Economic Modelling for Vascular Checks

A technical consultation on the work undertaken to establish the clinical and cost effectiveness evidence base for the Department of Health's policy of vascular checks

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Economic Modelling for Vascular Checks

A technical consultation on the work undertaken to establish the clinical and cost effectiveness evidence base for the Department of Health's policy of vascular checks

Prepared by the Vascular Team, Department of Health

Contents

Purpose of this document

1. The Department of Health published "Putting Prevention First" on 1st April 2008 which set out plans for the NHS to introduce a systematic and integrated programme of vascular risk assessment and management for those aged between 40 and 74. This announcement was premised on economic modelling undertaken by Department of Health analysts that showed a policy of vascular checks was likely to be very cost effective and result in significant health improvements. This paper provides a full description of this modelling.

2. The purpose of publishing this document is to enable experts and practitioners in the field of vascular prevention to feed into this piece of work. We are asking for responses to the following questions:

    - Are there any assumptions in this work that you think could be improved? If so can you provide evidence of this and make suggestions for improvement?

    - Are there any factors which haven't been considered which could be usefully incorporated?

    - Are there any improvements to the modelling methodology that would give more robust results?

Methodology

3. There were three key objectives of this work:
   1. To establish whether a policy of vascular checks was likely to be cost effective
   2. To identify the optimal starting age and the frequency for re-testing
   3. To provide indicative cost estimates of such a policy

4. The "VRA model" was designed to meet these objectives. Its architecture is represented in Figure 1 below.

Figure 1: VRA Model Architecture
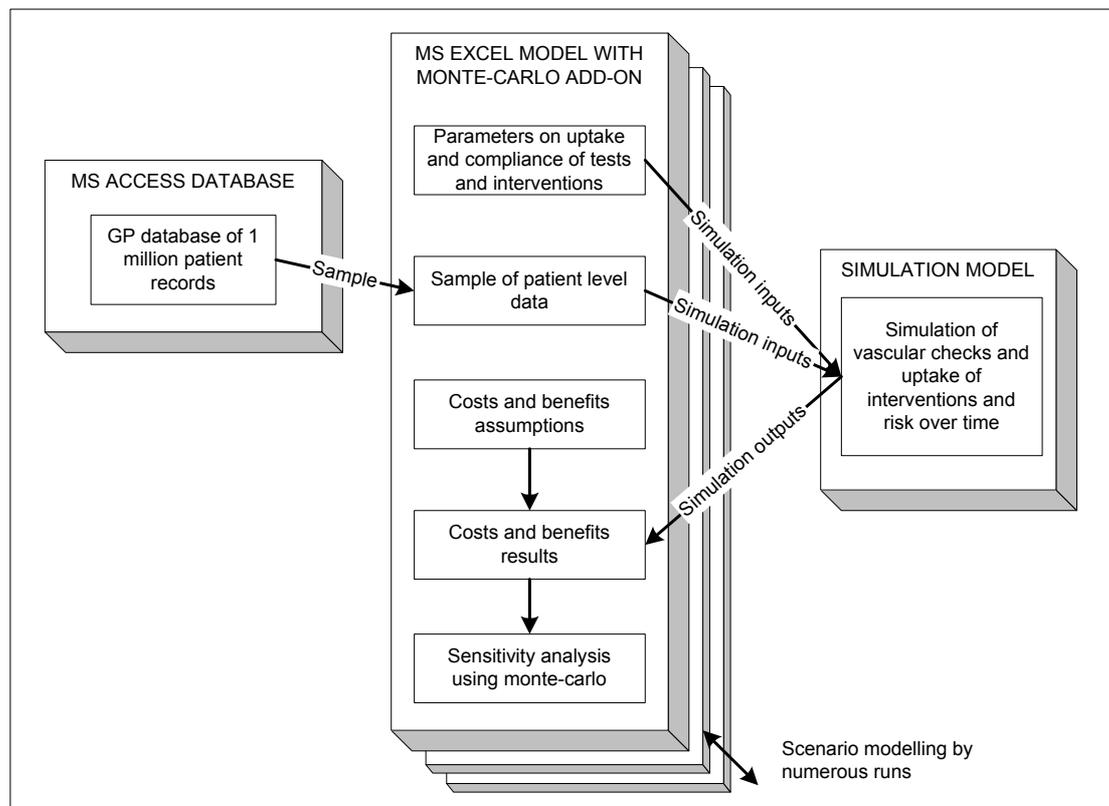
5. There are three sections to the model:
   - Database of GP data: This holds patient level (anonymised) data which are sampled for each run of the model to give the characteristics of individuals receiving vascular checks
   - Excel model of assumptions, calculations and Monte Carlo simulation: A single Excel file contains a number of key elements:
     - Parameters used by the simulation model
     - Sample of patient level data used by the simulation model
     - Costs and benefits assumptions
     - Calculation of overall costs and benefits, using outputs from the simulation model
   - Simulation model: This simulates individual patients being invited for vascular checks and their outcomes over time including take up of the interventions available and incidence of vascular disease.

6.   Scenario modelling is done by carrying out multiple runs of the model and comparing the results. Sensitivity analysis is then done on the Excel results using Monte Carlo simulation techniques.

7.   A fuller description of these various components is given in the sections to follow. These are structured in terms of the steps undertaken to build the model which are represented in the schema below:

Figure 2: Steps in model build
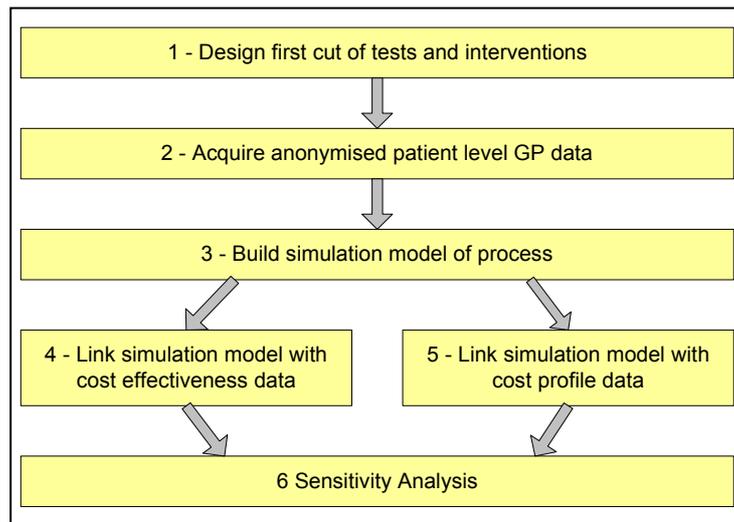
Step 1: Determine tests and interventions included in vascular checks

8.   The purpose of a vascular check is to identify an individual's risk of coronary heart disease, stroke, diabetes and kidney disease, and to recommend interventions and lifestyle changes to reduce that individual's risk. The design of vascular checks is based on advice from numerous experts inputting to the Vascular Programme Board[1] who oversaw its development. There already exists a wealth of evidence around the effectiveness of the questions and measurements that the test would include. The principle used in the design was that interventions would be included only if there was cost effectiveness data to support them and tests would be included only if there was cost effectiveness evidence of their use and the interventions that they indicated.

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[1] The Vascular Programme board is a Department of Health board chaired by Dr Bill Kirkup, Associate Medical Director. Membership includes: Prof Roger Boyle (National Clinical Director for Heart Disease and Stroke), Prof Sue Roberts (National Clinical Director for Diabetes), Dr Donal O'Donoghue (National Clinical Director for Kidney Disease), Dr David Colin-Thome (National Clinical Director for Primary Care), Sir George Alberti (National Clinical Director for Emergency Access and Service Design), and Dr Anne Mackie (Chair of National Screening Committee).

What would a vascular check involve?

9.   A vascular check would include a set of straightforward questions, measurements and blood tests. These would record basic information such as height, weight, current medication, age, family history, smoking and blood pressure, and include a simple blood test for cholesterol and (in some cases) glucose levels. Those who have been identified as at risk of kidney disease may then have further blood and urine tests.

10.   This would be followed up with an individually tailored assessment setting out the person's level of vascular risk and what steps they could take to reduce it. For those at low risk, this might be no more than general advice on how to stay healthy. Others at moderate risk may be recommended a weight management programme, stop smoking service, or a brief intervention to increase levels of physical activity. Those at the highest risk might also require medication with statins (which help control cholesterol levels) or blood pressure treatment, or an intensive lifestyle management programme for those identified with impaired glucose regulation. A few may need further assessment that would require referral to a hospital consultant.

11.   We also expect to identify people who already have a vascular disease where it has so far gone undetected, particularly diabetes and chronic kidney disease. In such cases, patients may benefit from an immediate start on a disease management programme to manage their condition and prevent adverse complications

Figure 3: Vascular checks
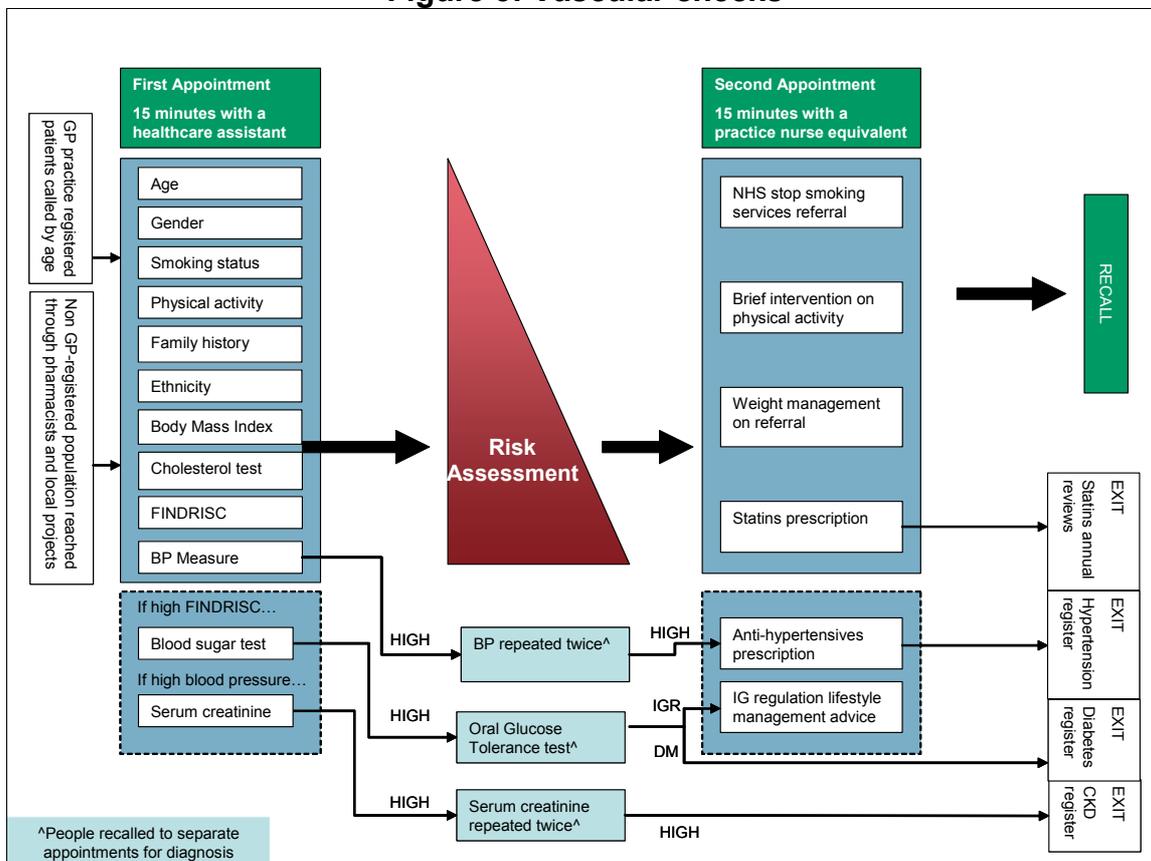
Who would be eligible for vascular checks?

12.   We considered a population-wide programme where everyone within a defined age criterion is eligible and invited at regular intervals. We modelled three starting ages: 40, 45 and 50; and assumed people would be eligible up to age 75. The reason for this cut-off is two-fold: firstly, cardiovascular risk algorithms are poor in identifying risk in this age group, and secondly the majority of over 75 year olds are in frequent contact with their GP so an additional invitation to a specific vascular check is unlikely to be useful. The reason for the starting ages not going below 40 is because cardiovascular risk algorithms tend not to work below this age (the Framingham equation starts at age 35 and the QRISK algorithm at age 40). In addition the evidence for a number of the interventions do not cover people below 40.

13.   For modelling purposes we have excluded individuals with a diagnosed vascular disease and those on statins and/or anti-hypertensives. The rationale for this is that the existing best practice guidelines state that these individuals should already be receiving annual reviews; in which case their vascular risk should already be reviewed regularly.

Testing Strategies

14.   As already stated, tests were included only if there was cost effectiveness evidence to support their inclusion. There were two areas of testing where the evidence was difficult to decipher. These were testing strategies for blood glucose and testing for kidney functioning. These strategies are still being considered, and the evidence is being compiled for the National Screening Committee. In the meantime we adopted the following testing strategies based on the evidence available at the time:

- Blood glucose testing
  The checks would include all the questions that make up the FINDRISC score[2]. People with a high FINDRISC score would receive an initial blood glucose test at the first appointment; and those with a value over 6 would be called back to receive an oral glucose tolerance test (OGTT). This would identify both diabetes and Impaired Glucose Regulation (IGR). This strategy was recommended in the Vascular Risk Assessments Handbook[1] based on work undertaken by University of Leicester.
- Kidney function testing
  The strategy for testing for chronic kidney disease (CKD) was to include a serum creatinine test in the vascular check appointment for people who have a one-off high blood pressure. The rationale was that it is best practice for people with diagnosed hypertension to have a serum creatinine test, and while a one-off high blood pressure measure is not a diagnosis for hypertension, there is a low marginal cost to including the serum creatinine test within the vascular check (where blood is taken anyway for cholesterol measurement) compared to the cost of taking blood specifically for this purpose. As there is no cost effectiveness data that we identified for CKD testing in England we were unable to justify a more sophisticated or wide-ranging strategy.

Interventions offered

15.   We only included interventions for which there is good evidence of their cost effectiveness. The table below shows the interventions included along with the existing guidance that they feature in. As they are all recommended by NICE they all have

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[2] FINDRISC is a score that indicates risk of diabetes designed in Finland. For details see *The Handbook for Vascular Risk Assessment, Risk Reduction and Management* by the University of Leicester. National Screening Committee, March 2008.

reasonable cost effectiveness data available from the literature published alongside the NICE reports.

Table 1: Interventions offered and their respective NICE guidance

Intervention offered	Existing guidance
Brief exercise intervention	NICE guidance PHI002 "Four commonly used methods to increase physical activity", March 2006
Multi-component weight loss programmes	NICE clinical guideline CG43 "Obesity", December 2006
IGR intensive lifestyle management	NICE clinical guideline CG43 "Obesity", December 2006 and Health Technology Assessment 2004; Vol 8: No.21
Stop Smoking Services	NICE guidance PHI001 "Brief interventions and referral for smoking cessation in primary care and other settings", March 2006
Anti-hypertensives for those with hypertension	NICE clinical guideline 34 "Management of hypertension in adults in primary care: partial update", June 2006
Statins for primary prevention	NICE technology appraisal 94 "Statins for the prevention of cardiovascular events", January 2006

16. As well as these interventions we included the estimated costs and benefits of earlier detection of diabetes, which were provided in a study by the University of Sheffield for the National Screening Committee[2].

Step 2: Acquire sample of anonymised patient level GP data

17. Whatever type of modelling was undertaken, it was necessary to acquire a sample of patient level GP data to understand how risk factors vary from individual to individual, and with, for example, age, gender, and socio-demographics. There are a number of primary care database providers on the market, including EPIC (THIN data), GPRD and QRESEARCH. At the time, research on QRISK[3], a new cardiovascular risk algorithm based on the QRESEARCH database, had just been published and they had a database readily to hand to satisfy our needs. We acquired data for all practices in England contributing to the QRESEARCH database on 1 April 2007. The fields included in the data are listed below. The results were in terms of categories which are detailed in brackets.

- Five year age band (40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74)
- Gender (Male, Female)
- Townsend score quintile [*] (1, 2, 3, 4, 5)
- Body mass index (<25; 25-29.99; 30 plus, not recorded)
- Systolic blood pressure (<120; 120-129; 130-139; 140-149; ≥150 mm Hg, not recorded)
- Smoking status (current smoker, non smoker, not recorded)
- Total cholesterol/HDL ratio (<4; 4-4.9; 5-5.9; ≥6, not recorded)
- Record of family history of CHD in a first degree relative < 60 years (yes, no)
- QRISK score (10-year CVD risk)

18. We have used the QRISK score for CVD risk, rather than any others available such as the Framingham score, for of a number of reasons including:

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[*] The Townsend Score is a measure of levels of material deprivation by postal area. It includes variables for unemployment, overcrowding, lack of owner occupied accommodation and lack or car ownership.

- QRISK is based on recent UK population data whereas Framingham is based on a US population in the 1970s which was predominantly white and had a much higher rate of cardiovascular disease than is experienced now in the UK.
- QRISK includes a factor for socioeconomic deprivation so it may be instrumental in reducing inequalities – a key objective of this policy.

19. We intend to repeat this analysis using the Framingham equation. However, we do not expect this to make a significant difference to our overall conclusions. For our rationale see Appendix C.

20. We used the most recently recorded clinical values for an individual patient within the preceding five years. We excluded patients with any of the following diagnoses from the analysis:

- diagnosis of cardiovascular disease (defined as computer recorded coronary heart disease, stroke or transient ischaemic attack (TIA))
- diagnosis of peripheral vascular disease
- diagnosis of congestive cardiac failure
- diagnosis diabetes
- diagnosis of chronic kidney disease
- patients currently taking statins (defined as those prescribed a statin in the preceding 6 months).
- Patients taking anti-hypertensives (defined as more than one prescription for at least one of the following drugs in the preceding 6 months: Alpha blockers, ACE inhibitor, Beta blockers, A2 antagonist, Calcium channel blockers, Thiazide diuretics)

21. This gave data on approximately one million individuals aged 40 to 74 years.

Missing Values

22. A significant proportion of the patient records had missing values:
- 72% did not have a cholesterol reading
- 47% did not have a BMI reading
- 24% did not have a blood pressure reading
- 8% did not have a record of smoking status

23. In order to simulate the test results of their vascular checks, we needed to compute these missing values. Firstly we checked for measurement bias by comparing the completed data with Health Survey for England data which agreed reasonably well. We then used random sampling from the age/gender distribution of the recordings of risk factors to get the missing values. This was more appropriate than using mean values because we needed to ensure the correct *proportion* of individuals were in the different categories of risk factor values. This should not be confused with another scenario where missing values are computed which is estimate CVD risk without seeing an individual so as to prioritise who to call in first.

Step 3: Build simulation model of the process

24. The objective of this stage of the modelling was to provide estimates of the number of people who would receive the various interventions and tests over time. There are a number of reasons why it was necessary to build a simulation model to achieve this. Firstly, there are complex dynamics which need to be considered such as how

individuals' risk factors change over time. Secondly, there are complicated logical rules determining which individuals receive which interventions, and a discrete event simulation model is a good way to handle this complexity in a manageable and flexible way.

25.   Figure 4 shows a screen shot of the simulation model, which uses the software package SIMUL8. Essentially, this is a sophisticated routing model at an individual patient level, which simply selects individuals and routes them according to their individual characteristics and/or random sampling. This is a logical representation of the tests and referrals for interventions, and is not a simulation of the actual order of events within the checks themselves.

Figure 4: Screenshot of simulation model
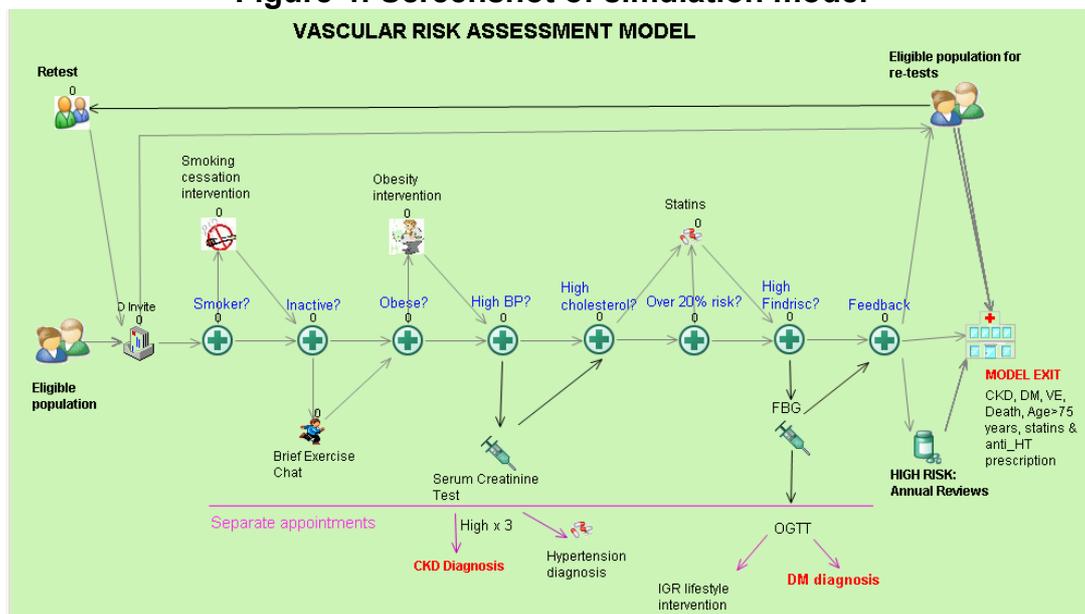
Assigning Individuals' Characteristics

26.   Individuals are fed into the model in appropriate numbers according to their age. Each individual that enters the model is assigned the characteristics of a patient picked at random from the QRESEARCH data in their age group. The characteristics are assigned using *labels* whereby an individual has a number of labels attached to him or her. The labels that are fed in from QRESEARCH data are: gender, BMI, systolic blood pressure, cholesterol ratio (Total Cholesterol to High Density Lipids or TC:HDL), smoking status and cardiovascular disease (CVD) risk. These labels represent what the outcome of the corresponding tests or measurements will be when they attend their vascular check.

Routing Individuals

27.   Individuals are routed according to either their individual characteristics (i.e. labels) or by a probability which may or may not be based on some of their labels. The table below details how the routing works at each stage and the values of any probabilities applied.

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Table 2: Parameters within SIMUL8 model

Step	Question	Probability or label?	Value	Source
Invite	Does s/he attend (Y/N)?	For their first invitation, each individual is labelled as either: (1) always attends (2) never attends (3) has a 33% probability of attending. This is based on random probability	Overall 75% attend. (1) 70% always attend (2) 15% never attend (3) 15% have a 33% chance of attending	Uptake of national breast screening programme, with assumptions about proportion that never attend
Smoke	Does s/he smoke?	Smoking label (Y)	N/A	QResearch data
	If a smoker, is s/he willing to be referred to stop smoking services (Y/N)?	Probability	19%	See Table B1 in Appendix B
	If referred to a stop smoking service, does s/he quit?	Probability	15%	See Table B1 in Appendix B
Inactive	Does s/he do sufficient activity (5 x 30 minutes per week)?	Probability based on age and gender	Table A1	Health Survey for England 2004
	If under-active, is s/he willing to take up brief exercise chat	Probability	77%	See Table B1 in Appendix B
	If given a brief exercise chat, will s/he increase his/her physical activity as a result?	Probability	23%	See Table B1 in Appendix B
Obese	Is s/he obese?	BMI label (>30)	N/A	QResearch data
	If obese, is s/he willing to take up weight loss programme	Probability	85%	See Table B1 in Appendix B
	If s/he takes up the weight loss programme, will s/he complete it?	Probability	68%	See Table B1 in Appendix B
High BP	Does s/he have high blood pressure (BP)?	Systolic blood pressure label (>140)	N/A	QResearch data
	Does s/he go on to receive anti-hypertensives	Probability	40%	See Table B1 in Appendix B

Step	Question	Probability or label?	Value	Source
	Does s/he go on to get a diagnosis of CKD	Probability based on age and gender	Table A2	Reference[4]
	If s/he is prescribed anti-hypertensives, will s/he comply with the medication?	Probability	87%	See Table B1 in Appendix B
High cholesterol	Does s/he have high cholesterol?	TC:HDL ratio label (≥6)	N/A	QResearch data
	If so does s/he take up statins?	Probability	85%	See Table B1 in Appendix B
Over 20% risk	Does s/he have ≥ 20% 10-year CVD risk?	CVD risk label	N/A	QResearch data
	If so does s/he take up statins?	Probability	85%	See Table B1 in Appendix B
	If s/he is prescribed statins, will s/he comply with the medication?	Probability	70%	See Table B1 in Appendix B
Blood glucose testing	Does s/he have high FINDRISC score and hence have a blood glucose test?	Probability	40%	Reference[1]
	Does s/he have a high blood glucose result and hence go on to have OGTT?	Probability	70%	Reference[1]
	Does s/he go on to be diagnosed with IGR?	Probability based on age and whether obese or not	Table A3	Data on STAR Study provided by University of Leicester
	Does s/he go on to be diagnosed with diabetes?	Probability	Table A3	
	Does s/he take up IGR lifestyle intervention?	Probability	85%	See Table B1 in Appendix B
	Compliance			
Feedback	Go to Model Exit	Label: whether diagnosed with CKD or diabetes	N/A	Model dynamics
	Go to high risk area	Label: whether put on anti-hypertensives or statins	Note these all then go to the Model Exit	Model dynamics
	Eligible for re-test	All other individuals	N/A	Model dynamics

Step	Question	Probability or label?	Value	Source
Low risk waiting area	Go to Model Exit from low risk waiting area	Annual probability of non-vascular mortality	Non-vascular mortality rate based on age and gender	ONS Mortality data 2005
		Annual probability of vascular event	Risk based on CVD risk label divided by 10	QResearch data
		Label age >75	N/A	Model dynamics
Retest	Eligible for retest	Label of time since last test	N/A	Model dynamics

Modelling changes over time

28.　The model needs to simulate changes to risk factors over time. For all individuals, it increases their age label by one and increases their QRISK score accordingly (as age is a key independent risk factor in QRISK). But it also needs to simulate other changes to risk factors with age. How it does this is set out below.

Blood pressure
29.　We used Health Survey for England 2005 data to calculate the impact of age on blood pressure, assuming the rates of hypertension (defined as over 140/90 mmHg or on anti-hypertensive medication) by age would stay the same in future years. This provided us with an age-band specific annual probability of becoming hypertensive. For the purposes of the model, we assumed that blood pressure stays the same for all individuals except a proportion who become hypertensive each year. We only use systolic blood pressure because our analysis of Health Survey for England 2003 data suggested 99% of people with diastolic blood pressure >90mmHg also had systolic blood pressure >140mmHg. For those individuals that become hypertensive, their SBP label increases to 141 mmHg and they are picked out for the hypertension diagnosis on their next vascular check. See Table A4 in Appendix A.

30.　This is a simplistic model for how blood pressure changes. In fact most people's blood pressure will change year on year whereas this assumes just a proportion become hypertensive and everyone else has constant blood pressure. Another option would be to adopt a far more complex method for simulating individuals' blood pressures over time. However, the model's results are dependent on the proportion of people with hypertension rather than the actual blood pressure reading of individuals, so the simpler method was considered appropriate in this context.

Body Mass Index (BMI)
31.　For BMI we modelled two scenarios:
　　　　SCENARIO A:　　Current rates of obesity by age
　　　　SCENARIO B:　　Increasing rates of obesity using forecasts from the Foresight report[5].

32. For Scenario A we used Health Survey for England 2005 data to calculate the impact of age on BMI. Obesity rates do fall very slightly for men from aged 55-64 to aged 65-74 but as this is against the trend for other age groups, we decided to assume no change between these age bands. See Table A5 for the results.

33. For Scenario B we took forecasts by age and gender from a report by the *Foresight Tackling Obesities: Future Choices Project*[5] and calculated the average percentage increase in rates of obesity by age group per year. These forecasts a far higher rate of increase in obesity compared to scenario A. See Table A6.

34. We could have adopted a more complex method of simulating individuals fluctuating weight, as for blood pressure, but considered this to be a reasonable methodology for predicting the number of people who will require the weight loss intervention.

Cholesterol
35. There have been significant decreases in cholesterol levels recorded in Health Survey for England over the last 10 years[3]. However, there were no reliable data sources on the expected future trends of cholesterol by age. Given the uncertainty over future trends in cholesterol, we assumed no change in individuals' cholesterol scores over time in our analysis, but performed sensitivity analysis on this assumption.

Smoking status
36. We made the assumption that no-one in the modelled age range would take up smoking if they do not smoke already, and those that quit for more than 12 months do not take up smoking again.

Individuals' CVD risk scores over time

37. The original QResearch data included a 10 year CVD risk score for each individual, based on the QRISK algorithm. This gives an estimate of CVD risk in individuals' first assessments. We then needed to model how CVD risk would change over time and as risk factors changed. This would be in terms of:
    - Changes in risk with changing risk factors (including age)
    - Changes in risk with interventions

Changes in risk with changing risk factors

38. The QRISK algorithm itself was not available at the time of this work so it was not possible to calculate precisely how an individual's score would be effected by age and changes in other risk factors. Therefore, we ran a multi-variate first order regression analysis on the QResearch data, with the CVD risk data as the target variable[4]. The data included all the fields that QRISK requires (a list of which was available from the published paper[3]) but they are in terms of categories instead of actual values. This method gave a Multiple R-squared value of 0.9. From the coefficients produced, we had estimates for the average change in risk associated with moving between categories of each risk factor, for example the increased risk of BMI going from category 25-29.9 to category 30+. The high R-squared value suggests these are reasonable estimates,

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[3] For example, in 1994, 53% of people aged 65-74 had total cholesterol over 6.5 mmol/l compared to 31% in 2003.
[4] In this case, for missing values we used the mean for age and gender. This is the same method used by the QRISK algorithm when data is missing from a field.

although this method is simplistic and will miss any second order interactions. Due to the uncertainty of these values we performed extensive sensitivity analysis on these values and found that the cost effectiveness conclusions were not sensitive to them (see the Results section).

Changes in risk with interventions

39.   When individuals take up an intervention, their CVD risk should decrease if they comply with the intervention. The equation we used to assess their new risk was as follows:

$$CVD\ risk_{(new)} = CVD\ risk_{(prior)}\ x\ (1 - RRR)$$

where RRR is relative risk reduction of the intervention in question.

40.   This equation applies only to those who *comply* with the intervention. The values used for compliance and RRR for the individual interventions are in Appendix B along with supporting assumptions. If an individual takes up two or more interventions then we assume their relative risks will be multiplicative, in other words:

$$CVD\ risk_{(new)} = CVD\ risk_{(prior)}\ x\ (1 - RRR)_{(int'n\ 1)}\ x\ (1 - RRR)_{(int'n\ 2)}\ \ldots$$

Step 4: Link simulation results with cost effectiveness data

41.   Two of the key objectives of this work were (a) to establish whether a policy of vascular checks was likely to be cost effective, and (b) to identify the optimal starting age and frequency for re-testing. Cost effectiveness for health policies is commonly defined in terms of cost per quality adjusted life year (QALY[*]) gained. The use of QALYs is particularly useful for this policy because it allows the range of different health benefits that would result from the policy (e.g. cases of diabetes diagnosed earlier, heart attacks prevented) to be quantified in the same currency. There is also a reasonable body of literature on the cost effectiveness of the interventions included in this policy in terms of QALYs, so this also made it a good choice of measures.

42.   The cost calculations include two components:
- The cost of the actual assessments plus any follow-on tests or monitoring that are required, in terms of staff time and lab costs
- The cost impact of the interventions that are provided as a result of the vascular checks.

43.   The benefits are calculated as the total of the estimated QALYs that result from the interventions that are provided as a result of the vascular checks.
The overall calculation is represented below.

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[*] Quality adjusted life years, or QALYs, are a measure of the health benefits that result from health interventions. They represent the benefit in terms of extending life and/or improving individuals' quality of life.

Figure 5: Calculation of overall cost effectiveness

$$\text{Cost effectiveness} = \frac{\text{Sum of}\left(\boxed{\text{Referrals (A)}} \times \boxed{\text{Lifetime net costs (A)}} \times \boxed{\text{Attribution (A)}}\right)\text{over all interventions} + \boxed{\text{Cost of vascular checks}}}{\text{Sum of}\left(\boxed{\text{Referrals (A)}} \times \boxed{\text{Lifetime net QALYs (A)}} \times \boxed{\text{Compliance (A)}} \times \boxed{\text{Attribution (A)}}\right)\text{over all interventions}}$$

44.   The SIMUL8 model provides estimate of how many individuals are expected to take up each intervention. This is then multiplied by costs and QALYs, attribution (see below) and compliance figures, in order to give an overall cost per QALY of the programme over its first 20 years. This figure can then be compared against the NICE lower threshold of £20,000 per QALY gained.

45.   Our aim was not to produce an estimate of the actual cost per QALY to the highest level of accuracy possible, as we knew that some of the data to do this would not be readily available. We therefore took the approach that, where there was a range of equally likely estimates for a parameter, we would take the most conservative estimate so as to, if anything, over-estimate the cost per QALY gained. We also used the lowest NICE threshold of £20,000 although NICE's threshold is often quoted as between £20,000 and £30,000 because if the cost effectiveness estimate was below the £20,000 figure, we could be confident that the policy is cost effective.

Lifetime costs and QALYs

46.   For this analysis we used lifetime QALYs and lifetime costs, and calculated the net present value for the first 20 years of the programme. This included, for example, the full costs and QALYs that would result over an individual's lifetime of an intervention that is initiated from a check in Years 1-20 (even though the benefits being counted would potentially occur over years outside this period), but the costs and benefits of any interventions initiated from Year 21 onwards would not be included. Lifetime costs are used because this is a prevention policy so the benefits are likely to accrue 20 to 40 years into the future for many individuals.

Gross or Net Costs

47.   Where possible we used net costs to the NHS: that is, the costs incurred net of any savings that occur as a result of that intervention (for example, through prevention of future vascular events). The negative cost figures in table 6 for diabetes and IGR lifestyle interventions show they are net saving to the NHS over the patient's lifetime. However, we were reliant on estimates already available from other studies and for smoking cessation, exercise intervention and weight management, no reliable estimates of net costs were found so it was decided to use gross costs instead. This was considered sensible as it would provide a conservative estimate of cost effectiveness.

Discount rates

48.   Department of Health guidance for Impact Assessments is to discount future costs at 3.5% and QALY benefits at 1.5%. For the costs this has been adhered to. However, for benefits, all the sources of QALY figures used a discount rate of 3.5%, which is in line with NICE guidance. As a discounting rate of 3.5% gives lower figures for lifetime QALYs than the 1.5% figure recommended for DH, this was deemed acceptable as it would lead to more conservative estimates of the overall cost effectiveness of this policy. However, a 1.5% discounting rate was still applied to QALY benefits in for the

period before an intervention is initiated. For example, if an intervention with a quoted lifetime QALY figure of 1.0 (discounting rate 3.5%) initiated in Year 6 will have an net present value (NPV) in Year 1 of 0.93 QALYs (i.e. 1.0 QALYs discounted at 1.5% over 5 years).

Attribution

49.   The SIMUL8 model calculates how many people would be eligible for the various interventions assuming they haven't been offered them outside the context of a vascular check. In reality, as there is existing guidance for all the interventions on offer, it is likely that individuals will be offered these tests or interventions at other opportunities, such as when GPs check individuals' blood pressure as part of a normal consultation. To account for this, we include a factor called "attribution" which is an estimate of the proportion of the overall number of referrals for each intervention that would be done in the vascular check as opposed to at other opportunities. The sources for these estimates are given in Appendix B.

Cost of vascular checks

50.   The average cost for a basic vascular check is £23.70. This is broken down in table 3 below:

Table 3: Breakdown of the costs of vascular checks

Cost element	£ per unit	% patients who receive it	Avg £ per check
Assessment			
Admin time (invites plus appointments)	4.70	100%	4.70
Healthcare assistant time	5.40	100%	5.40
lab tests - Cholesterol	4.20	100%	4.20
lab tests - FBG	6.10	38%	2.30
lab tests - Serum Creatinine	0.71	18%	0.10
Feedback appointment			
Nurse time	7.00	100%	7.00

51.   We assumed 15 minutes face-to-face with a healthcare assistant for the initial assessment and 15 minutes face-to-face with a practice nurse time for the feedback session. Unit costs are adjusted to account for time spent in preparation and non-face-to-face work. We assumed that each individual would receive a cholesterol test, 38% would receive a fasting blood glucose (FBG) test (those with a high FINDRISC score) and 19% would receive a serum creatinine test (those with a high one-off blood pressure reading).

52.   As well as these costs, there are the costs of knock-on tests if an individual has high blood pressure or has a high FBG result. The cost of these averages £9.80 per vascular check. A breakdown of these costs is provided in table 4.

Table 4: Breakdown of costs for subsequent tests

Cost element	£ per unit	% patients who receive it	Avg £ per check
Follow-on tests: Oral Glucose Tolerance Test			
Healthcare assistant time - OGTT	9.00	27%	2.40
lab tests - OGTT	12.30	27%	3.30
Follow-on tests: Monitoring blood pressure			
Nurse time – BP monitoring	7.00	11%	0.80
Healthcare assistant time - BP monitoring	7.20	11%	0.80
Lab tests - BP monitoring	22.30	11%	2.50

53.   For a hypertension diagnosis we assume 20 minutes of healthcare assistant time and 15 minutes of practice nurse time, as well as lab costs for cholesterol, fasting blood glucose, liver function test and U and Es (urea and electrolytes). For diagnosis of diabetes or IGR we assume it requires an additional oral glucose tolerance test, requiring 25 minutes of a healthcare assistant's time and the lab costs.

54.   Unit costs and sources are provided in Table 5.

Table 5: Unit cost estimates

Cost element	Unit cost (£)	Source
Admin time: cost per hour	£15	Estimate
Healthcare assistant: cost per hour of patient contact	£22	PSSRU[6]
Practice nurse: cost per hour of patient contact	£28	PSSRU
Cholesterol test: lab costs per test	£4.20	SRNFT[7]
Fasting blood glucose test: lab costs per test	£6.20	SRNFT
Serum creatinine test: lab costs per test	£0.70	SRNFT
Oral glucose tolerance test: lab costs per test	£12.30	SRNFT

Cost and QALY assumptions by intervention

55.   Table 6 gives the lifetime costs and lifetime QALYs expected for each intervention. Further explanation of the sources of these figures and how they have been derived are given below.

Table 6 – Lifetime costs and QALYs for each intervention

Intervention	Age	Gender	Lifetime cost (£)	Lifetime QALYs
IGR lifestyle intervention	25-44	All	-398	0.63
	45-54	All	493	0.63
	55-64	All	1821	0.53
	65-74	All	2637	0.39
Statins	40-49	Male	2374	0.47
	50-59	Male	2241	0.30
	60-69	Male	2092	0.18
	70-79	Male	1695	0.08

Intervention	Age	Gender	Lifetime cost (£)	Lifetime QALYs
	40-49	Female	2658	0.35
	50-59	Female	2633	0.27
	60-69	Female	2517	0.17
	70-79	Female	2113	0.08
Anti-hypertensives	40-49	Male	1020	0.79
	50-59	Male	894	0.71
	60-69	Male	815	0.60
	70-79	Male	641	0.57
	40-49	Female	1047	0.88
	50-59	Female	899	0.74
	60-69	Female	826	0.60
	70-79	Female	605	0.45
Smoking cessation	All	All	177	0.39
Exercise intervention	All	All	33	0.17
Weight management	All	All	51	0.01
Earlier detection of diabetes	40-49	All	452	0.12
	50-59	All	-296	0.17
	60-69	All	-111	0.18
	70-75	All	-111	0.18

IGR lifestyle intervention

56.   These figures are taken from a cost effectiveness study of the American Diabetes Prevention Programme (DPP)[8] in the absence of any UK cost effectiveness study of IGR lifestyle interventions. The cost in dollars was converted into pounds sterling using the average exchange rate in 2000, and then adjusted for 2008 prices using the health and social care pay index (DH).

Statins

57.   To estimate the net lifetime cost of statins, we used figures from the NICE technology report[9] which gave an estimate of the cost per QALY for statins for primary prevention. It also gave the lifetime net costs and QALYs gained from statins for secondary prevention, but did not give this breakdown for primary prevention. Therefore we assumed that the net costs of primary prevention would be approximately equal to those for secondary prevention. We could then divide the cost by the cost per QALY to get an estimate for the QALYs gained from primary prevention with statins.

58.   As the cost of statins has reduced significantly since this report, we adjusted the cost for this. Our analysis suggested the annual price of statins for new people being put on them would be £60.52 (assuming 80% of new statin prescriptions are for simvastatin, 15% are for atorvastatin and the other 5% are distributed across the other common statins) compared to £273 assumed in the report. To estimate the total cost reduction, we multiplied the saving by the expected life expectancy of individuals taking statins, assuming average continuance of 70% over this period.

Anti-hypertensives

59.   The net lifetime costs and QALYs were taken from work for the NICE Hypertension Clinical Guideline 18[10] for ages 50 to 79. For those under 50 we plotted the lifetime

costs and QALYs by age band for ages 50-79 and assumed a straight line fit to give an expected value for ages 40-49. We then inflated all figures from 2005 prices to 2008 prices using the health and social care pay and prices index (DH).

Smoking Cessation
60.   The cost is taken from the NICE costing report on brief interventions for smoking cessation[11], inflated from 2005/06 prices to 2008 prices using the health and social care pay index (DH). Although this is a gross cost and there are likely to be significant lifetime savings to the NHS, no accurate estimate of the net cost could be found so the gross cost provides a conservative estimate for these calculations.

61.   The QALY estimates are taken from the HTA for NICE technology appraisal on bupropion (Zyban) and Nicotine Replacement Therapy for smoking cessation[12] which states that the QALYs gained per lifetime quitter are 2.7. Assuming stop smoking services results in 1 quitter for every 7 referrals[13], this is equivalent to 0.39 QALYs per referral.

Exercise Intervention
62.   NICE recommended a brief exercise intervention in its guidance on increasing physical activity[14]. Their own costing report assumes this will be given by GPs opportunistically at no cost, so the only cost will be for a 15 minute follow-up estimated at £4.26. In the case of vascular checks this will not be given opportunistically so we cannot exclude the cost of the initial consultation. Therefore we used the calculations within the background report to NICE[15] which estimated the total cost of an initial assessment and a motivational interview to be £28.67. We inflated this from 2004 to 2008 prices using the health and social care pay index (DH).

63.   The same report estimated the QALYs gained for this intervention to be 0.34 per referral. This assumes 50 percent of participants maintain any improved levels of physical activity after the intervention for long enough to derive the health benefits. However there was no long term follow-up data to back up this assumption. We therefore decided to make a more conservative estimate and assume that only 25% of people would maintain their improved level of physical activity past the end of the intervention. This would give an average QALY per person taking up the intervention of 0.17.

Weight loss intervention
64.   The costs are taken from a study of a "Slimming on Referral" service[16] which was for 12 free vouchers to a commercial weight loss programme. The QALYs gained was taken from Section 6 of the NICE Clinical Guideline on Obesity[17] on Health Economics which estimated the QALYs gained from three interventions: a weight loss programme, behavioural treatment and exercise. The benefits were lowest for exercise at 0.01 QALYs. These QALY gains are particularly low because of the assumptions about weight re-gain post treatment, which assumes individuals will re-gain 5.6kg post treatment per annum until they return to their original weight. While we expect this intervention is likely to give greater health benefits than these figures suggest, we decided to use the 0.01 QALY figure as a conservative estimate of the benefits of this intervention. However, we would like to investigate more robust evidence around this as this estimate does not appear consistent with the estimate of the benefits of the exercise intervention which assumes 17 times greater benefit.

65.   A report by ScHARR to the National Screening Committee set out the estimated costs and QALYs gained from earlier detection of diabetes[2]. The report gives the costs net of any savings and the QALYs gained from detection through screening versus clinical detection per case diagnosed. The costs were uplifted to 2008 prices using the health and social care pay index (DH).

Step 5: Link simulation results with primary care cost profile

66.   The objective of this step is to estimate the year-by-year profile of costs to primary care and the resources required. Step 4 estimated the net cost of the programme over its first 20 years which included the lifetime costs of any new interventions initiated and netted off any savings to secondary care. This section considers the actual in-year costs incurred to primary care.

67.   Note that the cost assumptions are for a GP practice service. If other delivery options are used then this would affect the cost impact. Refinements of these costs to reflect different delivery options are already planned for future iterations of this work.

68.   In order to estimate the annual profile of costs it was necessary to estimate the profile of costs over time for each intervention. These estimates are provided in Appendix A, tables A8-A13. The methodologies and sources used are provided in table 7 below.

Table 7: Cost profile of interventions

Intervention	Sources and methodology of cost estimates
IGR lifestyle intervention	These figures are taken from a health technology assessment on obesity interventions[18] and uplifted to 2008 prices.
Statins	We costed the following components: • Average annual drugs cost at £60.52 (assuming 80% of new statin prescriptions are for simvastatin) based on NHS Drugs tariff[19] • Liver function tests at baseline, 3, 6, 12 months, annual • Cholesterol tests at baseline, 6, 12 months, annual • Serum creatinine test at baseline and annual if required (10%) • Practice nurse time for monitoring (4 visits in the first year plus 1 visit a year in subsequent years @15 mins each) • GP time for monitoring (one appointment p.a.) We factored in the average mortality rates by age to get expected cost profile for 20 years from initiation of treatment.

Intervention	Sources and methodology of cost estimates
Anti-hypertensives	We assumed individuals under 70 years receive ACE inhibitors (£29.64 annually based on Ramipril) and individuals over 70 years receive calcium-channel blockers (£70 annually based on Amlodopine).
	For diagnosis of hypertension, and for subsequent annual monitoring of hypertension, we assumed the following tests were required: blood glucose, TC:HDL, Liver Function Test, U and Es. For diagnosis of hypertension this would require 15 minutes of practice nurse time and 20 minutes of healthcare assistant time. For monitoring of hypertensive patients each would require on average 10 minutes of practice nurse time, 10 minutes of healthcare assistant time and 10 minutes of GP time for monitoring per annum
Smoking cessation, brief exercise intervention and weight loss programme	For these three interventions, the costs used in Step 3 for lifetime costs were actually the total gross costs incurred within the first year following referral.
Earlier detection of diabetes	The cost components are taken from the ScHARR report[2] and are: two GP appointments, two HBA1c tests, one proteinuria screening and one retinopathy screening p.a. plus drug costs for anti-hypertensives, insulin and statins. It is estimated that screening results in diabetes being identified 7 years earlier than it would be clinically diagnosed.
Earlier detection of CKD	We assumed that cases of CKD diagnosed through the vascular check were diagnosed on average 10 years before they would otherwise be diagnosed. We estimated that each such patient would require 2 GP visits and 2 serum creatinine tests per annum in addition to the care they would otherwise have received.

69.   A summary of the workforce requirements per individual receiving each intervention is given in table 8. The cost for GP time is estimated to be £138 per hour in patient contact.

Table 8: Workforce input for interventions

Staff	Intervention	Time required
GP	CKD management	30 min/year
	Diabetes management	30 min/year
	Hypertension management	10 min/year
	Statins	10 min/year
Practice nurse	Hypertension management	10 min/year
	Statins	60 min in 1st year, 15 mins/year subsequently
Healthcare assistant	Hypertension management	10 min in 1st year

Step 6: Sensitivity Analysis

70. There were two objectives for the sensitivity analysis:
1. To ascertain the extent to which the overall conclusions are sensitive to the assumptions made for changes with age in terms of the QRISK score, cholesterol levels and obesity rates For this we used scenario modelling.
2. To quantify the likely range of overall costs and benefits based on a range of uncertainties including uptake, compliance with interventions, and cost assumptions. For this we used scenario modelling combined with Monte Carlo simulation.

71. Before undertaking the sensitivity analysis we needed to consider the accuracy of a single run of the simulation model.

Accuracy of a single run

72. The SIMUL8 model is a simulation of a stochastic process whereby individuals' routes through the model are not pre-determined but are based on probabilities. Running the model with a sufficiently large number of individuals will ensure that the overall results are not skewed by the characteristics of a small number of individuals. We have modelled a population equivalent to 50 GP lists, or approximately 90,000 people (all ages). This equates to approximately 35,000 first checks and 42,000 subsequent checks over the 20 years of the policy, which is sufficient to avoid any sensitivity to small numbers and variations in individuals' characteristics. To illustrate this we ran the model three times all the results were within a range of ±1% of the mean.

Scenario Modelling

73. In order to ascertain the extent to which the overall conclusions are sensitive to the assumptions made for changes with age in terms of the QRISK score, cholesterol levels and obesity rates, we performed scenario modelling. This is where the model is re-run

with alternative parameters. We created a number of scenarios to test the ageing assumptions for which there was a lack of reliable data but which we expected would not significantly impact the overall cost and QALY estimates. This are summarised in table 9 below:

Table 9: Scenario Modelling for ageing assumptions

Scenario name	Changes from the base case assumptions
High obesity	The proportion of people who become obese over time is in line with the Foresight report
High QRISK	The coefficients for the increase in CVD risk with age are multiplied by 1.25
Low QRISK	The coefficients for the increase in CVD risk with age are multiplied by 0.8
High Cholesterol	0.5% of people with TC:HDL<6 develop TC:HDL≥6 per year.

Scenario Modelling with Monte Carlo Simulation

74.   In order to quantify the likely range of overall costs and benefits based on a range of uncertainties, we combined scenario modelling with Monte Carlo simulation.

75.   We needed to determine a methodology by which we could vary a number of assumptions simultaneously and determine the overall impact on costs and benefits. The assumptions which are considered to be particularly uncertain and likely to impact on overall costs and benefits are:
- Uptake of interventions
- Compliance with interventions
- Attribution of interventions (how much would be done as a direct result of the policy)
- Workforce time estimates
- Lab costs

76.   Using Monte Carlo simulation it is possible to assign variables a distribution of possible values and see the impact on the overall results. The user defines the parameters that should be varied and assigns them a distribution of values. The computer package then performs random sampling of the distributions of each parameter and calculates the outputs over multiple trials to generate a distribution of results.

77.   The software package Crystal Ball® was used for the Monte Carlo simulation option. This is compatible with Microsoft Excel so it can work within the Excel file that contains the SIMUL8 results and the various assumptions, calculations and results. However, it cannot interface with the SIMUL8 software so it is not possible to see the full impact when variables used by the SIMUL8 model are assigned a distribution of possible values. For this reason, we decided instead to create two scenarios which vary the assumptions used in SIMUL8 model and then perform Monte Carlo simulation on these results. These two scenarios are defined as follows.

High cost

We increased the uptake and compliance assumptions by 5-15% compared to the base

case depending on the intervention. We defined these by first judging the highest likely value possible and then took the mid-point.

Low cost
We decreased the uptake and compliance assumptions by 5-15% compared to the base case depending on the intervention. We defined these by first judging the lowest likely value possible and then took the mid-point.

78.   These scenarios are not designed to represent extreme assumptions but as the limits of what is considered reasonably likely to occur. Although there is a possibility that some values will fall outside the range of these scenarios, it is very unlikely that all assumptions would be overestimated or all would be underestimated. For more details on this sensitivity analysis see Appendix D.

Results

Headline messages

- This policy is highly cost effective, with a conservative estimate of its cost per Quality Adjusted Life Year (QALY) of around £3,000. Although there is some uncertainty in many of the parameters used, sensitivity analysis shows the cost effectiveness of the policy is robust against these uncertainties.
- Of all the options considered, the optimal is a starting age of 40 with vascular checks every 5 years
- The estimates from the model are that costs will increase over time before levelling out at between £180m to £243m p.a. from Year 6 onwards. The costs in the first 5 years will depend on the speed of roll-out. If we assume roll-out will start at 40% in Year 1 and increase to 100% by Year 5, the estimated cost impact will be £40m in Year 1, increasing steadily to £210m by Year 5. However, these estimates are based on scenarios which are fed into the model and should not be taken as final estimates of the cost of the policy. We expect the true costs to depend significantly on the delivery route for the programme and roll-out plans which will be developed via engagement with stakeholders over the coming months.

A Cost effectiveness results

79. We ran six scenarios with different start ages and frequencies of retesting and compared their cost per QALY over the first 20 years of the policy.

80. The results are given below for an equivalent population of 90,000 population or 50 GP lists:

Table 10: Cost per QALY of each age/frequency scenario

Scenario	Starting age	Frequency	NPV Costs (£m)	NPV QALYs	Cost per QALY
Scenario 1	40	5 years	4.47	1804	2,480
Scenario 2	40	10 years	3.32	1433	2,320
Scenario 3	45	5 years	3.90	1455	2,684
Scenario 4	45	10 years	2.84	1154	2,458
Scenario 5	50	5 years	3.26	1098	2,966
Scenario 6	50	10 years	2.46	912	2,697

81. The first test of cost effectiveness is to compare the overall cost per QALY of each scenario with the NICE lower cost-effectiveness threshold of £20,000 per QALY. We use the lower NICE threshold because there is some inherent uncertainty in our estimates. As all the scenarios give a cost per QALY below £3,000, all scenarios are very cost effective according to this test.

82. The second test of cost effectiveness is to compare the *incremental cost effectiveness ratio* (ICER) of each scenario against the next cheapest option with the NICE threshold. ICER of scenario A compared to scenario B is defined as:

$$ICER_{a,b} = \frac{Cost_a - Cost_b}{QALY_a - QALY_b}$$

83. If ICER$_{a,b}$ below £20,000 then scenario A is desirable over scenario B, as long as Scenario A is also affordable.

84. Table 11 shows the scenarios ordered with the lowest cost scenario first, and the *incremental cost effectiveness ratio* of each scenario over next cheapest one.

Table 11 Incremental Cost Effectiveness Ratios

Scenario	Starting age	Freq.	NPV Costs (£m)	Δ Cost (£m)	NPV QALYs	Δ QALYs	ICER (£/QALY)
Do nothing	-	-	0	-	0	-	-
Scenario 6	50	10 Y	2.46	2.46	912	912	2697
Scenario 4	45	10 Y	2.84	0.38	1154	242	1556
Scenario 5	*50*	*5 Y*	3.26	0.42	1098	-56	-7453
Scenario 2	40	10 Y	3.32	0.49*	1433	279*	1752*
Scenario 3	*45*	*5 Y*	3.90	0.58	1455	22	26156
Scenario 1	40	5 Y	4.47	1.15**	1804	371**	3096**

*Incremental values of scenario 2 over scenario 4 ** Incremental values of scenario 1 over scenario 2

85. From this analysis, Scenario 1 is the optimal scenario. This can be explained as follows:
   - Scenario 6 is preferable to doing nothing because the incremental cost per QALY is just £2,697
   - Scenario 4 is preferable to scenario 6 because the incremental cost per QALY is just £1,556.
   - Scenario 4 is also preferable to scenario 5. In this case it is because scenario 4 is both cheaper and has more benefits to scenario 5. This is why the ICER of scenario 5 over scenario 4 is negative.
   - Scenario 2 is preferable to scenario 4 because the cost per QALY is just £1,752.
   - Scenario 3 would be *just* preferable over scenario 2 if we applied the NICE upper threshold of £30,000 per QALY because it would cost £26,156 per additional QALY achieved, but, in line with the overall approach to these figures, we have chosen to treat the estimates in a conservative way and use the lower threshold of £20,000. In this case we discard scenario 3 because it is not justifiable over scenario 2.
   - Lastly, Scenario 1 is justified over scenario 2 because it has an incremental cost per QALY of £3,096.

86.   The incremental cost effectiveness of scenario 1 over the other scenarios is shown in
      table 12 below. This confirms that the scenario 1 is optimal as its ICER over all
      scenarios is well below the £20,000 threshold.

Table 12: ICER (£ per QALY) of Scenario 1 over every other scenario

Scenario	ICER (£ per QALY)
Do nothing	2,480
Scenario 2	3,096
Scenario 3	1,629
Scenario 4	2,519
Scenario 5	1,724
Scenario 6	2,258

Sensitivity Analysis

87.   We then performed sensitivity analysis on Scenario 1 by creating two scenarios – High
      Cost and Low Cost and performing Monte Carlo simulation for each. A full description of
      this is given in *Step 6: Sensitivity Analysis*. The cost per QALY results are given below.
      The minimum and maximum figures are taken from the Monte Carlo results:

Table 13: Sensitivity analysis results for cost per QALY

Scenario	Cost per QALY – base (£)	Cost per QALY – min (£)	Cost per QALY – max (£)
High cost	2,417	1,851	3,243
Low cost	2,617	1,954	3,498

88.   This shows that despite these scenarios being wide ranging for overall costs, the *cost
      effectiveness* in terms of cost per QALY still remains safely below the £20,000
      threshold.[5]

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[5] Note that the High Cost scenario actually has a low cost per QALY. This is because the High Cost scenario increases the
number of people taking up interventions as a result of vascular checks (through increasing attribution and uptake
assumptions) rather than the unit cost of individual interventions, which is varied in the Monte Carlo sensitivity analysis.

B Cost estimates

89. The cost estimates provided here are based on scenarios which are fed into the model and should not be taken as final estimates of the cost of the policy. We expect the true costs to depend significantly on the delivery route for the programme and roll-out plans which will be developed via engagement with stakeholders over the coming months. In the meantime these costs are based on assuming general practice surgeries will undertake the checks and the follow-up work. We expect to carry out further modelling to support the choice of delivery options and roll-out plans.

90. The figures presented below are based on a screening programme for all people aged 40-74 every 5 years, and assume 75% uptake of invitations from Year 1 unless otherwise stated.

Invitations and Additional Checks p.a.

91. Nationally there would be 3 million[6] invitations for vascular checks per year and 2.2 million actual checks carried out. We assume that 1.1 million checks are already done each year, or 125 per GP practice. This is based on QRESEARCH data for the number of people on statins for primary prevention and the number who have had a cholesterol test in the last 5 years[7]. This leaves 1.1 million additional checks being performed each year. Per average GP practice (3 GPs), this is equivalent to 330 invitations per year and 250 attendances per year of which 125 will be additional to what is done already.

Overall Cost

92. The overall cost of the programme is estimated to be from £180m to £243m p.a. at full implementation. The three scenarios (base case, high cost and low cost) are given in graphs 1, 2 and 3. The red error bars represent the 10th to 90th percentile results from the Monte Carlo sensitivity analysis. The costs increase over years 1-5 because the cost of interventions such as statins and IGR lifestyle management occur over a number of years so there is a cumulative effect until a steady state is reached whereby approximately constant number of individuals are on the interventions.

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[6] Note the figures here are for primary prevention. More vascular checks would be carried out if those for secondary prevention were also included.

[7] QRESEARCH data shows that 28% of people in this age group who are not on statins or have a vascular disease have had a cholesterol test in the last 5 years. We estimate from this that this is equivalent to 4.2 million individuals, or an average of 850,000 tests p.a. QRESEARCH data also shows 6% of this age group are on statins for primary prevention (i.e. a prescription of statins without a diagnosis of any vascular disease). Assuming these have all been initiated in the last 5 years, this is equivalent to an average of 250,000 checks p.a.

Graph 1: Total cost impact of vascular checks policy assuming no staged roll-out with 10th and 90th percentile error bars
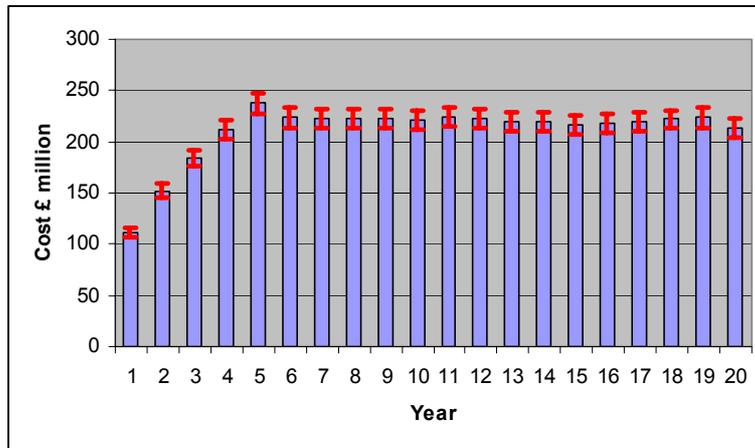
Graph 2: High Cost scenario with 10th and 90th percentile error bars
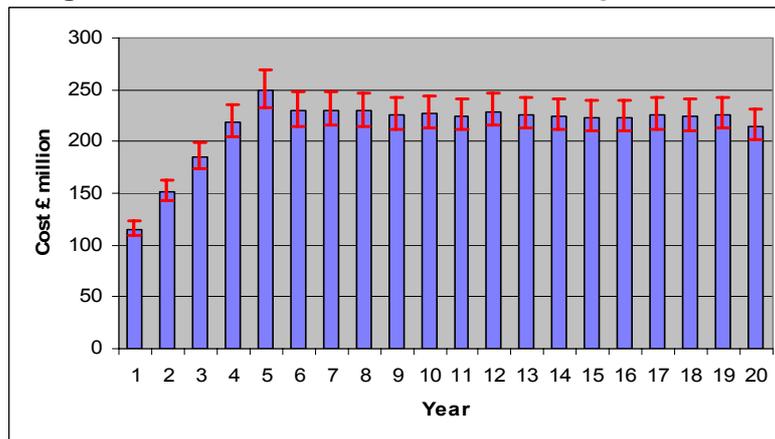
Graph 3: Low Cost scenario with 10th and 90th percentile error bars
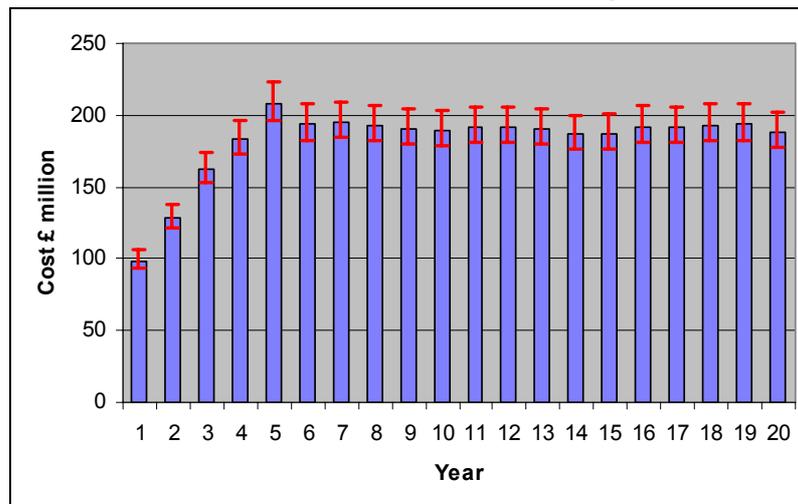
Cost of Vascular Checks

93.   The estimated additional cost of vascular checks is approximately £40 million per annum nationally in years 1-5 and £36 million per annum thereafter.

Cost of Interventions

94.   The average cost across years 1-20 in the base case scenario assuming full uptake from Year 1 is provided in table 14 below:

Table 14: Average total costs per annum by intervention

Cost component	£m p.a.	%
IGT lifestyle intervention	67.8	42%
Statins – drugs and lab costs	28.3	18%
Anti-hypertensives – drugs and lab costs	20.9	13%
Exercise chat	4.7	3%
Stop Smoking Services	4.3	3%
Diabetes management	3.4	2%
Weight loss programme	2.1	1%
Intervention costs: nurse time	1.9	1%
Intervention costs: GP time	27.6	17%
Intervention costs: Healthcare Assistant time	0.1	0%
TOTAL	**161.1**	**100%**

Scenarios for Staged Roll-Out

95.   We anticipate that implementation will begin in 2009/10 but there will be a staged roll-out that will ramp up over time. The roll out may be phased by PCT with some PCTs implementing first and others following, or may be in terms of all PCTs doing some activity in 2009/10 and increasing the activity over time. The simplest way to represent this is to apply an overall percentage implementation. This reflects the percentage of full implementation that is achieved each year. Graph 4 below assumes the following profile of implementation using the base case assumptions:

- Year 1: 40%
- Year 2: 55%
- Year 3: 70%
- Year 4: 85%
- Year 5 onwards: 100%

Graph 4: Total cost impact of vascular checks policy with staged roll-out
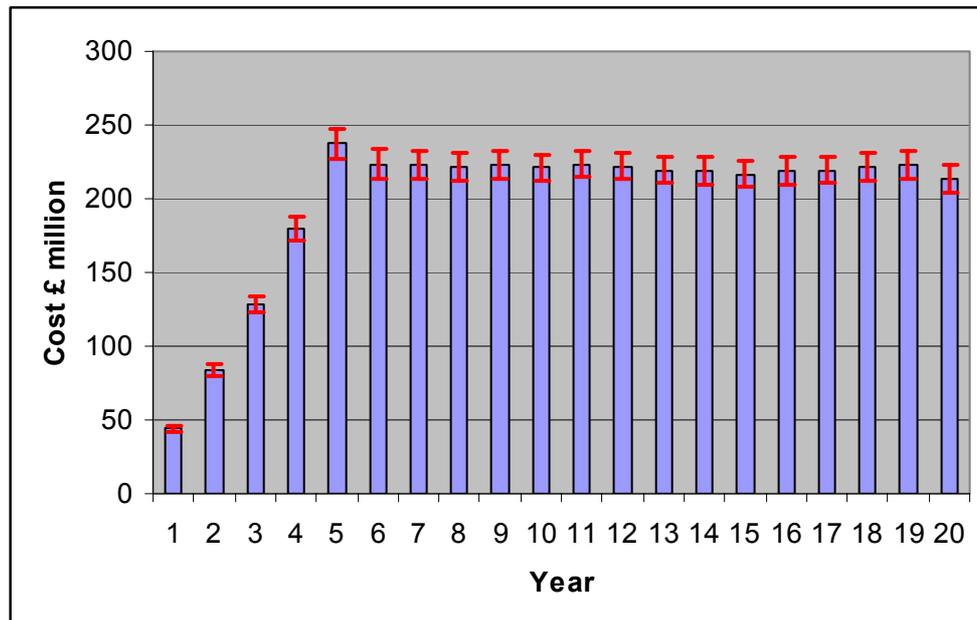
C Workforce Impact

96. The workforce impact can be split into two elements:
    - The workforce required for vascular checks
    - The workforce required for interventions

97. The assumptions on the workforce requirements for the vascular checks, subsequent tests and interventions are provided in the section Step 4 and Step 5. These figures assume all vascular checks are provided by GP practices. If other providers are used for the checks this will decrease the impact on GP practices but they would still need to manage the additional people put on pharmacological interventions.

98. As for the cost estimates, the workforce estimates provided here are based on scenarios which are fed into the model and should not be taken as final estimates of the workforce implications of the policy. We expect the true workforce impact to depend significantly on the delivery route for the programme and roll-out plans which will be developed via engagement with stakeholders over the coming months.

99. Tables 15 and 16 give the results in terms of whole time equivalents for all England and hours per week in direct patient contact for an average GP practice (population size 5,600, or 3 GPs) The results are given for years 1, 6, 11 and 16 to show the changing impact over time.

100. Table 16 demonstrates that the impact on an average GP practice. While this is not an insignificant addition to the practice staff's workload, it is also not so large as to require significant disruption to current provision of services. It equates to approximately one hour a week of healthcare assistant time, one hour a week of admin staff time, and one to one and a half hours a week of nurse time. The requirement on GP time will only be 10 minutes a week initially and increase to less than an hour a week.

Table 15: Workforce impact - WTEs - all England

	Year 1	Year 6	Year 11	Year 16
Vascular Checks				
Practice nurse	244	213	225	231
Healthcare Assistant	278	236	250	257
Admin staff	240	234	246	254
Interventions				
GP	53	219	250	227
Practice nurse	84	133	157	178
Healthcare Assistant	18[8]	2	2	2

Table 16: Workforce impact – Hours per week for average GP practice

	Year 1	Year 6	Year 11	Year 16
Vascular Checks				
Practice nurse	0.9	0.8	0.8	0.8
Healthcare Assistant	0.9	0.7	0.8	0.8
Admin staff	0.9	0.8	0.9	0.9
Interventions				
GP	0.2	0.7	0.8	0.7
Practice nurse	0.3	0.5	0.6	0.6
Healthcare Assistant	0.1	0.0	0.0	0.0

101. Practices that have a larger catchment population to an average GP practice will require more workforce input, but the average impact per staff member should be roughly the same. Practices that do little or no vascular checks currently will have almost double the workforce impact identified here, as these figures assume half of the total checks required are already undertaken (see assumptions in paragraph 91). If other providers are used for the checks themselves then this will decrease the workforce impact significantly.

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[8] There is a decrease in the "intervention" element of healthcare assistant time required from Year 5 onwards. This is because we assume the only intervention requiring healthcare assistant time is anti-hypertensive management and only in the first year of treatment. This decrease occurs because the first round of checks is expected to identify a large number of people with undiagnosed hypertension but subsequent rounds are expected to identify much lower rates of undiagnosed hypertension.

D Sensitivity Analysis of assumptions on physiological changes over time

102. Table 17 below gives the results for the various scenarios regarding changes in physiological measurements over time. Note that these are all based on a starting age of 40 and a frequency of re-testing every 5 years.

Table 17: Scenarios testing assumptions on physiological changes over time

Scenario	Cost per QALY	20Y Cost (£m)	Δ cost/QALY compared to baseline	Δ 20Y Cost compared to baseline
Base case	2,458	7.1	n/a	n/a
High obesity	2,613	7.2	-1%	1%
High QRISK	2,360	7.2	5%	1%
Low QRISK	2,563	7.1	-5%	-1%
High Chol	2,458	7.2	3%	1%

Values are equivalent to a service for 90,000 population or 50 GPs.

103. These results demonstrate that the overall conclusions are not sensitive to the uncertainties in how these physiological measures will change over time. The cost varies within ±1% of the base case for all these scenarios, and although the cost per QALY varies slightly more, it is still below £3,000 per QALY for each scenario so the conclusion that the policy is cost effective is robust against the uncertainty in these figures.

Next Steps

104.   There are a number of refinements to this piece of work which are already planned over the coming months. These are:

- Incorporate the Framingham equation so the model can be run using either the QRISK or Framingham score. If the QRISK2 algorithm is made publicly available, we will also incorporate this into the model
- Repeat the analysis using the THIN database for primary care data and compare results
- Assess the impact of different implementation options of this policy on health inequalities
- Refine views on the delivery strategy and prepare the final Impact Assessment which will reflect the expected costs of the chosen delivery strategy.

105.   An Equality Impact Assessment will also be undertaken alongside the development of this policy to determine the potential effects on particular populations and to ensure the policy is designed to increase the probability of equity outcomes.

Appendix A – Key Assumptions in Simulation Model

Table A1: Proportion of people doing less than 5 x 30 mins intense exercise

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.59	0.63	0.63	0.68	0.68	0.82	0.82
Female	0.68	0.7	0.7	0.8	0.8	0.86	0.86

Table A2: Proportion of people with one off high blood pressure who go on to get CKD diagnosis

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.03	0.07	0.07	0.10	0.10	0.21	0.21
Female	0.18	0.09	0.09	0.21	0.21	0.32	0.32

Table A3: Proportion of people with high FINDRISC and high fasting blood glucose whose results from OGTT indicate IGR or diabetes

Male and Obese	40-45	45-49	50-54	55-59	60-64	65-69	70-74
Diabetes	0.20	0.21	0.21	0.22	0.23	0.24	0.25
IGR	0.21	0.29	0.37	0.45	0.54	0.62	0.70
Female and Obese	**40-45**	**45-49**	**50-54**	**55-59**	**60-64**	**65-69**	**70-74**
Diabetes	0.00	0.04	0.08	0.12	0.17	0.21	0.25
IGR	0.16	0.24	0.32	0.40	0.48	0.56	0.65
Male not Obese	**40-45**	**45-49**	**50-54**	**55-59**	**60-64**	**65-69**	**70-74**
Diabetes	0.06	0.07	0.07	0.07	0.08	0.08	0.08
IGR	0.13	0.18	0.23	0.28	0.33	0.38	0.44
Female not Obese	**40-45**	**45-49**	**50-54**	**55-59**	**60-64**	**65-69**	**70-74**
Diabetes	0.00	0.01	0.03	0.04	0.05	0.07	0.08
IGR	0.10	0.15	0.20	0.25	0.30	0.35	0.40

Table A4: Annual chance of systolic blood pressure increasing to over 140 mmHg.

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.02	0.02	0.03	0.03	0.03	0.03	0.00
Female	0.01	0.01	0.04	0.04	0.04	0.04	0.03

Table A5: Annual chance of BMI increasing to over 30 – no period effects

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.001	0.001	0.000	0.000	0.000	0.000	0.000
Female	0.004	0.004	0.000	0.000	0.008	0.008	0.000

Table A6: Annual chance of BMI increasing to over 30 – Foresight predictions

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.028	0.038	0	0.008	0.034	0.009	0
Female	0.013	0.021	0	0.019	0.023	0	0

Table A7: Annual percentage increase in 10 year CVD risk

Age	40 - 44	45 - 49	50 - 54	55 - 59	60 - 64	65 - 69	70-74
Male	0.5	0.7	0.9	1.0	1.2	1.3	0.0
Female	0.3	0.5	0.7	0.8	1.0	1.1	0.0

Table A8: Cost of IGR lifestyle management intervention by year

Year	Year 1	Year 2	Year 3	Year 4	Year 5
(all ages, male and female)	461.56	253.57	253.57	253.57	253.57

Table A9: Cost of earlier detection of diabetes

Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
(all ages, male and female)	145.21	145.21	145.21	145.21	145.21	145.21	145.21

Table A10: Cost of statins

Age	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
40-49	117.63	98.81	97.14	97.14	97.14	97.14	97.14
50-59	117.63	98.81	93.57	93.57	93.57	93.57	93.57
60-69	117.63	98.81	86.82	86.82	86.82	86.82	86.82
70-79	117.63	98.81	73.06	73.06	73.06	73.06	73.06

Cont.

Age	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	Year 14
40-49	94.11	94.11	94.11	94.11	94.11	89.14	89.14
50-59	86.65	86.65	86.65	86.65	86.65	76.21	76.21
60-69	68.75	68.75	68.75	68.75	68.75	48.69	48.69
70-79	48.93	48.93	48.93	48.93	48.93	25.90	25.90

Cont.

Age	Year 15	Year 16	Year 17	Year 18	Year 19	Year 20
40-49	89.14	89.14	89.14	82.56	82.56	82.56
50-59	76.21	76.21	76.21	60.44	60.44	60.44
60-69	48.69	48.69	48.69	29.72	29.72	29.72
70-79	25.90	25.90	25.90	0.00	0.00	0.00

Table A11: Cost of anti-hypertensives

Age	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
40-49	64.59	83.27	81.46	81.46	81.46	81.46	81.46
50-59	64.59	83.27	77.82	77.82	77.82	77.82	77.82
60-69	64.59	83.27	69.94	69.94	69.94	69.94	69.94
70-79	104.95	123.63	82.79	82.79	82.79	82.79	82.79

Cont.

Age	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	Year 14
40-49	78.15	78.15	78.15	78.15	78.15	73.04	73.04
50-59	71.40	71.40	71.40	71.40	71.40	59.96	59.96
60-69	51.71	51.71	51.71	51.71	51.71	34.63	34.63
70-79	43.83	43.83	43.83	43.83	43.83	0.00	0.00

Cont.

Age	Year 15	Year 16	Year 17	Year 18	Year 19	Year 20
40-49	73.04	73.04	73.04	67.01	67.01	67.01
50-59	59.96	59.96	59.96	44.34	44.34	44.34
60-69	34.63	34.63	34.63	18.33	18.33	18.33
70-79	0.00	0.00	0.00	0.00	0.00	0.00

Table A12: Cost of other interventions

Intervention	Cost in Year 1 (£)
Stop smoking services	176.80
Weight loss	51.00
Brief exercise intervention	33.50

Table A13: Cost of earlier detection of CKD

Year	Year 1	Years 2-10
All ages, male and female	71.34	70.63

Appendix B – Assumptions on uptake, compliance, attribution and relative risk reduction (RRR) of CVD

For each intervention, we needed to make assumptions on the uptake, compliance, attribution and relative risk reduction of CVD. The definitions of these are given below:

Uptake   Percent of patients who take up an intervention for which they are recommended, including those that do not complete the programme or comply with the intervention; e.g. percent of people who are obese who attend their first weight loss class.

Compliance   Percent of patients who initiate an intervention who complete it. For pharmaceutical interventions this was taken to be the reported continuance on the therapy at 1 year. For smoking cessation it was the proportion of people who actually successful quit smoking at 1 year. For the interventions: brief exercise intervention, IGR lifestyle intervention and weight loss programmes, this is taken to be the proportion of people who complete of the programme from those that start it.

Attribution The model does not factor in other opportunities for referral to the interventions except for the vascular check; whereas in reality these interventions are available at any time to those with an indication for them. Therefore, the attribution figure represents the proportion of the activity which happens only as a result of the vascular check policy and would not happen otherwise.

CVD RRR   This is the relative risk reduction of cardiovascular disease for each intervention.

Table B1 Compliance and Relative Risk Reduction of interventions

Intervention	Uptake	Compliance	Attribution	RRR of CVD
Smoking	19%	15%	51%	0.36
Anti-Hypertensives	40%	87%	24%	0.24
Exercise	77%	23%	63%	0.14
IFG lifestyle intervention	85%	90%	90%	0.09
Statins prescribing	85%	70%	50%	0.31
Weight management	85%	68%	47%	0.36

Evidence on Smoking Cessation:

Uptake	25% of smokers will be willing to try to give up smoking at any point in time. Conservative estimate is 75% of this figure. Based on expert opinion
Compliance	One in seven people referred to stop smoking services are confirmed quitters at 1 year[13]
Attribution	GPs currently refer 8% of smokers they see each year to stop smoking services. This is 32% of the potential referrals. Therefore, the maximum attribution is 68%. However, we assume a conservative estimate is 75% of this figure, or 51%.
CVD RRR	Based on academic literature[20]

Evidence on Anti-hypertensives:

Uptake	Expert opinion is that, of people with a one-off high blood pressure reading, 50% will go on to be diagnosed with hypertension and of these 80% will be prescribed anti-hypertensives.
Compliance	Adherence on a twice daily dosage at 1 year[21].
Attribution	24% of the eligible group did not have a blood pressure reading in the last 5 years. However, as the model assumes no one already on anti-hypertensives enters the model, the attribution is 100% in Year 1 and reduces steadily to 24% by Year 6. Source: QResearch data
CVD RRR	NICE hypertension guidelines report[10]

Evidence on Exercise:

Uptake	Based on a RCT of methods to promote physical activity in primary care[22]
Compliance	Percent of people with an increase in physical activity score at 1 year following a motivational interview[22]
Attribution	NICE assume that their guidance, which is based on brief exercise intervention being given opportunistically, will result in up to 50% of appropriate instances being used to give this advice. From their estimates of the proportion of visits that are appropriate, we estimate each individual that is inactive have a 74% chance of having an appropriate instance of being given this intervention opportunistically. This leaves an estimated 63% of appropriate instances not being taken up.
CVD RRR	INTERHEART study[23]

Evidence on IFG lifestyle intervention:

Uptake	Expert opinion
Compliance	From the Finnish Diabetes Prevention Study
Attribution	Expert opinion. This is particularly high compared to the other interventions because anecdotally we have found no evidence of this being offered systematically currently.
CVD RRR	From the Diabetes Prevention Program, US[24]

Evidence on Statins prescribing:

Uptake	Expert opinion
Compliance	5 year continuance for statins for primary prevention [9]
Attribution	This is derived from data that show that 5.4 million people are eligible for statins[25], but only 2.7 million are on them[26]. However, as the model assumes no one already on statins enters the model, the attribution is 100% in Year 1 and reduces steadily to 50% by Year 6.
CVD RRR	This is derived from the Heart Protection Study for prevention of MI and CVD death[27], and from the NICE TA094 for prevention of stroke[9]

Evidence on Weight Management:

Uptake	Percent of patients initially recruited who enrolled in Slimming on Referral programme
Compliance	Percent of patients who completed the Slimming on Referral programme [28]
Attribution	Percent of people eligible for checks who do not have a BMI measure in the last 5 years (source: QResearch data)
CVD RRR	There was little evidence on this. The value we took is from a study from 1991[29]

Appendix C - Expected difference to model results using Framingham instead of QRISK

The CVD risk algorithm has two impacts on the results of this model:
1. The number of people put on statins
2. The number of people that leave the model due to having a CVD event.

Framingham and QRISK will give different scores to the same individual so the results will change accordingly. Using QRISK 8.5% of patients aged 35-74 are at high risk (20% risk or higher over 10 years) compared with 13% when using the Framingham algorithm[3]. Therefore with Framingham, more people will be eligible for statins for primary prevention and more would have a CVD event and leave the model. There will also be differences in the effect for different sub-groups of the population, for example QRISK assigns a higher value to women from the lower socioeconomic groups, but the model thus far only considers the overall picture.

The cost of statins accounts for £28.3m of the £199m average annual cost of this policy; or 14%. Increasing the proportion of people on statins by 53% (equivalent to increasing from 8.5% to 13% as stated above) would increase the overall costs by £15m. This is well within the confidence intervals we have set. The cost effectiveness of statins is the least cost effective of all the interventions included at around £10,000 per QALY. Therefore, if more statins are prescribed the overall cost effectiveness would increase, but the incremental cost effectiveness would be around £10,000 per QALY which is still considered cost effective against the NICE threshold of £20,000.

In conclusion, the impact of using Framingham instead of QRISK is expected to increase the overall costs by around £15m for statin prescribing, and increase the average cost per QALY figure but this would still remain far below the £20,000 NICE threshold.

Appendix D – Sensitivity Analysis

Tables D1 and D2 give the assumptions used for the High Cost and Low Cost scenarios.

Table D1: Assumptions for the scenario High Cost

Intervention	Attribution	Uptake	Compliance
Smoking	60%	22%	15%
Exercise	64%	81%	23%
Weight management	49%	89%	72%
IFG management	95%	89%	93%
Anti-Hypertensives	27%	43%	91%
Statins prescribing	55%	89%	74%
Diabetes management	63%	-	-
CKD management	57%	-	-

Table D2: Assumptions for the scenario Low Cost

Intervention	Attribution	Uptake	Compliance
Smoking	43%	16%	14%
Exercise	64%	64%	23%
Weight management	45%	81%	65%
IFG management	86%	81%	83%
Anti-Hypertensives	20%	38%	83%
Statins prescribing	45%	81%	67%
Diabetes management	57%	-	-
CKD management	51%	-	-

Table D3 provides the distribution of values used for the Monte Carlo simulation results.

Table D3: Monte Carlo Simulation parameters

Variable	Distribution
Multiplier for cost of statins	Continuous, 0.8 to 1.2
Multiplier for QALYS from statins	Continuous, 0.8 to 1.2
Multiplier for cost of antihypertensives	Continuous, 0.8 to 1.2
Multiplier for QALYS from antihypertensives	Continuous, 0.8 to 1.2
Multiplier for cost of stop smoking services	Continuous, 0.8 to 1.2
Multiplier for QALYS from stop smoking services	Continuous, 0.8 to 1.2
Multiplier for cost of exercise intervention	Continuous, 0.8 to 1.2
Multiplier for QALYS from exercise intervention	Continuous, 0.8 to 1.2
Multiplier for cost of IGR lifestyle intervention	Continuous, 0.8 to 1.2
Multiplier for QALYS from IGR lifestyle intervention	Continuous, 0.8 to 1.2
Multiplier for cost of weight loss intervention	Continuous, 0.8 to 1.2
Multiplier for QALYS from weight loss intervention	Continuous, 0.8 to 1.2
Nurse time per feedback appointment	Continuous, 10-25 minutes
Healthcare assistant time per vascular check	Continuous, 10-25 minutes
Healthcare assistant time per OGTT	Continuous, 15-30 minutes
Admin time per invitation	Continuous, 2-7 minutes
Admin time per appointment	Continuous, 2-7 minutes
Unit cost of cholesterol test	Continuous, £3 to £6
Unit cost of blood glucose test	Continuous, £4 to £8
Unit cost of serum creatinine test	Continuous, 20p to £1.20

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