the end

of 2009.

Another factor to consider is that even with an agreed standard screening protocol, variation in the cost of a screening strategy will occur when it is actually delivered in practice as practitioners and professional teams exercise discretion and choose different ways of implementing screening, follow-up and medical management. It appears to be difficult and probably undesirable to standardise screening if the experience reported by the ADDITION-Cambridge study[10] is a valid reflection of the pragmatic decisions that are taken when a screening programme is implemented.

The first period or start-up costs of screening will eventually be offset against some of the costs of subsequent treatment and management. It is not clear how long this time-horizon would have to be but a reasonable estimate is probably at least 5 to 10 years assuming that screening does lead to improved health outcomes. The earlier diagnosis of diabetes will be associated with increased costs to the NHS but again these may be partly offset against longer-run cost "savings" if the frequency and severity of complications is reduced.

3.3 Budget impact analysis conclusions

The short term budget impact of introducing population based screening for diabetes in Scotland is difficult to assess.

The level of resources required to implement a *new* programme that is scaled up sufficiently to address the size of the target population is initially at least £10m for the

nation as a whole. The actual budget impact will reflect how quickly and widely a national programme could be rolled out. The annual budget impact beyond year 1 would decline as the number of screen-detected prevalent cases in the early stages fell and the screening programme focussed on capturing the new incident cases that emerged each year.

A formal analysis of the budget impact of screening would also require a more detailed description of programme characteristics, the frequency of sequential screening and a decision on the target population. Whether the costs of screening could be fully offset against future treatment costs remains uncertain. A more likely scenario is that additional resources would be required which could diminish the burden of ill health attributable to diabetes in the Scottish population.

4 General Conclusions

This note has considered the cost-effectiveness and budget impact of screening for Type 2 diabetes in for NHSScotland.

Several models suggest that screening for diabetes may be cost effective. The degree of uncertainty and the difficulty of easily transferring results from studies in different population settings, or to targeted subgroups within the population raise questions over whether these findings are robust and directly relevant to NHSScotland. These are no direct studies which have looked at the cost-effectiveness of Type 2 diabetes screening in the context of vascular risk management programmes.

The short term budget impact of introducing population based screening for diabetes in Scotland is difficult to assess. The initial level of resources required can be estimated to be at least £10m for Scotland as a whole, though the annual budget impact beyond year 1 would decline as the number of screen-detected prevalent cases in the early stages fell and the screening programme focussed on capturing the new incident cases that emerged each year.

As a general caveat it should be remembered that the evidence base for both these analyses is limited and there is an urgent need for research to be undertaken to allow a full budget impact analysis of the proposed approach of implementing Type 2 diabetes screening as part of a vascular risk management programme.

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