

Management of Coronary Heart Disease

A national clinical and resource impact assessment
February 2007

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Executive Summary

SIGNIFICANT RECOMMENDATIONS

The lack of robust information on the resources required and associated costs is one of the biggest difficulties in developing plans to implement clinical guidelines¹. The CHD Steering Group requested that this report be developed to provide such information, with the objective of facilitating more rapid implementation of the key recommendations in the CHD guidelines. It contains estimates of the resources required and associated costs of implementing key recommendations in the SIGN Coronary Heart Disease (CHD) guidelines, together with estimates of the resulting clinical benefits.

The five CHD guidelines cover the topics of Acute Coronary Syndromes (ACS) (SIGN 93), Arrhythmias (SIGN 94), Chronic Heart Failure (SIGN 95), Stable Angina (SIGN 96) and Risk Estimation and the Prevention of Cardiovascular Disease (CVD) (SIGN 97). This report should be read in conjunction with the appropriate SIGN guidelines.

The recommendations in these guidelines were prioritised according to their likely effect on patient outcomes and NHSScotland. The recommendations identified as potentially having a major benefit for patients and a significant effect on the Service are:

- Patients presenting with ST elevation acute coronary syndrome should undergo primary percutaneous coronary intervention (pPCI) where available, within 90 minutes of diagnosis, rather than the normal practice of undergoing thrombolysis.
- Risk scores should be used to stratify patients with non-ST elevation acute coronary syndrome, with those at medium or high CVD risk receiving early coronary angiography and revascularisation where necessary. Whilst this currently occurs in some tertiary centres, it is not common practice throughout Scotland.
- More patients with arrhythmias and heart failure should receive implantable cardiac defibrillators (ICDs) and cardiac resynchronisation therapy (CRT), in addition to current standard drug therapy.
- Discharge arrangements for patients with heart failure should be improved to augment the existing primary care services.
- Asymptomatic individuals aged 40 or over should receive a risk assessment every 5 years. Any with a 10-year CVD risk of 20% or greater should be offered lifestyle advice and drug therapy, including generic statins. Currently therapy is offered if 10-year CHD risk is assessed at 30% or greater. The estimates assume risk is assessed using Framingham equations and not a risk scoring system including deprivation as a contributory factor.
- Secondary prevention measures should be offered to all patients who have suffered a cardiovascular event; currently such therapy is normally offered to patients with coronary heart disease or after a stroke but not to those with peripheral vascular disease.
- All other drug recommendations that change current prescribing regimes.

CLINICAL BENEFIT

Events avoided and related bed days and cost savings

In Scotland in the year ending 31 March 2006 over 10,300 patients died from CHD and 5,800 from cerebrovascular disease, with almost 49,000 hospital admissions for CHD and a further 22,050 for cerebrovascular disease².

Implementing the recommendations in the SIGN CHD guidelines should markedly improve patient outcomes. Over the next five years, it is estimated that over 7,200 premature deaths from CVD and over 27,000 vascular events could be avoided. This is equivalent to a 9% reduction from the current CVD mortality rate and an 8% reduction from the current CVD event rate. The CHD mortality rate fell by 5.2% in the two year period from April 2004 to March 2006, and the benefits from implementing the recommendations in these guidelines should be additional to this improvement.

As a direct result of avoiding CVD events, NHSScotland could release over 60,000 bed days a year for alternative uses, with associated cost savings of over £20 million from fewer inpatient stays. In comparison, in the year to 31 March 2006, the cost of managing inpatients with unstable angina, acute myocardial infarction (MI) and re-infarction, other chronic ischaemic heart disease, heart failure and stroke was 380,000 bed days and £125 million³. The potential savings associated with guideline implementation represent about 16% of the current bed days and cost of managing CVD patients in the acute sector.

Table 1 shows the estimated potential clinical benefits of treating patients and high risk individuals in accordance with the recommendations in the five guidelines.

Table 1: Potential mortality and vascular events avoided by guideline, with sub-analysis of Prevention guideline

Recommendation by guideline	Mortality avoided over 5 years	Events avoided over 5 years	Bed days saved per year	Cost savings per year (£ million)
Statins – primary prevention	2,678	7,229	17,052	5.9
Statins – secondary prevention	718	9,437	19,770	6.8
Antihypertensive drugs	950	2,761	9,108	2.5
Prevention - other	740	2,614	5,135	1.9
Prevention - total	5,086	22,041	51,065	17.1
Acute Coronary Syndromes guideline	896	2,176	2,394	1.2
Arrhythmia and Heart Failure guidelines	1,232	2,851	7,074	2.3
Total events	7,214	27,068	60,533	20.6

The recommendations contributing greatest benefits are associated with identifying individuals at high risk of CVD and managing their condition with lifestyle advice, statins and, where appropriate, antihypertensive drugs. Approximately one third of the Scottish population of over 40 years of age will be considered to have a 10-year CVD risk of greater than 20%. Providing statins to asymptomatic individuals at high risk of CVD provides about 37% of the mortality benefit and 30% of the potential clinical and related resources released benefits. Prescribing statins to patients with existing peripheral vascular disease and higher dose statins to those who are currently receiving statins but have a total cholesterol above 5mmol/L may reduce events by over 9,000 over five years, about 35% of the total events saved but contribute a lower proportion (10%) of mortality gains. Treating high risk individuals with blood pressure above 140/90 mmHg is estimated to provide 13% of the potential mortality benefit and a similar proportion of potential events saved and related resources released.

Recommendations from the Acute Coronary Syndromes guideline (SIGN 93) provide about 12% of the mortality benefits, whilst the guidelines on Arrhythmias and Chronic Heart Failure (SIGN 94 and 95) provide 1% and 16% of the mortality benefits respectively but a lower proportion of the events saved.

Sensitivity analyses

The mean length of stay and associated costs for each diagnosis used to derive the estimates of potential clinical benefit were provided for year end 31 March 2006 by ISD³. The cost base applied includes direct costs such as medical, nursing, pharmacy, allied health professionals (AHP), theatre and laboratory costs. Support services (overheads) are attributed to the direct costs using appropriate methods⁴. The overhead element (approximately 30% of the cost base), is unlikely to change with marginal variations in workload and a better reflection of the savings is about £15 million a year, equivalent to 12% of the current costs.

A significant proportion of bed days and costs saved are associated with strokes avoided. The base case assumed all patients had a haemorrhagic (subarachnoid or intracerebral) stroke, requiring very high resource use, with a mean length of inpatient stay of over 23 days and associated costs of over £5,955 per patient. However transient ischemic attack (TIA) may not require admission. To test the sensitivity of the analyses to the stroke diagnosis used in trials, it was assumed that 33%⁵ of recorded strokes are TIAs and require no inpatient resources. As a result the annual savings fell by £1 million from £20.7 million to £19.7 million. However many trials only reported all vascular events and so the true sensitivity to this variable could not be tested.

In the base case, no resources savings were attributed to the reduction in deaths. This was to avoid the possibility of double counting events; if a patient has a stroke that proves fatal some trials count this as two events. If both events are attributed bed days saved then there could be a material overstatement of the resources saved. However, if a value of £2,270 per death avoided was imputed (the recorded cost of managing patients in hospital who subsequently died in the Heart Protection Study⁶) and such savings accrue over a 5-year period, then the annual savings rise by £3.3 million to £24 million.

These analyses do not capture improvements in patients' quality of life because very few of the clinical trials reported this clinical end point. The absence of this information is regrettable and as a consequence the report understates benefits to patients. This is particularly true of some of the devices for patients with heart failure where the intervention reduces cardiac mortality and significantly improves quality of life. However it does not reduce other cardiovascular events.

RESOURCE IMPACT

Staff

In total 188 additional staff members are required in the first year of guideline implementation, rising to a maximum of 208 in year 5 and falling to a steady state of 143 in year 6. Of the 143 staff members required, 62 (44%) are required to manage high risk individuals and patients with established cardiovascular diseases, 61 (43%) to deliver services to patients discharged with heart failure and the remaining 20 (13%) to undertake additional duties in catheterisation laboratories.

Primary care staff comprise approximately 55% of additional staffing requirements in years 1-5, dropping back to approximately 45% in year 6. These staff members are required to risk assess the asymptomatic population over the first 5 years, and to manage the one third of individuals above the 20% CVD risk threshold who require lifestyle advice and drug therapy.

These estimates assume existing staff are fully employed and no re-prioritisation of their workload takes place; in reality new tasks may displace existing duties so that these estimates of additional workload overstate the staff required. Further savings are possible if general practitioners (GPs) adopt opportunistic screening of all asymptomatic individuals during the first four years and only formally risk assess in year 5 those otherwise not identified.

Capital – Buildings and Equipment

In order to implement pPCI for ST elevation acute coronary syndrome patients, early revascularisation for non-ST elevation acute coronary syndrome patients, greater use of ICDs in arrhythmia patients and greater use of CRT in heart failure patients, 2.6 additional catheterisation laboratories are required across Scotland. However as the requirements for the North, East and West planning regions are 0.6, 0.5 and 1.5 laboratories respectively, four catheterisation laboratories may be needed (with one each in the North and East and two in the West). Alternatively, greater use could be made of portable catheterisation laboratories and out of hours working.

In the first year of implementation 71 additional rooms may be required in Scottish GP practices, rising to almost 84 by the fifth year. This space is required to accommodate the additional staff needed to manage patients identified as at high CVD risk and assumes no existing capacity is available. It is estimated that only 46 of these rooms would be required for their original purpose from year 6, however it has been assumed that the 38 excess rooms would then be utilised in a different capacity. Again if existing rooms were used more intensively then the additional space requirements would be reduced. Office space for about 35 heart failure nurses and administrators may also be required.

COST IMPACT

Annual costs

The total estimated annual cost of implementing key recommendations within the CHD guidelines in the first year (assuming full implementation across Scotland) is £40 million excluding VAT (£44 million including VAT), rising to £69 million per annum in year 6 (£78 million including VAT). Table 2 details the estimated costs of implementing the key recommendation within each guideline.

Table 2: Estimated annual cost of implementing key recommendations by guideline

	Cost (£ million)	
	Year 1	Year 6
ACS	5 (5)	5 (5)
Arrhythmias	4 (5)	4 (5)
Heart Failure	7 (7)	7 (7)
Prevention	24 (27)	53 (61)
Total	40 (44)	69 (78)

Note: figures in brackets are including VAT, otherwise exclude VAT

The costs relating to statin therapy for the prevention of CVD events are the highest of all recommendations making up approximately 25% and 45% of all costs in years one and six respectively.

No recommendations within the Stable Angina guideline (SIGN 96) were identified as requiring significant change to current practice, thus no additional resource requirements have been cited.

Capital costs

If an additional 2.6 catheterisation laboratories are provided across Scotland then the capital cost will be £3.2 million (£3.7 million including VAT). If the requirements in the East and North planning regions can only be met by purchasing one laboratory for each region, with two also being required for the West, then costs rise to £4.8 million (£5.6 million including VAT) with spare capacity available in all areas.

The estimated cost excluding VAT of providing the additional accommodation in primary care is £1.9 million in year 1 and approximately £0.2 million in years 4 and 5, giving a cumulative capital cost of £2.3 million (£2.7 million including VAT). This assumes that there is no spare capacity within existing practices, however practices may be able to run assessment clinics outside of peak hours thereby avoiding many of these costs.

Hospital accommodation will be required for the heart failure service administrators and 50% of the heart failure discharge nurses. If this cannot be found from existing accommodation this cost will reach about £0.4 million (£0.5 million including VAT).

Thus the total capital requirements are approximately £5.9 million (£6.9 million including VAT), with up to £5.5 million being required in the first year (£6.5 million including VAT).

Cost per recommendation

The estimated additional annual operating and capital costs associated with each of the key recommendations are summarised below, with the report and appendices providing more detailed analyses of the costs.

- The additional cost of providing pPCI to ST elevation acute coronary syndrome patients is estimated at approximately £1.0 million per annum, with estimated capital costs of £1.3 million (£1.5 million including VAT).
- The additional cost of providing early therapeutic intervention to non-ST elevation acute coronary syndrome patients at medium or high CVD risk is estimated at £3.4 million per annum, with capital costs of £0.7 million (£0.8 million including VAT).
- The estimated annual cost of greater use of ICDs and CRTs is £8.0 million (£9.2 million including VAT), with estimated capital costs of £1.2 million (£1.4 million including VAT).
- Improved discharge arrangements for patients with heart failure are estimated to cost £2.3 million per annum, with capital costs estimated at £0.4 million (£0.5 million including VAT).
- CVD risk assessment for asymptomatic patients, using Framingham risk equations, is estimated to cost £1.3 million per annum in years 1-5, reducing to less than £0.1 million thereafter, with capital costs of £0.3 million in year 1.
- Management of patients identified as being at high CVD risk is estimated at £10.9 million in year 1 (£11.1 million including VAT), reducing slightly in year 2 before increasing steadily to an annual cost of £16.0 million in year 5 (£16.3 million including VAT) and stabilising at £11.3 million in year 6 (£11.5 million including VAT). An initial capital cost of approximately £1.7 million is required in year 1 (£2.0 million including VAT), with an additional £0.2 million required in years 4 and 5, with total capital costs estimated at £2.0 million (£2.4 million including VAT).
- The total estimated effect on the drugs budget is to increase costs by £14 million in year 1 and £44 million in year 6 (£17 million and £51 million respectively including VAT). Approximately 72% of the additional costs arise due to changes in statin prescribing profiles.
- Statin costs assume that 70% of patients with established CHD are being prescribed simvastatin 40mg and 30% atorvastatin (weighted average dose) at the time of guideline implementation⁷. No benefits of adopting generic statins were assessed within this report.

Sensitivity analysis

Sensitivity analyses shows the costs are very sensitive to the assumed price of statins. For example, in 2011 atorvastatin comes off patent and should the price of generic atorvastatin drop to the price of generic simvastatin then the additional annual cost of treating patients for secondary prevention could reduce from £17 million to £2 million. The cost of implementing the guidelines in steady state could therefore fall from £69 million to £54 million (excluding VAT) as a result of this single factor.

COSTING TOOLS

An Excel tool is available on the SIGN website (www.sign.ac.uk) to aid the estimation of local costs and resource requirements associated with implementing risk assessment for asymptomatic patients and the subsequent management of patients identified as being at high CVD risk, in line with the Prevention guideline. This tool only provides an indication of resource requirements and costs involved, and should be adapted to suit the user's needs.

DEMONSTRATION PROJECT

This is a demonstration project and not a standard component of the SIGN development process. SIGN assessments provide an estimate of resource implications but do not undertake any assessment of costings. As a non-standard component, the effectiveness of this project will be evaluated independently for SIGN Council.

1 Introduction

1.1 OBJECTIVES OF THIS REPORT

The CHD Steering Group requested that this report be developed with the objective of facilitating more rapid implementation of key recommendations in the CHD guidelines. It is anticipated that providing resource and cost information to decision makers, primarily in the NHSScotland boards and the Scottish Executive Health Department (SEHD), will assist them to develop business cases at the local, regional and national level and introduce changes in line with the guidelines. Improving implementation should enhance patient care and enable more equitable patient access throughout Scotland.

The evidence base to support this objective comes mainly from recent developments in England. Since January 2005, the National Institute for Health and Clinical Excellence (NICE) has provided information relating to the cost of implementing “significant resource impact recommendations” in its clinical guidelines, as part of its commitment to assist implementation. In October 2005, the Audit Commission¹ reported that the absence of an awareness of costs is one of the biggest difficulties in developing plans to implement guidelines. It added that the most useful implementation tool is the provision of robust cost information, noting that boards adopting the tool were more likely to implement a guideline. Noting this evidence, the SIGN CHD Steering Group recommended trialling a process to estimate the resource requirements and costs of implementing key recommendations in the CHD guidelines, together with the key clinical benefits for Scotland’s population.

For each key recommendation in the guidelines the report presents estimates of:

- The number of individuals in Scotland who will have better health outcomes following its implementation.
- The associated clinical benefits, expressed as clinical events avoided, including mortality where appropriate.
- Any resulting bed days saved or required.
- The resources required to implement the recommendation.
- The associated costs.

Clinical benefits are estimated by generalising the clinical evidence that informed the recommendations to the relevant Scottish population. Cost and resource assessments are estimates, based on a number of assumptions. They provide an indication of the impact of the key recommendations based on assessment of current baseline practice, however local practice may vary from this. An Excel template accompanies the report, for use by planners to estimate local impact.

1.2 SIGN CORONARY HEART DISEASE GUIDELINE PROCESS

SIGN published five CHD guidelines in February 2007, covering the topics of Acute Coronary Syndromes (SIGN 93), Arrhythmias (SIGN 94), Chronic Heart Failure (SIGN 95), Stable Angina (SIGN 96) and Risk Estimation and the Prevention of CVD (SIGN 97). This report should be read in conjunction with the appropriate SIGN guidelines.

SIGN guidelines are based on systematic review of the clinical evidence and for key topics the cost effectiveness evidence. A detailed description of the SIGN methodology is available at <http://www.sign.ac.uk/methodology/index.html>. SIGN acknowledges that its recommendations are not resource neutral and a section entitled ‘Resource Implications of Recommendations’ has been included in recent guidelines. This section is developed in discussion with the guideline development group, considering current resource use across Scotland and identifying those

recommendations most likely to have significant resource implications. It does not, however, express the costs of implementation, primarily because of differing levels of baseline resource use by each NHSScotland board.

This established methodology was followed for each of the five CHD guidelines. For each guideline a development group was formed, comprising multidisciplinary, nationally representative members. The members agreed the clinical areas for review and undertook systematic review of the evidence, with support from the SIGN Executive. They developed recommendations that are explicitly linked to the supporting evidence and were subject to consultation and peer review before final publication. The recommendations were then reviewed to establish which were most likely to have significant resource implications. For the CHD guidelines only, estimates of the resources and associated costs required to implement key recommendations were made and are discussed in this report.

Estimated resource use and costs were informed by the available Scottish epidemiology and cost data and through consultation with four healthcare professionals, who were independent of the SIGN process, members of the CHD guideline development groups, the CHD Steering Group and CHD Implementation Group and peer review.

This is a demonstration project and is not a standard component of the SIGN guideline development process. The effectiveness of this project will be subject to independent evaluation by SIGN Council.

1.3 OTHER INITIATIVES TO SUPPORT IMPLEMENTATION

A CHD Implementation Group has been in existence throughout the guideline development process, with the remit of bridging the gap between guideline development and implementation. Its role and functions are set out in Section 9 of 'SIGN 50: A guideline developers' handbook'. Its members have adopted a range of implementation strategies to raise awareness of the CHD guidelines and to reduce barriers to implementation. This report is a further practical step to promote implementation.

1.4 STATEMENT OF INTENT

This report is intended to provide an indication of the potential clinical benefits following implementation, the resources required and associated costs involved in the implementation of key recommendations within the SIGN CHD guidelines. However the baseline practice assumed throughout Scotland will vary between NHS boards, and therefore the resource requirements outlined in this report may not reflect the actual requirements.

The aim is to provide as detailed and comprehensive information as possible, quoting sources and assumptions so that users can adapt the information for their own purposes. The relevant resource use and costs will vary depending on the context and purpose of the decision maker, thus users should adapt the estimated values to suit their needs. The report, of necessity, has had to omit some of the finer detail underpinning the estimates. If users require further information or advice on using the data, they should contact Ms Joyce Craig, Senior Health Economist, NHS Quality Improvement Scotland by email at joyce.craig@nhshealthquality.org.

1.5 DOCUMENT OVERVIEW

In Section 2 the methodology used to estimate the resources required for implementation of each key recommendation, and the associated clinical benefits is discussed. Sections 3 to 9 outline the clinical benefits and associated resource impact of each of the five key themes and consider the implications for the drugs budget. Sensitivity analyses are provided in each relevant section. Section 10 details the report development process with abbreviations, appendices and references following.

2 Methodology

2.1 SCOPE

This report provides estimates of the clinical benefits, together with the additional resources and associated costs required to implement the key recommendations within the SIGN CHD guidelines. The estimates are based on assumptions regarding current baseline practice and predicted changes following implementation of each recommendation. The assumptions are informed by available information and consultation with healthcare professionals. In general current standard practice, rather than best practice, has been used as a baseline. For example in respect to statin use, the base case assumes 70% of statin prescriptions are generic and 30% are branded⁷. Thus the report includes no savings of adopting generic statin use.

The relevant CHD guideline development group chairs advised whether each draft recommendation was likely to change current practice and, if so, whether the change was considered significant. Recommendations judged to follow current practice or to only effect a marginal change were not considered further. The remaining recommendations were prioritised according to the following criteria:

- They resulted in a major change in current patient numbers or a major redesign of an existing patient pathway.
- They required introduction of a new service, affecting a material number of patients.
- They changed medications prescribed or increased the use of a currently prescribed medication.

The key themes that emerged were:

- Patients presenting with ST elevation acute coronary syndrome should undergo pPCI where available, within 90 minutes of diagnosis, rather than thrombolysis as per current practice.
- Risk scores should be used to stratify patients with non-ST elevation acute coronary syndrome, with those at medium or high CVD risk receiving early coronary angiography and revascularisation where necessary. Whilst this currently occurs in some tertiary centres it is not common practice throughout Scotland.
- More patients with arrhythmias and heart failure should receive ICDs and CRT, in addition to current standard drug therapy.
- Discharge arrangements for patients with heart failure should be improved, to augment the existing primary care services.
- Asymptomatic individuals aged 40 or over should receive a risk assessment every 5 years. If they have a CVD risk of 20% or greater over 10 years then they should be offered lifestyle advice and drug therapy, including generic statins. Currently therapy is offered if coronary heart disease risk is assessed as 30% or greater over 10 years. This assumes risk is assessed using Framingham equations, and not a risk scoring system including deprivation as a contributory factor.
- Secondary prevention measures should be offered to all patients who have suffered a cardiovascular event; currently such therapy is normally offered to patients with coronary heart disease or after a stroke but not to those with peripheral vascular disease.
- All other drug recommendations that change current prescribing regimens.

The additional staff required, by speciality and their accommodation needs, were identified for each key recommendation. The cost of providing these resources plus the related consumables and overheads were estimated. The resources and costs involved in the redesign of service were excluded, except where specifically recommended in the guidelines.

Cost and resource requirements were estimated at the national level and, where appropriate, at the NHSScotland board or regional level as detailed in the appendices. All costs were estimated annually at 2006/2007 prices. Where there was variation between years, the resource requirements and costs for each year are detailed.

While it is recognised that implementing some of these recommendations may impact on other organisations, this report only considers the cost and resource implications for NHS Scotland.

It is important to note that the clinical benefits, costs and resource requirement estimates are for the additional patients identified to date only, and do not include additional patients identified in future years.

No cost effectiveness analyses are presented within this report. Rather the CHD guidelines include a review of the cost effectiveness of certain clinical procedures, as part of the standard SIGN guideline methodology.

This report does not reproduce the SIGN CHD guidelines and should be read in conjunction with the appropriate guideline or guidelines (SIGN 93 to SIGN 97).

2.2 PROCESS

2.2.1 METHODOLOGY TO ESTIMATE CLINICAL BENEFIT

Clinical benefits were estimated by synthesising the evidence used to inform each key recommendation and generalising it to the Scottish context. Usually, the evidence was from meta-analyses or randomised control trials (RCTs). Where studies reported a central estimate of absolute risk reduction, relative risk reduction, associated 95% confidence intervals and the numbers needed to treat for each clinical endpoint, these statistics are reproduced in this report.

Estimates of the annual number of patients treated, the associated bed days used and costs thereof for each CVD-related diagnosis were provided by ISD. Table 3 summarises the diagnosis related information on bed day and cost per patient discharged.

Table 3: Inpatient discharges by main diagnosis in Scotland for the year ending 31 March 2006

Principal diagnosis	Number of inpatients	Average length continuous inpatient stay (days)	Average cost per patient
Unstable angina	7,604	4.28	£1,760
Acute MI	7,956	9.53	£3,990
Subsequent MI	819	9.54	£4,240
Heart failure	5,978	16.02	£5,105
Stroke	6,792	23.19	£5,955
Chronic ischaemic heart disease unspecified	1,415	8.30	£2,765
Stable angina ^a		0	£1,500
Severe bleeds ^{a,b}		6.00	£2,300

^a Data not requested from ISD

^b The cost and bed days for a severe bleed use the mean value from two submissions to Scottish Medicines Consortium (SMC) for drugs to reduce the risk of this event in patients with CVD.

No savings from deaths avoided were included in the base case. A sensitivity analysis assumed a value of £2,270 per death avoided. This was the observed cost to manage patients in the acute sector who were participants in the Heart Protection Study⁸ and who died from a vascular related event during follow-up. The Study also estimated an annual saving of £190 for each survivor of a major vascular event in the years following the event. This benefit has not been included in any of the analyses.

No savings have been estimated for avoided outpatient appointments or day cases associated with such diagnoses. The only assumed savings in primary care are from fewer people managed for angina.

2.2.2 METHODOLOGY TO ESTIMATE RESOURCE USE AND ASSOCIATED COSTS

Following a review of international best practice, primarily from England⁹, Australia¹⁰ and Canada¹¹, the resource impact assessment process outlined in Appendix 1 was developed. Once the key themes and associated recommendations had been identified draft patient pathways, showing the changes required to implement each key recommendation, were developed. Three independent experts from primary care, acute care and pharmacy were asked to advise on the pathways and assist in developing the assumptions required to undertake the resource and costing exercise. The resulting assumptions were then considered by the guideline development group members. Where possible published costs from ISD Scotland² were used and supplemented by other published data as appropriate. Occasionally unpublished sources were used and referenced.

An estimate of the number of individuals likely to be affected by changes in risk assessment and treatment thresholds in the primary prevention setting was commissioned¹². This work is referred to as 'the risk factor analysis'¹² in this report and updates earlier estimates that informed the previous primary prevention guideline (SIGN 40). A summary of this work is provided in Appendix 2.

A survey of CHD managed clinical networks (MCN) was undertaken to identify variations in primary prevention practice.

The report was subject to peer review by three clinicians, who are independent from the SIGN process. Data values and associated spreadsheets were quality assured by an independent health economist.

As this resource impact assessment is a demonstration project, an independent evaluation will be commissioned by SIGN Council to evaluate its effectiveness in assisting the implementation of the SIGN CHD guidelines.

2.2.3 COSTING PRINCIPLES

Costing approach

Where necessary costs were developed using a 'bottom-up' approach. For example, the cost of implanting more cardiac defibrillators is estimated for each step in the patient journey, from the pre-operation night in hospital, relevant tests, the device and associated consumables, the laboratory staff and subsequent programming time, to time to discharge and follow up at clinics. For this example a percentage of patients have been assumed to acquire an infection that necessitates a longer hospital stay.

However, for certain procedures, eg pPCI the Scottish tariff costs published by ISD have been adopted³. In such instances relevant staff at ISD were contacted in an effort to ensure the components of the published cost were fully understood.

Staff

The analyses assume existing staff are fully utilised and re-prioritisation of existing workload does not take place. In reality re-prioritisation will take place, particularly in general practice, eg to risk assess the population aged over 40 years. The estimated staff requirements therefore overstate the future need. The number of staff members required are expressed in whole time equivalents (WTE).

VAT

Costs excluding and including VAT at 17.5% are detailed, as VAT payable on drugs and other goods purchased by NHSScotland boards is irrecoverable.

Prescription charges

Where applicable drug costs include a prescription charge of 91.7 pence per item on each prescription (the standard fee stated in the Scottish Drug Tariff, September 2006¹³). The pharmacist contract is currently under review, but it was assumed that the cost to NHSScotland boards will be similar to current levels.

Drug costs

Published drug costs at December 2006 have been used to estimate the cost of drugs.

Overheads

Overheads have been added to cover employers' national insurance, superannuation contributions, training and indirect expenditure. Where appropriate capital overheads based on the accommodation requirements for NHS staff facilities, reflecting shared use of space and including recreational and changing facilities have been added. The values adopted are published by Netten and Curtis¹⁴ and the document also references publications explaining their approach. Examples of the resulting overheads for various staff functions are summarised in Table 4.

Table 4: Overhead cost estimation

Function	Community nurses	Acute sector	Consultants
NI and superannuation only as % of salary	22%	21%	25%
Total overheads including capital and training	50%	32%	50%

GPs are responsible for meeting their own NI and superannuation costs. For each GP an area of 16.5 square metres is assumed to be required to provide consultation space and patient waiting areas. A 10% overhead is added to GP remuneration for other indirect costs, including IT related expenditure.

Capital expenditure

Capital expenditure is reported in two ways, firstly as a lump sum in the year required and secondly as an annual depreciation charge. The latter assumes the following relevant asset lives:

Buildings – 20 years

Equipment and Machinery – 10 years

For example catheterisation laboratory equipment has an assumed 10-year life, with a 20-year life for the associated building and civil work. The method of funding, eg using a Private Finance Initiative rather than own funds, has not been considered.

Patients identification and treatment phasing

It has been assumed throughout this report, except where otherwise stated (ie. risk estimation and prevention of CVD), that all patients are identified and receive treatment as per the recommendations in the first year of implementation.

Throughout this report where long term drug therapy is required, it was assumed that all patients receive the recommended drug therapy for the full year (including the year of identification) unless otherwise stated (i.e. statin therapy).

2.3 LIMITATIONS

This exercise is subject to several limitations including:

- Uncertainty as to what comprises current clinical practice. Various methods were used to try to address this uncertainty, including requesting that guideline chairs and members provide input to developing treatment pathways before and after implementation of key recommendations and using a questionnaire to establish current primary prevention practice. As detailed design of the new service is undertaken the accuracy of the costings will improve.
- The analysis could be improved by the availability of improved epidemiological and resource use data, informing the assumptions on current practice.
- Some significant cost categories have been excluded, particularly the cost of service redesign and associated training and recruitment costs.
- The analyses implicitly assume that staff and facilities will be shared efficiently across Scotland. For example, there may be a need for an extra 19 dieticians across Scotland to advise obese patients identified as at high CVD risk. The cost estimates include salaries, direct overheads and consultation room costs but do not allow for diseconomies of scale arising because patients require access to the service at a local level, rather at board or regional level.
- Building costs assume an existing site is available for expansion, which is not always the case.
- No re-prioritisation of existing workloads is assumed but such action would be appropriate, to ensure that staff are used as efficiently as possible given the new requirements.
- The analyses assume that trained staff can be recruited immediately, incurring no recruitment or training costs, and that they work solely on the task being considered. For example, to meet the requirements for use of CRT and ICD devices, an additional skilled cardiologist and an additional catheterisation laboratory are required. The analyses assume that one individual will work solely on this activity for six of the contracted 10 weekly sessions.
- Clinical judgement will result in some patients following care pathways that differ from those recommended. The resulting costs may differ from those forecast, as costings assume that all patients are treated identically in accordance with the recommendations.
- The terminology refers to bed days 'saved', these are bed days that are no longer required as a result of implementing the recommendations, as the intervention reduces the risk of future cardiovascular events. In reality these beds are likely to be occupied by patients with other conditions and thus the beds will still be used.

- The accuracy of the estimated clinical benefits is limited because the results of trials may not generalise to the Scottish population. SIGN processes seek to minimise such risks. However for some recommendations, for example the estimation of the benefits from treating individuals with hypertension, the clinical benefits were estimated using risk reductions reported in a meta analysis. The trials pooled in this analysis include more high risk individuals than the potential sub-group of the Scottish population who will be treated. This could cause the clinical benefit to be over-estimated.
- Where trials did not include hospitalisation as a distinct endpoint, strokes and MI events were assumed to avoid an inpatient stay. This will not be a valid assumption if the trial records multiple events over a short timeframe or very minor events.
- The event data from trials have not been expressed as annual savings, by dividing the observed reduction in event rates by the mean follow-up period. For trials with a short follow-up period this may underestimate the longer term benefits of the intervention.
- The number of deaths avoided was calculated using data from clinical trials which followed patients over a number of years. These estimates may understate the true effect as some trials were not powered to show a mortality benefit and others had short follow-up periods that may not have fully captured the benefit.
- The analyses do not aggregate the resources required to implement a revised service with the potential savings from fewer clinical events. This is partly because of timing differences but also because the two estimates are made using different approaches. However, users may wish to consider a net figure.

3 Total clinical benefits and resource impact of key recommendations

3.1 BACKGROUND

This section summarises the estimated aggregate resource requirements, and costs and clinical benefits associated with implementing the key recommendations identified in Section 2. Sections 4 to 9 consider the impact of each key recommendation in detail.

3.2 AGGREGATE CLINICAL BENEFITS

The estimated benefits of applying the absolute and relative risk reductions reported in the relevant trials to individuals treated with the intervention gives the clinical benefits, as shown in Table 5.

Table 5: Potential mortality and vascular events avoided by guideline, with sub-analysis of Prevention guideline

Recommendation by guideline	Mortality avoided over 5 years	Events avoided over 5 years	Bed days saved per year	Cost savings per year (£ million)
Statins – primary prevention	2,678	7,229	17,052	5.9
Statins – secondary prevention	718	9,437	19,770	6.8
Antihypertensive drugs	950	2,761	9,108	2.5
Prevention - other	740	2,614	5,135	1.9
Prevention - total	5,086	22,041	51,065	17.1
Acute Coronary Syndromes guideline	896	2,176	2,394	1.2
Arrhythmia and Heart Failure guidelines	1,232	2,851	7,074	2.3
Total events	7,214	27,068	60,533	20.6

In Scotland in the year ending 31 March 2006 over 10,300 patients died from CHD and 5,800 from cerebrovascular disease, with almost 49,000 hospital admissions for CHD and a further 22,050 for cerebrovascular disease².

Implementing the recommendations in the SIGN CHD guidelines should markedly improve patient outcomes. Over the next five years, it is estimated that over 7,200 premature deaths from CVD and over 27,000 vascular events could be avoided. This is equivalent to a 9% reduction from the current CVD mortality rate and an 8% reduction from the current CVD event rate. The CHD mortality rate fell by 5.2% in the two year period from April 2004 to March 2006, and the benefits from implementing the recommendations in these guidelines should be additional to this improvement.

As a direct result of avoiding CVD events, NHSScotland could release over 60,000 bed days a year for alternative uses, with associated cost savings of over £20 million from fewer inpatient

stays. In comparison, in the year to 31 March 2006, the cost of managing inpatients with unstable angina, acute myocardial infarction (MI) and re-infarction, other chronic ischaemic heart disease, heart failure and stroke was 380,000 bed days and £125 million³. The potential savings associated with guideline implementation represent about 16% of the current bed days and cost of managing CVD patients in the acute sector.

The recommendations contributing greatest benefits are associated with identifying individuals at high risk of CVD and managing their condition with lifestyle advice, statins and, where appropriate, antihypertensive drugs. Approximately one third of the Scottish population of over 40 years of age will be considered to have a 10-year CVD risk of greater than 20%. Providing statins to asymptomatic individuals at high risk of CVD provides about 37% of the mortality benefit and 30% of the potential clinical and related resources released benefits. Prescribing statins to patients with existing peripheral vascular disease and higher dose statins to those who are currently receiving statins but have a total cholesterol above 5mmol/L may reduce events by over 9,000 over five years, about 35% of the total events saved but contribute a lower proportion (10%) of mortality gains. Treating high risk individuals with blood pressure above 140/90 mmHg is estimated to provide 13% of the potential mortality benefit and a similar proportion of potential events saved and related resources released

Recommendations from the Acute Coronary Syndromes guideline (SIGN 93) provide about 12% of the mortality benefits, whilst the guidelines on Arrhythmias and Chronic Heart Failure (SIGN 94 and 95) provide 1% and 16% of the mortality benefits respectively but a lower proportion of the events saved.

Sensitivity analyses

The mean length of stay and associated costs for each diagnosis used to derive the estimates of potential clinical benefit were provided for year end 31 March 2006 by ISD³. The cost base applied includes direct costs such as medical, nursing, pharmacy, allied health professionals (AHP), theatre and laboratory costs. Support services (overheads) are attributed to the direct costs using appropriate methods⁴. The overhead element (approximately 30% of the cost base), is unlikely to change with marginal variations in workload and a better reflection of the savings is about £15 million a year, equivalent to 12% of the current costs.

A significant proportion of bed days and costs saved are associated with strokes avoided. The base case assumed all patients had a haemorrhagic (subarachnoid or intracerebral) stroke, requiring very high resource use, with a mean length of inpatient stay of over 23 days and associated costs of over £5,955 per patient. However transient ischemic attack (TIA) may not require admission. To test the sensitivity of the analyses to the stroke diagnosis used in trials, it was assumed that 33%⁵ of recorded strokes are TIAs and require no inpatient resources. As a result the annual savings fell by £1 million from £20.7 million to £19.7 million. However many trials only reported all vascular events and so the true sensitivity to this variable could not be tested.

In the base case, no resources savings were attributed to the reduction in deaths. This was to avoid the possibility of double counting events; if a patient has a stroke that proves fatal some trials count this as two events. If both events are attributed bed days saved then there could be a material overstatement of the resources saved. However, if a value of £2,270 per death avoided was imputed (the recorded cost of such events in the Heart Protection Study⁶) and such savings accrue over a 5-year period, then the annual savings rise by £3.3 million to £24 million.

These analyses do not capture improvements in patients' quality of life because very few of the clinical trials reported this clinical end point. The absence of this information is regrettable and as a consequence the report understates benefits to patients. This is particularly true of some of the devices for patients with heart failure where the intervention reduces cardiac mortality and significantly improves quality of life. However it does not reduce other cardiovascular events.

3.3 AGGREGATE RESOURCE REQUIREMENTS

No recommendations within the Stable Angina guideline (SIGN 96) were identified as requiring significant change to current practice, therefore additional resource requirements specific to SIGN 96 were not costed.

The total resource requirements for implementing all of the key recommendations from the CHD guidelines are outlined in Table 6.

A total of 188 additional whole time equivalent staff are required in the first full year of guideline implementation. Approximately 55% (107) of staff are required to manage the additional primary prevention workload and 30% (61) to support heart failure discharge services. Staff numbers required for prevention reduce to 92 in year 2 before increasing to a total of 127 in year 5, because the initial screening of asymptomatic individuals aged over 40 once every 5 years is concurrent with the management of those identified at high CVD risk. One fifth of this group are screened annually with one third of that number being identified as high risk and requiring therapy.

By year 6, the staffing needs for prevention reduce to around 60 staff members and total requirements are 143. At steady state (from year 6) 44% are GPs who provide an annual check-up for all high CVD risk patients, a further 43% of the new staff required are nurses who provide an improved heart failure discharge service and the remainder are required to staff the additional catheterisation facilities.

Table 6: Estimated resource requirements for implementing key CHD guideline recommendations

		ACS	Arrhythmias	Heart failure	Prevention		Totals	
					Year 1	Year 6	Year 1	Year 6
STAFFING	GP				23.5	47.0	23.5	47.0
	Practice nurse				46.1		46.1	
	Administrator			11.0	19.0	15.4	30.0	26.4
	Dietician				18.8		18.8	
	Cardiologist	3.6	1.7				5.3	5.3
	Technician	2.5	1.0				3.5	3.5
	Radiographer	2.4	1.0				3.4	3.4
	Nurse	3.2	2.0	50.0			55.2	55.2
	Surgeon	0.4					0.4	0.4
	Registrar	0.1	1.0				1.1	1.1
	Anaesthetist	0.7					0.7	0.7
	Perfusionist	0.4					0.4	0.4
	Total Staff	13.3	6.7	61.0	107.4	62.4	188.4	143.4
CAPITAL	GP practice rooms				71.0	84.0	71.0	84.0
	Catheterisation laboratory	1.6	1.0				2.6	2.6
	Staff desks			35.0			35.0	35.0
	Surgery rooms	0.1					0.1	0.1

3.4 AGGREGATE COSTS

The total estimated costs of implementing key recommendations from the CHD guidelines are outlined in Tables 7 and 8.

Table 7: Estimated annual costs (excluding VAT) of implementing key CHD guideline recommendations

	Costs (£ million)			
	Drugs (excluding statins)	Statins	Other	Total
ACS	1		4	5
Arrhythmias			4	4
Heart Failure	1		6	7
Prevention				
Year 1	2	10	12	24
Year 2	5	22	11	38
Year 3	6	25	13	44
Year 4	8	28	15	51
Year 5	10	31	17	58
Year 6	10	32	11	53
Totals:				
Year 1	4	10	26	40
Year 6	12	32	25	69

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Table 8: Estimated annual costs (including VAT) of implementing key CHD guideline recommendations

	Costs (£ million)			
	Drugs (excluding statins)	Statins	Other	Total
ACS	1		4	5
Arrhythmias			5	5
Heart Failure	1		6	7
Prevention				
Year 1	3	12	12	27
Year 2	5	25	12	42
Year 3	7	29	14	50
Year 4	9	33	16	58
Year 5	11	36	18	65
Year 6	11	38	12	61
Totals:				
Year 1	5	12	27	44
Year 6	13	38	27	78

After 5 years, the total annual costs of guideline implementation are about £80 million. Almost 80% (£62 million) of this cost is related to additional prevention measures, primarily comprising statins (£38 million). The remainder of costs are spread across the other three guidelines.

Statin costs represent about 27% of the total costs in the first year of implementation, increasing to 48% from year 6 (steady state).

The total capital costs, associated with building and equipment requirements in year 1 are £5.5 million excluding VAT (£6.5 million including VAT). Of this £5.5 million: £3.2 million is required for new catheterisation facilities, £0.4 million for additional accommodation for the heart failure service and £1.9 million for primary care accommodation. An additional £0.2 million is required in years 4 and 5 to provide further primary care accommodation. Table 9 outlines the capital costs for each guideline.

Table 9: Estimated capital costs of implementing key CHD guideline recommendations

	Costs (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
ACS	2.0 (2.3)					2.0 (2.3)
Arrhythmias	1.2 (1.4)					1.2 (1.4)
Heart Failure	0.4 (0.5)					0.4 (0.5)
Prevention	1.9 (2.3)			0.2 (0.2)	0.2 (0.2)	2.3 (2.7)
Total	5.5 (6.5)			0.2 (0.2)	0.2 (0.2)	5.9 (6.9)¹

Note: figures in brackets are including VAT, otherwise exclude VAT

¹ This figure was misprinted within the report and should be 5.9 (6.9) and not (0.2)

Sensitivity analysis

Sensitivity analyses shows the costs are very sensitive to the assumed price of statins. For example, in 2011 atorvastatin comes off patent and should the price of generic atorvastatin drop to the price of generic simvastatin then the additional annual cost of treating patients for secondary prevention could reduce from £17 million to £2 million. The cost of implementing the guidelines in year 6 (steady state) would fall from £69 million to £54 million (excluding VAT) as a result of this single factor.

4 Acute Coronary Syndromes

4.1 BACKGROUND

The key recommendations identified in the Acute Coronary Syndromes guideline (SIGN 93) will result in a major redesign of patient care pathways. These recommendations relate to:

- Provision of pPCI and related services for ST elevation acute coronary syndrome patients.
- The use of risk stratification scores to identify non-ST elevation acute coronary syndrome patients requiring early therapeutic intervention.

The changes in practice as a result of these recommendations are discussed below.

4.1.1 ST ELEVATION ACUTE CORONARY SYNDROME

The majority of Scottish patients presenting with ST elevation acute coronary syndrome currently receive thrombolysis. Since May 2006, pre-hospital thrombolysis delivered by ambulance crew has been available across Scotland. It is anticipated that approximately 900 patients may benefit from this service in the first year, with numbers likely to increase in future years as technical limitations are overcome¹⁵.

Under SIGN guideline 93 patients presenting with ST elevation acute coronary syndrome should undergo pPCI, where available, within 90 minutes of diagnosis. Where this procedure cannot be provided patients should receive immediate thrombolytic therapy (pre-hospital where possible) and early revascularisation (unless contraindicated). Intracoronary stent implantation should be used for all patients undergoing pPCI and protocols should be developed to enable such changes to operate effectively.

Sensitivity analyses (Section 4.6) were carried out varying:

- The number of patients undergoing pPCI within 90 minutes of diagnosis.
- The number of patients admitted via the Scottish Ambulance Service (SAS) and those who self present.
- The proportion of patients returning to their local district general hospital (DGH) following revascularisation.

The following key recommendations relating to the treatment of ST elevation acute coronary syndrome patients were identified in the Acute Coronary Syndromes guideline:

4.1 [A] *Patients with an ST elevation acute coronary syndrome should be treated immediately with primary percutaneous coronary intervention.*

4.2.1 [D] *When primary percutaneous coronary intervention cannot be provided within 90 minutes of diagnosis, patients with an ST elevation acute coronary syndrome should receive immediate thrombolytic therapy.*

4.4 [B] *Patients presenting with ST elevation acute coronary syndrome within six hours of symptom onset, who fail to reperfuse following thrombolysis should be considered for rescue percutaneous coronary intervention.*

6 [C] *Patients with ST elevation acute coronary syndromes treated with thrombolytic therapy should be considered for early coronary angiography and revascularisation.*

4.1.1 [A] *Intracoronary stent implantation should be used in patients undergoing primary percutaneous coronary intervention.*

4.2.3 [C] *Local protocols should be developed for the rapid treatment of patients presenting with ST elevation acute coronary syndromes. Consideration should be given to pre-hospital and admission thrombolysis, and to the emergency transfer of patients to interventional centres for primary percutaneous coronary intervention.*

4.1.2 NON-ST ELEVATION ACUTE CORONARY SYNDROME

According to SIGN guideline 93 a risk stratification score, assumed for this purpose to be validated by the Global Registry of Acute Coronary Events (GRACE), should be used to identify patients presenting with non-ST elevation acute coronary syndrome who are at medium or high risk of recurrent cardiovascular events. Such patients should undergo early coronary angiography and revascularisation. Currently risk stratification scores are used to identify patients appropriate for treatment in some tertiary centres, however the score is not generally used to prioritise patients transferring from DGHs.

A sensitivity analysis was carried out varying the proportion of patients who are at high or medium risk of cardiovascular events (Section 4.6).

The following key recommendations relating to the treatment of non-ST elevation acute coronary syndrome patients were identified in the Acute Coronary Syndromes guideline:

6 [B] *Patients with non-ST elevation acute coronary syndromes at medium or high risk of early recurrent cardiovascular events should undergo early coronary angiography and revascularisation.*

5.1 [C] *Risk stratification using clinical scores should be conducted to identify those patients with an acute coronary syndrome who are most likely to benefit from early therapeutic intervention.*

4.2 PATIENT GROUP

There are approximately 17,000 acute coronary syndrome admissions per year in Scotland¹⁶, of which approximately 42% (7,115) are unstable angina patients and 58% (9,885) MI patients¹⁷. Of the MI patients 33% (3,295) have ST elevation acute coronary syndrome and 67% (6,590) have non-ST elevation acute coronary syndrome¹⁸. The number of ST elevation acute coronary syndrome patients was validated using estimates in the report by the National Advisory Committee on CHD¹⁶.

4.2.1 ST ELEVATION ACUTE CORONARY SYNDROME

As SIGN guideline 93 recommends that all ST elevation acute coronary syndrome patients receive pPCI within 90 minutes of diagnosis and early revascularisation where this is not possible, the patient pathway and treatment of all 3,295 ST elevation acute coronary syndrome patients is affected by these recommendations. Table 10 outlines the estimated number of patients undergoing revascularisation per annum, based on the assumptions outlined in Appendix 3.

Table 10: ST elevation acute coronary syndrome patient revascularisation

Revascularisation method	Patient numbers		
	Post-implementation	Current position	Variance
pPCI	2,043	99	1,944
Rescue PCI	296	811	(515)
Emergency PCI	83	248	(165)
Elective angiography and subsequent PCI	552	641	(89)
Elective angiography and subsequent coronary artery bypass graft (CABG)	184	214	(30)
Patients unable to undergo intervention due to co-morbidities	138	107	31
Other patients who do not undergo revascularisation	0	1,176	(1,176)
Total number of patients	3,296	3,296	0

Table 11 outlines the estimated number of patients who receive thrombolysis per annum in both the pre-hospital and acute settings. Currently, patients may undergo early revascularisation, but post-recommendation they should all undergo early revascularisation. It is recognised that a proportion of patients who could receive pre-hospital thrombolysis may not, due to SAS protocols in place for patient safety.

Table 11: ST elevation acute coronary syndrome patients receiving thrombolysis

Setting	Patient numbers		
	Post-implementation	Current position	Variance
Pre-hospital	692	892	(200)
Acute (SAS admitted)	0	999	(999)
Acute (self presenting)	296	811	(515)
Total	988	2,702	(1,714)

4.2.2 NON-ST ELEVATION ACUTE CORONARY SYNDROME

In order to estimate the number of additional non-ST elevation acute coronary syndrome patients who should receive angiography and subsequent revascularisation under the SIGN recommendation, it was assumed that tertiary centres currently identify and manage medium and high CVD risk patients in accordance with best practice. Assuming that approximately 29% (1,900) of patients should receive an angiogram¹⁹, an additional 900 patients compared with current practice. Of these additional patients it is assumed that 50% will be at high CVD risk²⁰, and will receive emergency angiography and subsequent revascularisation on initial admission. The remaining 50% will be medium CVD risk and will return for elective angiography and revascularisation. Table 12 outlines the estimated additional number of interventions to be carried out per annum, based on this assumption.

Table 12: Additional number of non-ST elevation acute coronary syndrome interventions

Intervention	Patient numbers
Emergency PCI	235
Elective angiography and subsequent PCI	235
Elective angiography and subsequent CABG	88
Elective angiography only	347
Total number of patients	905

4.3 CLINICAL BENEFITS AND ASSOCIATED RESOURCE SAVINGS

4.3.1 ST ELEVATION ACUTE CORONARY SYNDROME

A recent health technology assessment by Hartwell²¹ et al compared pPCI with thrombolytic therapy for patients with ST-segment elevation. The analysis used data from four earlier systematic reviews and 11 RCTs. The reported event rates expressed as absolute risk reduction (ARR), relative risk reduction (RRR) and numbers needed to treat (NNT) are shown in Table 13.

Table 13: The effect of angioplasty compared with thrombolysis for specified clinical events

Events	PCI event rate	Thrombolysis event rate	ARR %	RRR %	NNT
Long term mortality	5	8	3	38	32
Stroke	1	2	2	64	64
Re-infarction	3	8	5	58	22
Recurrent ischaemia	7	18	11	59	9

(Figures rounded to nearest whole number).

The cost and bed days for the relevant diagnoses, taken from Table 3, were used to estimate the potential NHSScotland resource savings from avoided events. The annual cost of recurrent ischaemia was estimated using values derived from a 3-year follow-up of patients receiving medical therapy in the RITA 2 randomised trial²². The total medical costs were £3,610 at 1998/99 prices or £4,500 at 2006 prices, equivalent to £1,500 each year.

Approximately 1,940 additional patients would be expected to undergo pPCI (Table 9) and Table 14 estimates the clinical benefits that implementing the recommendations may have for Scottish patients, assuming that the absolute risk reduction values used generalise to the Scottish setting.

Table 14: Annual clinical benefit of adopting pPCI within 90 minutes for an additional 1,940 patients in Scotland

Event	Annual patients benefiting	Annual bed days saved	Annual savings (£ million)
Mortality	55	0	0.0
Stroke	32	742	0.2
Re-infarction	91	868	0.4
Recurrent ischaemia	217	0	0.3
Total	395	1,610	0.9

Sensitivity analysis assumed £2,270 per death avoided being the observed cost for the participants who died in the Heart Protection Study⁶ (see section 2.2.1). Inclusion of this value increased the total savings to over £1 million.

The same study calculated the cost of managing patients who had undergone a previous vascular event within the 5-year study period as £190 per annum. This saving has not been included in any of the costings shown.

4.3.2 NON-ST ELEVATION ACUTE CORONARY SYNDROME

The clinical benefits of implementing the recommendation to use a risk score to identify patients at medium and high risk of early recurrent cardiovascular events, with such individuals undergoing early coronary angiography and revascularisation are twofold. Firstly more patients will receive intensive therapy, thereby reducing mortality and readmissions, and secondly there should be equality in access to treatment.

Data from ISD for the period April 2002 March 2004¹⁹, standardised for age, sex and deprivation were analysed for Scottish hospitals admitting patients with acute coronary syndromes. Hospitals were classified as transfer hospitals with no facility for angiography, PCI equipped (able to perform coronary angiography but not intervention), PCI equipped (able to perform PCI but not CABG) or able to perform both CABG and PCI.

The data¹⁹ show that patients admitted to hospitals equipped for CABG/PCI were significantly more likely to undergo angiography (23.6% vs. 13.2%), PCI (15.8% vs. 9.5%) and CABG (3.9% vs. 2.0%) than the overall patient population. Hospitals equipped to perform CABG/PCI had lower 1-year mortality rates (15.6% vs. 16.3%) and lower readmission rates (4.7% vs. 5.6%), whereas mortality and readmission rates were highest for transfer hospitals (16.6% and 6.0%, respectively). Readmissions were primarily for reinfarction (70%) and unstable angina (30%).

The clinical benefit of this recommendation was quantified by assuming that the current intervention levels observed in PCI/CABG centres are optimal and that facilitating the same level of intervention for all Scottish patients will reduce readmission and mortality rates to the levels observed in these hospitals (Table 15). The savings in bed days and cost assessments used the data from Table 3.

Table 15: Annual clinical benefit of treating 900 additional patients with non-ST elevation acute coronary syndrome in non tertiary hospitals using risk score to guide management

Event	Patients benefiting	Bed days saved	Annual savings (£ million)
Mortality	46	0	0.00
Readmissions			
Re-infarction	42	400	0.17
Unstable angina	18	77	0.03
Total	106	477	0.20

Attributing a saving of from each death avoided of £2,270 increased the total resource savings from £0.2 million to £0.3 million.

4.4 RESOURCE REQUIREMENTS

Throughout this section, it was assumed that a clinical session comprised 3.5 hours, with the number of each procedure that can be undertaken per session being estimated in Table 16. It was assumed that 15% of pPCI, rescue PCI and emergency PCI are performed out of hours.

Table 16: Assumed procedures that can be conducted per session

Procedure	Number per session
pPCI	2
Rescue PCI	2
Emergency PCI	3
Elective CABG	1
Elective Angiography	5

For health boards in the East, North and West certain cardiology services are currently planned regionally²³. This report assumes that coronary intervention special interest services and electrophysiology will be managed at the regional level, whilst others services will be managed in tertiary or DGHs.

This report assumes that resources requirements across the Scottish regions are in the proportions: 55% for the West, 24% for the North and for the 21% East²⁴.

4.4.1 STAFF REQUIREMENTS

It was assumed that consultants are contracted for 10 sessions per week, of which six are spent in the catheterisation laboratory, and that all other acute care staff are available for 37.5 hours per week over 42 weeks per year¹⁴.

If extended working hours were introduced the number of staff required would reduce, however the costs for existing staff would increase as an overtime rate would be payable. Overall this would result in a reduction in implementation costs.

The change in the clinical staff managing patients receiving thrombolysis, both in Accident and Emergency (A&E) and during their ward stay have not been considered, as the staff time released as a result of the reduced number of patients receiving thrombolysis will be required in a different capacity.

ST elevation acute coronary syndrome

The estimated number of staff required, taking into account staff resources released, as a result of implementing the ST elevation acute coronary syndrome recommendations are detailed as whole time equivalents (WTE) in Table 17.

Table 17: Additional staffing requirements assuming 62% of patients with ST elevation acute coronary syndrome to receive required interventions

Staff	WTE
Cardiologist	2.2
Technician	1.6
Radiographer	1.6
Nurse	1.6
Surgeon	0.0
Registrar	0.0
Anaesthetist	0.0
Perfusionist	0.0
Total staff	7.0

Appendix 4 details the estimated staffing requirements and associated costs for each of the three Scottish regions.

Non-ST elevation acute coronary syndrome

The estimated number of staff required, taking into account staff resources released as a result of implementing the ST elevation acute coronary syndrome recommendations, are detailed in Table 18.

Table 18: Staffing requirements for non-ST elevation acute coronary syndrome patients at high or medium CVD risk to undergo early coronary angiography and revascularisation

Staff	WTE
Cardiologist	1.4
Technician	0.9
Radiographer	0.8
Nurse	1.6
Surgeon	0.4
Registrar	0.1
Anaesthetist	0.7
Perfusionist	0.4
Total staff	6.3

Appendix 5 details the estimated staffing requirements and the associated costs for each of the three Scottish regions.

4.4.2 CAPITAL REQUIREMENTS

It was assumed that catheterisation laboratories are available for 10 sessions per week over 52 weeks per year. If catheterisation laboratory availability was extended and longer working hours were introduced the number of catheterisation laboratories required would reduce, thereby reducing in the cost of implementation.

ST elevation acute coronary syndrome

The estimated capital required to implement the ST elevation acute coronary syndrome recommendations are detailed in Table 19.

Table 19: Capital requirements for ST elevation acute coronary syndrome patients receiving interventions

Capital	Units
Catheterisation laboratories	1.1
Surgery rooms	0.0
Total capital	1.1

Appendix 4 details the estimated capital requirements and the associated costs for each of the three Scottish regions. Portable catheterisation laboratories may be an option for regions where a catheterisation laboratory is not required for the full 10 sessions per week.

Non-ST elevation acute coronary syndrome

The estimated capital required to implement the non-ST elevation acute coronary syndrome recommendations are detailed in Table 20.

Table 20: Capital requirements for non-ST elevation acute coronary syndrome patients at high or medium CVD risk to undergo early coronary angiography and revascularisation

Capital	Units
Catheterisation laboratories	0.5
Surgery rooms	0.1
Total capital	0.6

Appendix 5 details the estimated capital requirements and the associated costs for each of the three Scottish regions. Portable catheterisation laboratories may be an option for regions where a catheterisation laboratory is not required for the full 10 sessions per week.

4.5 COSTS

4.5.1 UNIT COSTS

Table 21 presents the unit costs used to calculate the total resource costs required to implement the key Acute Coronary Syndromes guideline recommendations.

Table 21: Unit cost of resources required to implement key Acute Coronary Syndromes recommendations.

Item	Unit Cost	Source
Intervention		
pPCI	£4,325	2005 Scottish National Tariffs ISD ³
Rescue PCI	£4,963	pPCI ³ + 2 additional days (assumed)*
Emergency PCI	£4,325	2005 Scottish National Tariffs ISD ³
Elective PCI	£2,832	2005 Scottish National Tariffs ISD ³
Elective CABG	£11,286	2005 Scottish National Tariffs ISD ³
Elective angiography	£849	2005 Scottish National Tariffs ISD ³
Pre-hospital thrombolysis (PHT)	£2,794	
PHT (tPA only)	£720	BNF 52 ²⁵ (Tenecteplase) + VAT
Length of stay*	£2,074	6.5 days ^{21, 26}
Thrombolysis - A&E	£3,547	
tPA	£705	BNF 52 ²⁵ (Alteplase) +VAT
Attendance	£768	ISD ² (2005/2006 A&E (Ro40))
Length of stay*	£2,074	6.5 days ^{21, 26}
*Length of stay - cost per day	£319	ISD ² (SMRo1 inpatient discharges with ACS 2002/2003)
Travel – Average cost per journey		
Current	£435	SAS ²⁷
Post-recommendation	£590	
Staff (including overheads)		
Cardiologist	£121,023	Salary ²⁸ Overheads ¹⁴ (derived) (Refer to table 4 for overhead allocation)
Technician (MTO4)	£36,927	
Radiographer (Senior 1)	£38,079	
Nurse (E Grade)	£27,911	
Surgeon	£121,023	
Specialist Registrar	£91,120	
Anaesthetist	£121,023	
Perfusionist (MTO5)	£47,605	

Table 21 (cont.): Unit cost of resources required to implement key Acute Coronary Syndromes recommendations.

Item	Unit Cost	Source
Capital (excluding VAT)		
Catheterisation laboratory	£1,200,000	Scottish DGH business case
Equipment cost	£1,000,000	
Building works	£200,000	
Surgery Room	£1,000,000	Assumed
Capital (including VAT)		
Catheterisation laboratory	£1,410,000	Scottish DGH business case
Equipment cost	£1,175,000	
Building works	£235,000	
Surgery Room	£1,175,000	Assumed
Intracoronary stents		
Drug eluting stents	£1,000	Western General ²⁹
Bare metal stents	£250	Western General ²⁹

4.5.2 TOTAL COSTS TO IMPLEMENT KEY ACUTE CORONARY SYNDROMES RECOMMENDATIONS

Tables 22 and 23 outline the annual costs involved in implementing the ST elevation acute coronary syndrome and non-ST elevation acute coronary syndrome recommendations respectively. Section 4.5.3 details each of the cost items.

Table 22: Additional annual cost for ST elevation acute coronary syndrome patients receiving interventions

	Cost (£ million)		
	Intervention	Protocols	Total
Post-recommendation	19.6	0.1	19.7
Current	18.7	0.0	18.7
Additional cost	0.9	0.1	1.0

The actual costs will be £3.6 million as A&E attendance and thrombolysis length of stay savings will not be realised.

A capital budget of £1.5 million including VAT (£1.3 million excluding VAT) is required in the first year to purchase additional catheterisation laboratories (Section 4.4.2).

Table 23: Additional annual costs for non-ST elevation acute coronary syndrome patients at high or medium CVD risk to undergo early coronary angiography and revascularisation

	Cost (£ million)
Intervention	3.3
Protocols	0.1
Total cost	3.4

A capital budget of £0.8 million including VAT (£0.7 million excluding VAT) is required in the first year to purchase additional catheterisation laboratories (Section 4.4.2).

4.5.3 BREAKDOWN OF TOTAL COSTS REQUIRED TO IMPLEMENT KEY ACUTE CORONARY SYNDROMES RECOMMENDATIONS

ST elevation acute coronary syndrome

INTERVENTION COSTS

Appendix 6 summarises of the additional costs of implementing ST elevation acute coronary syndrome recommendations for each of the three Scottish regions, while Appendix 7 provides costing information per procedure.

ADDITIONAL STAFF COSTS (INCLUDING OVERHEADS)

The total cost of the additional staffing requirements (Section 4.4.1) is £0.4 million. Appendix 4 details the estimated staffing requirements and the associated costs for each of the three Scottish regions.

TRAVEL COSTS

The additional travel costs incurred by the Scottish Ambulance Service (SAS) as a result of implementation of the Acute Coronary Syndromes recommendations are estimated at £1.3 million. Subsequently the SAS have advised that it anticipates these travel costs to be the worst case scenario.

INTRACORONARY STENTS

In order to estimate the additional expenditure on intracoronary stents in Scotland as a result of implementing the ST elevation acute coronary syndrome intervention recommendations, it is assumed in 95% of patients at least one stent is used and in 37%³⁰ of these patients two stents are used, 55% are drug eluting stents and 45% bare metal. Of the additional £10 million required to perform pPCI (Appendix 7) £1.7 million relates to increased stent usage. However, performing fewer rescue, emergency and elective PCI compared with the current baseline (Appendix 7) will save £3.4 million, of which £0.7 million relates to reduced stent usage. Thus, the total additional stent expenditure is £1.0 million per annum.

DEPRECIATION CHARGE

The annual depreciation charge of the additional catheterisation laboratory facilities is £0.1 million, where equipment and buildings depreciate on a straight-line basis over 10 and 20 years respectively.

THROMBOLYSIS DRUG COSTS

The estimated potential saving resulting from a reduction in patients receiving thrombolysis is £1.3 million including VAT (£1.1 million excluding VAT).

THROMBOLYSIS A&E COSTS

The estimated potential savings resulting from a reduction in the number of patients receiving thrombolysis at A&E is £1.2 million, however these savings will not be realised as expenditure associated with A&E attendance will be incurred regardless of implementation.

THROMBOLYSIS LENGTH OF STAY COSTS

The estimated potential savings resulting from a reduction in the number of patients receiving thrombolysis and the associated reduction in bed days required is £2.4 million, however these savings will not be realised as expenditure associated with a ward stay will be incurred regardless of implementation.

OTHER INTERVENTIONAL COSTS

The remaining interventional costs are estimated at £3.0 million, when calculated using national tariff charges and including costs for existing staff, consumables (excluding stents), existing depreciation charges and overheads. A breakdown of these costs is not available.

CAPITAL COSTS

The additional capital cost is £1.5 million including VAT (£1.3 million excluding VAT).

PROTOCOLS

It was assumed that defining protocols is meeting intensive, whereby tertiary centres develop a protocol which is then revised in accordance with issues raised during six, half day meetings attended by staff from a variety of disciplines.

It was estimated that 38 hospitals throughout Scotland would be involved protocol development, comprising six tertiary centres at a cost of £5,000 each and 32 DGHs at a cost of £2,000. The total cost associated with protocol development would, therefore, be £94,000. Variables required to identify the level of CVD risk are currently identified as: heart rate, systolic blood pressure, diastolic blood pressure, signs of heart failure, ST-segment depression, troponin and CK-MB mass. It was assumed that these variables are currently being assessed and that no additional costs would, therefore, be incurred.

Non-ST elevation acute coronary syndrome

INTERVENTION

Appendix 8 summarises the additional costs of implementing the non-ST elevation acute coronary syndrome recommendations for each of the three Scottish regions, while Appendix 9 provides costing information per procedure.

ADDITIONAL STAFF COSTS (INCLUDING OVERHEADS)

The total cost of the additional staff required (Section 4.4.1) was estimated at £0.4 million. Appendix 5 details the estimated staffing requirements and the associated costs for each of the three Scottish regions.

TRAVEL COSTS

The additional travel costs incurred by the SAS as a result of implementation of the Acute Coronary Syndromes recommendations were estimated at £0.1 million. It is assumed that no additional capital is required by the SAS to provide this service. Subsequently the SAS have advised that it anticipates these travel costs to be the worst case scenario.

INTRACORONARY STENTS

In order to estimate the additional expenditure on intracoronary stents in Scotland as a result of implementing the non-ST elevation acute coronary syndrome intervention recommendations, it was assumed that 95% of patients require at least one stent to be used and that in 37%³⁰ of those patients' two stents are used; 55% of these comprise drug eluting stents and 45% bare metal. The additional stent expenditure was estimated at £0.4 million per annum.

DEPRECIATION CHARGE

The annual depreciation charge of the additional catheterisation laboratory facilities is £0.1 million, where equipment and buildings depreciate on a straight-line basis over 10 and 20 years respectively.

OTHER INTERVENTIONAL COSTS

The remaining interventional costs were estimated at £2.3 million, when calculated using national tariff charges and including costs for existing staff, consumables (excluding stents), existing depreciation charges and overheads. A breakdown of these costs is not available.

CAPITAL COSTS

The additional capital cost is £0.8 million including VAT (£0.7 million excluding VAT).

PROTOCOLS

The cost of developing protocols was assumed to be comparable with those for ST elevation acute coronary syndrome. However in addition each DGH would require palmtops, associated with a total cost for the 38 hospitals of £126,000. This would comprise £5,000 for each of the six tertiary centres and £3,000 each for the 32 DGHs.

4.5.4 COST PER PATIENT

ST elevation acute coronary syndrome

The total cost per ST elevation acute coronary syndrome patient post-implementation was estimated at £5,947 and the additional cost per patient as £282. The cost per patient for each procedure was in line with the national tariffs outlined in Table 21.

Non-ST elevation acute coronary syndrome

The total cost per non-ST elevation acute coronary syndrome patient at medium or high risk was estimated at £3,662. The cost per patient for each procedure was in line with the national tariffs outlined in Table 21.

4.6 BED DAYS

It was assumed that the length of stay was incorporated into the unit cost for each intervention, hence any savings resulting from bed days saved are included in the costings (Section 4.4).

Table 24: Procedural length of stay

Procedure	Length of stay (days)	Source
pPCI	4.5	Scottish Coronary Revascularisation Register 2005/2006 ³¹ (not published)
Rescue PCI	6.5	Assumed - pPCI ³¹ + 2 days (Sensitivity analysis 2 assumes 4.5 days as per pPCI)
Emergency PCI	4.5	Scottish Coronary Revascularisation Register 2005/2006 ³¹ (not published)
Elective PCI	1.0	Derived from Scottish Coronary Revascularisation Register 2005/2006 ³¹ (not published)
Elective CABG	10.0	Scottish Coronary Revascularisation Register 2004/2005 ³¹ (not published)
Elective angiography	0.5	Assumed
Thrombolysis	6.5	Hartwell HTA ²¹ and MINAP ²⁶

4.6.1 ST ELEVATION ACUTE CORONARY SYNDROME

Assuming that the length of stay for each procedure was as per Table 24, the total bed days released as a result of implementing pPCI and early revascularisation for ST elevation acute coronary syndrome patients was estimated at approximately 3,400 days. Approximately 4,600 days are expected to be released in tertiary centres with 1,200 additional bed days being required in DGHs.

The potential savings arise in tertiary centres because it is assumed that in future 82% of patients will receive pPCI rather than thrombolysis, thereby reducing the number of rescue and emergency PCIs. As interventions requiring both thrombolysis and rescue PCI incur a longer hospital stay (6.5 vs. 4.5 days), patients will spend less time in the tertiary centre. Currently approximately 15% of patients for whom the tertiary centre is not their local hospital are taken by ambulance to the DGH on the day following primary, rescue or emergency PCI. It is assumed that post-recommendation all such patients will return, thereby reducing the time spent at the tertiary centre.

The main reason that treatment in a DGH is associated with more hospital bed days is that patients for whom the tertiary centre is not their local hospital will return to the DGH on the day following primary, rescue or emergency PCI in comparison with 15% of such patients currently returning. This outweighs the savings associated with fewer initial admissions for thrombolysis.

The division of hospitalisation time spent between tertiary and DGHs is sensitive to the proportion of patients transferred following revascularisation (Section 4.7, sensitivity analysis 3). Appendix 4 details the estimated bed days released or required for each of the three Scottish regions by hospital type and Appendix 7 by procedure.

These bed day values are not used directly in the subsequent costing analysis, rather the procedure costs used incorporated a bed day cost (Table 21).

4.6.2 NON-ST ELEVATION ACUTE CORONARY SYNDROME

The total number of bed days required for patients at medium and high risk to receive angiography and subsequent revascularisation was estimated at 2,500, assuming the length of stay for each procedure is as detailed in Table 24. These estimates assume that the current length of stay remains stable. Of the additional bed days, 1,700 are required in tertiary centres and 800 in DGHs. More bed days are required as patients who were not previously receiving intervention, would be doing so. Tertiary centres require the majority of beds, as this is where the interventions takes place. Patients only spend time in the DGH when transferred following emergency PCI, comprising all high risk patients not requiring CABG. It was assumed that all patients for whom the tertiary centre is not their local hospital return to their DGH on the day following emergency PCI. Appendix 5 details the estimated bed days required for each of the three Scottish regions and Appendix 9 provides this information per procedure.

4.7 SENSITIVITY ANALYSIS

4.7.1 SENSITIVITY ANALYSIS 1 - ST ELEVATION ACUTE CORONARY SYNDROME

POST IMPLEMENTATION 43% OF ST ELEVATION ACUTE CORONARY SYNDROME PATIENTS RECEIVE PRIMARY PCI WITHIN 90 MINUTES OF DIAGNOSIS

The base case assumed that 62% of patients would receive pPCI within 90 minutes of diagnosis, representing 65% less the 3% (5% of 65%) of patients unable to undergo pPCI due to co-morbidities. This sensitivity analysis assumes that 43% of patients receive pPCI within 90 minutes of diagnosis, representing 45% less the 2% (5% of 45%) of patients unable to undergo pPCI due to co-morbidities.

As a result the expected number of interventions and additional staff and capital requirements change, as detailed in Tables 25 and 26.

Table 25: ST elevation acute coronary syndrome patient revascularisation

Revascularisation method	Patient numbers		
	Post-recommendation	Current Position	Variance
pPCI	1,417	99	1,318
Rescue PCI	465	811	(346)
Emergency PCI	132	248	(116)
Elective angiography and subsequent PCI	866	641	225
Elective angiography and subsequent CABG	289	214	75
Unable to undergo intervention due to co-morbidities	127	107	20
Others not undergoing revascularisation	0	1,176	(1,176)
Total	3,296	3,296	0

The number of patients currently receiving thrombolysis was estimated to remain the same, however post-implementation the number of patients receiving thrombolysis would increase to 1,549 of whom 1,085 receive PHT.

Table 26: Additional staffing requirements for 43% of patients with ST elevation acute coronary syndrome to receive required interventions

Staff	WTE
Cardiologist	2.4
Technician	1.3
Radiographer	1.2
Nurse	1.9
Surgeon	0.4
Registrar	0.1
Anaesthetist	0.5
Perfusionist	0.4
Total staff	8.2

The total staff requirements increase from those in the base case, as an additional 2.2 surgical staff members will be required, due to the increase in CABG procedures undertaken (less pPCI results in more elective patients and more patients undergoing CABG). However, the total number of additional PCIs compared to the current position is now 1,081 (1,175 in the base case), therefore additional catheterisation laboratory staff requirements reduce from 7 in the base case to 6 staff members. The number of additional catheterisation laboratories required is estimated at 0.8 (1.1 in base case) with an additional 0.1 surgery room also required.

Current practice costs remain as per the base case, however the costs estimated post-implementation would be £21.2 million. Thus the total additional costs are £2.5 million, of which £0.9 million are travel costs and £1.6 million relate to intervention procedures, of the intervention costs £0.6 million are staff related. Capital costs of £1.2 million are also estimated. The current cost per journey remains at £435, however the post-implementation cost per journey drops from £590 to £518 under this model²⁷. As the number of journeys is reduced less staff are required than under the base case model.

4.7.2 SENSITIVITY ANALYSIS 2 - ST ELEVATION ACUTE CORONARY SYNDROME

LENGTH OF STAY FOR RESCUE PCI PATIENTS 4.5 DAYS

The base case assumed that the length of stay for rescue PCI patients was 6.5 days and thus a cost per patient of £4,963. This sensitivity analysis assumes a length of stay of 4.5 days as per the Scottish Coronary Revascularisation Register 2005/06 emergency PCI length of stay³¹. This change also affected the cost per patient undergoing rescue PCI which reduced to £4,325. All other assumptions remained as per the base case.

While the number of patients remained as per the base case, this change affected both the number of bed days saved and costs. The total number of days saved reduced by 1,030 to 2,372, with tertiary centres saving 3,290 bed days (reduction of 1,331) and DGHs requiring 918 bad days (reduction of 301).

As the cost of rescue PCI has reduced, the savings resulting from the decrease in patient numbers undergoing rescue PCI, has reduced by approximately £330,000. All other costs remained the same as the base case. Therefore the total additional cost was estimated at £1.3 million with capital costs remaining as per the base case.

4.7.3 SENSITIVITY ANALYSIS 3 - ST ELEVATION ACUTE CORONARY SYNDROME

90% OF ST ELEVATION ACUTE CORONARY SYNDROME PATIENTS ADMITTED TO HOSPITAL VIA SCOTTISH AMBULANCE SERVICE

The base case assumed that 70% of ST elevation acute coronary syndrome patients were admitted to hospital via the SAS and 30% self presented based on estimates from the Royal Infirmary Edinburgh and Royal Alexandra Hospital Paisley^{32,33}. However other experts advised that in other settings 90% of patients are admitted via the SAS and 10% self-present^{15,34}. This sensitivity analysis was undertaken assuming that 90% of patients present via the SAS and 10% self present, with all other assumptions being the same as for the base case.

Under this analysis, 2,432 patients currently present via the SAS and 270 self present, in comparison with the 1,891 and 811 used in the base case. However, the number of patients receiving PHT or thrombolysis in A&E remains the same as for the base case. Following implementation, the number of procedures would remain as per the base case, except for PHT and thrombolysis administered in A&E. However, the total number of patients receiving some form of thrombolysis would remain the same. It was estimated that the 890 patients who present via the SAS receive PHT and the 98 who self present receive thrombolysis in A&E, in comparison with 692 and 296 in the base case.

As more patients receive PHT following implementation, which is less expensive than treatment in A&E, the procedural costs were estimated at £0.1 million lower than for the base case. However, as the number of patients admitted via the SAS increases, the additional travel costs increase by £0.2 million. As a result the total estimated additional costs were £1.0 million. The travel costs also rose due to changes in cost per journey using this model, where the current cost per journey is £419 rising to £603 post-implementation²⁷.

4.7.4 SENSITIVITY ANALYSIS 4 - ST ELEVATION ACUTE CORONARY SYNDROME

POST IMPLEMENTATION 50% OF ST ELEVATION ACUTE CORONARY SYNDROME PATIENTS RETURNING TO THEIR LOCAL DGH FOLLOWING REVASCULARISATION

As the base case it was assumed that 100% of patients would return to their local DGH 24 hours after primary, rescue or emergency PCI (via the SAS). However as currently only 15% of rescue PCI patients return to the DGH, sensitivity analysis assumed that 50% of patients would return to their local DGH and 50% would remain at the tertiary centre. All other assumptions were the comparable with the base case.

The resulting change in the number of patients transferring to DGHs affected the number of bed days saved and the associated costs. The total number of days saved remained at approximately 3,400, but there was a saving at both tertiary centres (1,600) and DGHs (1,900).

As fewer patients use the SAS to return to their local DGH there is a reduction in additional travel costs, dropping from £1.3 million to £0.9 million per annum, despite an increase in the cost per journey to £630²⁷. All other costs remained the same as the base case. The total additional cost was estimated at £0.5 million, with capital costs remaining as per the base case.

4.7.5 SENSITIVITY ANALYSIS 5 - NON-ST ELEVATION ACUTE CORONARY SYNDROME

32% OF NON-ST ELEVATION ACUTE CORONARY SYNDROME PATIENTS AT HIGH OR MEDIUM RISK OF RECURRENT CARDIOVASCULAR EVENTS

The base case assumed that 28.7% of non-ST elevation acute coronary syndrome patients were at medium or high risk of early recurrent cardiovascular events. This sensitivity analysis assumed that 32.2% of non-ST elevation acute coronary syndrome patients were at medium or high CVD risk. The estimated additional number of interventions required per annum is outlined in Table 27.

Table 27: Additional interventions for 32.2% of patients with non-ST elevation acute coronary syndrome at medium to high risk

Intervention	Number
Emergency PCI	282
Elective angiography and subsequent PCI	282
Elective angiography and subsequent CABG	107
Elective angiography only	399
Total number of patients	1,070

As a result of the increased number of patients at medium or high CVD risk and the corresponding increase in the number of interventions, the additional annual costs rose to £4.0 million and Table 28 shows a breakdown of these costs. The additional capital costs were estimated at £1.2 million including VAT (£1.0 million excluding VAT).

Table 28: Annual cost requirements for additional interventions in non-ST elevation acute coronary syndrome patients

Component	Cost (£ million)
Additional Staff	0.5
Travel (SAS)	0.1
Intracoronary stents	0.5
Depreciation charge	0.1
Other	2.8
Total	4.0

5 CRT and ICDs

5.1 BACKGROUND

The Arrhythmias guideline (SIGN 94) and the Chronic Heart Failure guideline (SIGN 95) make recommendations on implanting additional devices in appropriate patients. The resources required to assess and manage such interventions are very similar and hence this section considers the clinical benefits and costs of these recommendations together.

CRT is recommended for patients with symptomatic heart failure despite optimal medical therapy, who are in normal sinus rhythm. Such patients have compromised ventricular function, severe symptoms and poor prognosis. CRT uses biventricular pacing to attempt to synchronise heart action and improve function, with trials showing that CRT reduces mortality and improves quality of life.

It is recommended that ICDs are considered for patients who have survived cardiac arrest due to ventricular fibrillation, or who have experienced an episode of sustained ventricular tachycardia. Other trials have also shown mortality benefits in patients after MI, with mild to moderate heart failure and an impaired ejection fraction. Trials have demonstrated that ICDs can reduce the risk of sudden death and all-cause mortality in such patients. Some heart failure patients who also have a risk of sudden cardiac death as demonstrated by spontaneous or induced arrhythmias or a previous MI may be considered for a combined CRT-D device, offering CRT, to help improve heart function and a defibrillator (D) to help prevent sudden cardiac death.

The procedures have similar staffing and equipment requirements, such that the cardiologist and team may undertake a mix of procedures within the one catheterisation laboratory session. Thus for resource planning purposes the recommendations on CRT, CRT-D and ICD are considered together in this section.

The specific recommendation on CRT in the Chronic Heart Failure guideline is:

5.1.1[A] *In patients with drug refractory symptoms of heart failure due to left ventricular systolic dysfunction (left ventricular ejection fraction < 35%) and who are in NYHA Class III and IV and who have a QRS duration of > 120 ms, cardiac resynchronization should be considered.*

The specific recommendations from the Arrhythmia guideline are:

4.2.2 [A] *Patients with moderate to severe LV dysfunction (eg ejection fraction < 0.35), in NYHA Class I-III at least 1 month after myocardial infarction should be considered for ICD therapy*

4.2.2 [B] *Patients with spontaneous nonsustained ventricular tachycardia (especially if sustained ventricular tachycardia is inducible), severely impaired ejection fraction (< 0.25) or prolonged QRS complex duration (> 0.12 sec) should be prioritised for ICD implantation.*

4.2.2 [A] *Patients meeting criteria for ICD implantation who have prolonged QRS duration (> 0.12 sec) and NYHA class III-IV symptoms should be considered for CRT-D therapy.*

5.2 PATIENT GROUPS

5.2.1 CRT AND CRT-D

An analysis of patients with chronic heart failure in Lothian suggests that about 30 new patients each year present with conditions that meet the criteria for CRT. This is equivalent to about 375 nationally³⁵. Some of these patients may prove unsuitable for therapy on further investigation or may not wish to undertake it, and so the base case assumed that 350 patients a year undergo CRT.

Some of these patients will be considered for additional ICD therapy through the use of CRT-D. Dr K Hogg³⁶ advised a ratio of 1:2 for CRT-D: CRT was appropriate and that assuming a re-intervention rate of 5.0% following technical issues or infection was realistic.

5.2.2 ICD

Currently, there are no robust estimates of the potential number of candidates for ICDs in Scotland, because systems are not in place to identify candidates³⁷. However, NICE has recommended that the implantation rate should rise to 100 per million per year³⁸. Adopting this as the target for Scotland, and assuming that the current number of ICDs used is 35 per million patients (approximating to about 100 cases per year), gives a base case of an additional 325 ICDs required each year. Professor Rankin³⁹ advised a re-intervention rate of 5.0% for such procedures.

5.3 CLINICAL BENEFITS AND ASSOCIATED RESOURCE SAVINGS

5.3.1 CRT and CRT-D

A systematic review and meta-analysis by Fremantle et al⁴⁰ included evidence from eight randomised controlled trials for 3,380 patients with a mean follow-up of between 1 and 29.4 months. Pooling these studies gave a statistically significant fixed effects odds ratio of 0.72 (95% confidence intervals 0.59-0.88) for all-cause mortality, with an absolute risk reduction of 2.7%.

Seven trials reported data on heart failure hospitalisation which gave a statistically significant fixed effects odds ratio of 0.55 (95% confidence intervals 0.44-0.68) when pooled and an absolute risk reduction of 8.9%.

ISD data shows that in the year to 31 March 2006, the mean length of stay for patients admitted with heart failure was 16.0 days, with an associated average cost per patient of £5,100 (see Table 3). The potential clinical benefit of introducing such a treatment programme for 350 patients annually is estimated in Table 29

Table 29: Annual clinical benefits of implanting 350 CRT and CRT-D devices

Event	AR	ARR	Annual clinical benefit in Scotland
All cause mortality	17.0%	2.7%	10 patients
Heart failure readmission	23.0%	8.9%	33 readmissions for heart failure Annual savings: 524 bed days saved £0.2 million costs saved

5.3.2 ICD

A recent HTA⁴¹ summarised the evidence that ICDs reduce mortality compared with medical therapy. For primary prevention two systematic reviews reported relative risk reductions in all cause mortality of 28-34% when ICDs were compared with placebo. Four RCTs reported a wider range of mortality benefits, in part because of the heterogeneity of patients included.

The reported results for secondary prevention are more consistent, with systematic reviews and a meta-analysis reporting a relative risk reduction in all cause mortality of 24 and 25% and a reduction in the hazard ratio of 2%. The absolute risk reduction due to using ICDs was 3.5-7% per year.

In the initial years after guideline implementation, the majority of patients treated are likely to have had a coronary event. Given the uncertainty concerning the level of benefit for primary prevention measures the analyses assumed an absolute risk of all cause mortality of 3.5-7% and relative risk reduction of 25% for all patients over the 10-year period. The benefits associated with ICD devices are quantified in Table 30.

Table 30: Annual clinical benefit of implanting 325 ICD devices

Event	Risk reduction	Annual clinical benefit
All cause mortality	ARR: Range 3.5-7 %	11 to 20 deaths avoided

The HTA did not report any other clinical endpoints and therefore no other benefits were generalised to the Scottish population.

5.4 RESOURCE REQUIREMENTS

5.4.1 STAFF REQUIREMENTS

The staff resources assumed for each catheterisation laboratory session are presented in Table 31, excluded staff provided by the manufacturer or in attendance for training purposes. It was assumed that staff can complete 1.5 CRTs or CRT-Ds or three ICDs per session.

Table 31: Staffing levels in catheterisation laboratory for ICD and CRT implants

Catheterisation laboratory staff	Per session
Cardiologist	1
Registrar	1
Nurse F	1
Nurse E	1
Technician MTO 4	1
Radiographer Senior	1

Given each cardiologist works 6 out of 10 sessions in a laboratory, 1 per session equates to 1.7 staff members.

5.4.2 CAPITAL REQUIREMENTS

The total number of catheterisation laboratory sessions required was estimated at about 395 per annum, assuming that 10% of patients cannot undergo the planned procedure and that capacity is not reallocated. This is equivalent to the capacity of a new catheterisation laboratory, assuming it is used for 48 weeks a year and experiences 15% downtime during these 48 weeks. The associated capital costs, informed by the business case for a recent new build at a Scottish DGH, was assumed to be £0.2 million for building works and £1.0 million for equipping the facility.

5.5 COSTS

5.5.1 UNIT COSTS

In addition to the staff costs associated with device implantation the main costs were associated with the device itself and the time in hospital before and after the procedure, as summarised in Table 32.

Table 32: Unit costs for CRT, CRT-D and ICD procedures

Resource	Cost (excluding VAT)	Basis of cost
Device cost:		
CRT	£4,500	Paper to SEHD by Dr E Cummins, March 2005 ⁴²
CRT-D	£13,500	
ICD	£10,500	
Programming costs		
CRT and CRT-D	£77	45 minutes with MTO ₄ + 10% see cardiologist for 20 minutes + echo 20 minutes MTO ₄
ICD	£10	
Pre-procedure outpatient tests and overnight stay	£640	Blue book 2005 ISD ⁴ :
Post-procedure night cost plus X-ray	£470	
Catheterisation laboratory staff per device		
CRT and CRT-D	£550	Assumes in one session can implant 1.5 CRT or CRT-D devices or 3 ICD devices.
ICD	£275	
Cardiologist	£288/session	Staff costs ²⁸ (derived)
Registrar	£217/session	
Nurse F	£77/session	Overheads ¹⁴ (derived) (Refer to table 4 for overhead allocation)
Nurse E	£66/session	
MTO ₄	£88/session	
Radiographer Senior 1	£91/session	
Other consumables per procedure: CRT, CRT-D and ICD	£125	Paper to SEHD by Dr E Cummins, March 2005 ⁴²

Table 32: Unit costs for CRT, CRT-D and ICD procedures (continued)

Resource	Cost (excluding VAT)	Basis of cost
Catheterisation laboratory capital and maintenance costs		Catheterisation equipment capital cost £1.0 m, life 10 years; building capital cost £0.2 m, life 20 years.
CRT and CRT-D	£250	Maintenance costs 3% per year for building costs and 5% per year for equipment
ICD	£125	
Follow-up costs in first year CRT, CRT-D and ICD	£545	In first year 3 MTO4 led clinics plus 3 alternate consultant/nurse led clinic, with tests.
Cost per infection	£5,325	Additional length of stay 8.1 days ⁴³ , at cost per day of £656 ³ (Infection rate 1 %).

5.5.2 TOTAL COST TO IMPLEMENT CRT AND ICD RECOMMENDATIONS

The total cost to manage patients receiving these devices during their first year was estimated at £8.0 million excluding VAT (£9.2 million including VAT). The largest cost element comprised the devices at £6.3 million (excluding VAT), with staffing at £0.25 million, overheads at £0.5 million and bed days at £0.7 million. The capital costs were £1.2 million excluding VAT (£1.4 million including VAT). Further costing details by device type excluding VAT are presented in Table 33.

Table 33: Total cost of implementing the CRT and ICD recommendations (excluding VAT)

Intervention	Patient numbers	Cost (£ million)*
CRT		
Patients (including re-interventions)	245	
Device and implantation costs		1.3
Other costs		0.5
Total costs		1.8
CRT-D		
Patients (including re-interventions)	122	
Device and implantation costs		1.7
Other costs		0.3
Total costs		2.0
ICD		
Patients (including re-interventions)	341	
Device and implantation costs		3.7
Other costs		0.6
Total costs		4.3
Totals		
Patients (including re-interventions)	708	
Device and implantation costs		6.7
Other costs		1.3
Grand total of costs		8.0

* Totals may not add due to rounding

These costs do not include those associated with operating clinics after the first year, or the cost of device replacement when the battery life is exhausted after 4-6 years. Follow-up clinics in the second and subsequent years are estimated to cost £350 for each patient receiving a CRT or CRT-D device and £175 for each patient receiving an ICD device. The costs assume that each ICD patient attends a technical clinic operated by an MTO4 and a clinic that alternates between nurse and consultant led. Patients receiving CRT are assumed to attend such clinics every 6 months.

5.6 BED DAYS

The total bed days assumed were 1,416, comprising an overnight stay before and after each procedure for the 708 patients. If centres have the support of pre-assessment clinics and can admit on the day of the procedure, then half of these days will not be required. Infections were assumed to require a further 57 hospitalisation days per year.

5.7 SENSITIVITY ANALYSES

5.7.1 PATIENT NUMBERS

These costs are most sensitive to the assumed number of patients. For example, if the number of patients receiving a device was 400 per year, rather than the base case estimation of 675, then the estimated annual operating costs fall to around £4.1 million (from a base case cost of £8.0 million) should the number of patients be 950 per year, annual costs would rise to almost £13.0 million (excluding VAT).

5.7.2 COST OF DEVICES

Recent experience in purchasing stents has shown a trend to lower prices. If such a trend materialises for these devices and the price drops by a third from the prices set out in table 32, the annual costs could fall by £2.1 million to £5.9 million.

5.7.3 LENGTH OF STAY

The base case assumes that each patient receiving a CRT or CRT-D device stays in hospital for 1 night before the procedure and 1 night after. If it is assumed that all ICDs are implanted on an emergency admission basis and that the procedure does not alter the length of stay and no CRT or CRT-D patients require a night pre-procedure but all require a night post-procedure, then hospitalisation costs would fall by about £0.3 million.

6 Heart failure post-discharge services

6.1 BACKGROUND

In addition to the key recommendation on CRT (Section 5), the other key recommendations identified in the Chronic Heart Failure guideline (SIGN 95) are the introduction of national post-discharge services, addressed in this section, and additional medication, addressed in section 9.

Currently, all heart failure patients on discharge from an acute event receive primary care services only. SIGN guideline 95 recommends that patients discharged with a diagnosis of heart failure receive home based post-discharge services from specialist nurses. In addition, stable heart failure patients on optimal drug treatment, should receive telephone follow up from specialist heart failure nurses.

The following key recommendations were identified in the Chronic Heart Failure guideline:

6.2 [A] *Comprehensive discharge planning should ensure that links with post-discharge services are in place for all those with symptomatic heart failure. A nurse led, home based element should be included.*

6.2.1 [A] *Follow up (including by telephone) by trained heart failure nurses should be considered for patients post-discharge or with stable heart failure. Nurses should have the ability to alter diuretic dose and the interval between telephone calls, and recommend emergency medical contact.*

6.2 PATIENT GROUP

Approximately 6,000 heart failure patients are discharged from Scottish hospitals each year². Some of these may not be eligible for nurse led post-discharge service because of co-morbidities, particularly if cognitively impaired, or if the patient is resident in a care home.

6.3 CLINICAL BENEFITS AND ASSOCIATED RESOURCE SAVINGS

A systematic review and meta-analysis by Gohler et al⁴⁴ considering the evidence on patient disease education programmes and continuing support after discharge, included 36 RCTs from 1993-2005 and a total of 8,341 patients. Pooling studies reporting all-cause mortality data identified a statistically significant mortality difference of 3% (95% confidence intervals 1-5%, $P < 0.01$), corresponding to a number needed to treat to avoid one event (NNT) of 33 (95% confidence intervals 1-55, $P < 0.01$).

Pooling data from studies reporting all-cause re-hospitalisation identified a statistically significant difference of 8% (95% confidence intervals 5-11%, $P < 0.0001$), corresponding to a NNT of 13 (95% confidence intervals 9-20%). The absolute risk reduction for all cause second readmissions was 19% (95% confidence intervals 2-35%, $P < 0.01$).

The re-hospitalisations avoided result from a combination of heart failure and all-cause events. A meta-analysis by McAlister⁴⁵ reported data on 13 trials with heart failure re-hospitalisation and all cause re-hospitalisation as endpoints. In the control arms, around 65% of re-admissions were for heart failure. This ratio dropped to 52% in the intervention arm and indicated that the intervention was more efficacious in reducing heart failure re-hospitalisations than other re-hospitalisations. Thus this analysis assumed that all re-hospitalisations avoided were for heart failure. A second meta-analysis by Phillips et al⁴⁶ reported that the intervention did not produce a statistically significant reduction in the mean length of stay for each patient.

ISD data³ show that in the year to 31 March 2006 the mean length of stay for patients admitted with heart failure was 16.0 days, with a mean cost of £5,105 per patient (see Table 3).

Combining this information gives estimates of the potential clinical benefit of introducing such a programme as shown in Table 34. These assume that 80% of the 6,000 heart failure patients discharged each year with heart failure are eligible for such a programme, with reasons for ineligibility including co-morbidities and residency in a care or nursing home.

No benefit from second and subsequent re-admissions was estimated because this was not an endpoint in the trials. However patients may see such benefits.

Table 34: Annual clinical benefit and associated savings from a heart failure discharge programme

Event	ARR	Annual clinical benefit
All cause mortality	3%	144 deaths avoided
All cause first readmission	8%	384 readmissions 6,150 bed days saved £2.0 million savings

These savings increase to about £2.3 million when a saving of £2,270 per death avoided is included (see section 2.2.1).

No studies have reported on the impact of introducing discharge support programmes on resources required from existing primary care physicians and nurses who currently manage these patients. However ISD data show the annual mean GP contact rate is 2.15 contacts per heart failure patient, suggesting that if 4,800 patients are managed by a post-discharge service the number of GP contacts could fall by around 10,000 annually.

Assuming a GP has 30 hours of patient contact for each of 44 weeks per year and each appointment avoided saves 12 minutes, this equates to an annual saving of about 1.5 GPs, equivalent to £150,000. However such savings are not evidenced based and are not considered further.

6.4 RESOURCE REQUIREMENTS

In order to provide comprehensive post-discharge services up to 50 nurses (G grade) and 10.5 administrators (A&C 3) were estimated to be required to allow symptomatic heart failure patients to receive nurse led home based services. A service with up to 50 nurses would provide one heart failure nurse per 100,000 population. This is the service level recommended in the Heart Failure Standards⁴⁷, adopted by the British Cardiac Society in 2004, and those of the European Society of Cardiology⁴⁸.

These estimates are based on the Glasgow heart failure discharge service which currently has 7.5 WTE heart failure specialist nurses and a nurse co-ordinator. Each nurse has 8 hours per week of administrative support to organise clinics and home visits, and record the outcomes of each patient contact. Currently this service provides home visits and nurse led clinics for more stable patients, with telephone follow up of any test results. In addition, IT support and other staff resources would be required to establish and maintain a robust audit database. This has been costed by rounding up the administration effort by 0.5 to 11.

The nature of the service and the interface with GP practices is likely to differ between urban and rural areas. For example in urban areas, nurses currently make home visits in response to patient needs, reducing the call on GP services. Such a demand-led service may not be feasible in rural areas because of the additional logistical problems associated with the need to cover large

geographic areas. In rural areas it is assumed that the ratio of nurses to patients is the same as in urban areas; in reality GPs are likely to retain a larger element of the caring duties. Thus the forecast resources and associated costs are likely to be higher than out-turns.

6.5 COSTS

6.5.1 UNIT COSTS

Table 35 presents the unit costs used to calculate the total resource required to providing comprehensive post-discharge services. Overhead costs of 50% and 35% were added to the unit staff costs for community nurses and administration staff respectively. In addition travel costs of £1.25 per visit were included¹⁴.

Table 35: Unit cost of resources required to provide comprehensive post-discharge services

Staff	Grade	Unit Cost	Source
Heart failure nurse	G	£30,748	SEHD ²⁷
Administrator	A&C 3	£15,087	SEHD ²⁷
Office 6.5 sq m each for 25 staff		£1,650 (per sq m)	Chartered surveyor CBRE

6.5.2 TOTAL COST TO IMPLEMENT HEART FAILURE DISCHARGE PLANNING RECOMMENDATIONS

The estimated total annual cost of implementing comprehensive discharge planning for heart failure patients is £2.3 million, comprising:

Staff costs	£1.54 million
Overheads	£0.75 million
Travel costs	£0.02million
Depreciation	£0.02 million

Capital costs were forecast at £0.4 million excluding VAT (£450,000 including VAT), and assumed that 11 administration staff and 25 nurses were provided with office space, with other nurses 'hot-desking'.

6.6 BED DAYS

Implementing the recommendation will have no direct impact on bed days in the acute sector, being a community based service. However, the intervention will save an estimated 6,150 bed days per year in the acute sector (Section 6.3) as a direct result of fewer re-hospitalisations.

6.7 SENSITIVITY ANALYSES

The Glasgow service manages patients with impaired systolic dysfunction only. If the service was provided to all patients with heart failure then patient numbers could increase by about a third and costs would rise in line with this change resulting in a revised annual cost of £3.3 million.

7 Prevention of Coronary Vascular Disease a

7.1 BACKGROUND

The key recommendations identified in the risk estimation and prevention of CVD guideline (SIGN 97), modify the risk assessment thresholds and subsequent management of individuals at high risk of CVD. These recommendations result in major changes in patient numbers and require additional resources.

7.1.1 RISK ASSESSMENT

Based on current procedures, risk assessment occurs in asymptomatic individuals aged 35-69 years with one or more of the following risk factors:

- diabetes
- hypertension
- smoking
- family history of premature CHD
- clinical signs of hyperlipidaemia.

SIGN 97 recommends risk assessment of all individuals over 40 years of age, except those with a history of CVD or diabetes and those being treated for blood pressure or lipid reduction. These changes are in line with the Joint British Society 2 (JBS2) guidelines⁴⁹ and will result in many more patients requiring CVD risk assessment.

The following recommendation was considered key to the Prevention guideline:

3.4 [D] *All adults over the age of 40 who have no history of cardiovascular disease or diabetes (type 1 or 2) and who are not being treated for blood pressure or lipid reduction should have their cardiovascular risk estimated at least once every five years.*

7.1.2 MANAGEMENT OF PATIENTS WITH HIGH CVD RISK

SIGN 40 (Lipids and the primary prevention of CHD), published in 1999, recommended that individuals with a 30% CHD risk over 10 years receive primary prevention therapy. This has been updated in SIGN 97, which modifies the risk threshold for primary prevention therapy to a 20% CVD risk over 10 years, and considers global patient risk rather than individual risk factors.

Estimates extrapolated from the Scottish Health Survey 2003⁵⁰ suggest that using the criteria set out in SIGN 40, 1 in 21 asymptomatic individuals aged 35-69 years of age fall within risk thresholds for treatment, reducing to 1 in 13 if extended to asymptomatic individuals aged 40 years of age or over. Updating these statistics using criteria set out in SIGN 97, means that almost 1 in 3 asymptomatic individuals aged 40 years of age or over will fall within the risk thresholds for treatment and 1 in 4 will be identified as being at high CVD risk and requiring lifestyle advice and drug therapy.

The following recommendations were considered the key to the Prevention guideline:

- 3.4[D] *Individuals with symptoms of cardiovascular disease or who are over the age of 40 years and with diabetes (type 1 or 2) or familial hypercholesterolaemia should be considered at high risk ($\geq 20\%$ risk over 10 years) of cardiovascular events.*
- 3.4[D] *Asymptomatic individuals should be considered at high risk if they are assessed as having $\geq 20\%$ risk of a first cardiovascular event over 10 years.*
- 3.4 [D] *Individuals at high cardiovascular risk warrant intervention with lifestyle changes and consideration for drug therapy, to reduce their absolute risk.*

7.2 PATIENT GROUP

The assumptions made to calculate the additional numbers of individuals requiring risk assessment and those identified at high CVD risk are outlined in Appendices 10 and 11. In order to calculate the additional patient numbers based on these assumptions, mid-2005 population estimates were used⁵¹, which provided analyses at the national and the health board level.

To inform on the likely numbers of additional individuals at high risk under SIGN 97, data from the risk factor analysis¹² were used to calculate the proportion of individuals with secondary and primary CHD and CVD in Scotland, by age and sex. The risk factor analysis¹² used the Framingham equation rather than the ASSIGN score. The latter was not validated at the time of producing this report. The proportion of high risk patients in each group was extrapolated to the national level using data from the Registrar General⁵¹.

In an attempt to understand current practice throughout Scotland a survey was sent to the CHD Managed Clinical Network (MCN) members⁵². The response to this survey informed the assumptions adopted.

7.2.1 RISK ASSESSMENT

The change in risk assessment criteria means that 1,485,000 individuals require a CVD risk assessment, instead of the 1,280,000 that currently require a CHD risk assessment. Of these 1,485,000 individuals it was assumed that 30% (445,000) do not attend risk assessment⁵³. Therefore approximately 1,040,000 individuals require a CVD risk assessment once every 5 years, and assuming these assessments are spread equally over the 5-year period 210,000 assessments could take place annually.

Of the 1,280,000 individuals who currently require risk assessment, it was estimated 775,000 receive a CHD risk assessment once every 5 years (155,000 per annum). It was assumed that of the 1,280,000 individuals who require risk assessment all patients with diabetes (95,000) and/or treated for hypertension, i.e. 340,000 patients with systolic blood pressure (SBP) > 150mmHg and/or diastolic blood pressure (DBP) > 90mmHg attend and receive formal risk assessment. Of the remaining 845,000 individuals it was assumed that 30%⁵³ do not attend and 30% represent existing unmet demand⁵². Thus it is estimated that of this group 340,000 individuals receive formal risk assessment.

As it is estimated 1,040,000 CVD risk assessments are required in comparison with 775,000 CHD risk assessments, an additional 265,000 individuals require a CVD risk assessments once every 5 years.

Assuming that the 265,000 risk assessments are spread equally over the 5-year period (ie. 20% of risk assessments take place each year) approximately 50,000 additional risk assessments would be required each year. This number reduces after 5 years, as a proportion of individuals assessed will have been identified at high risk. The risk factor analysis¹² suggests that 4.7% of those currently assessed will be identified at high CHD risk ($\geq 30\%$ CHD risk over 10 years) and

28.4% of those who have their CVD risk assessed would be identified as being at high CVD risk (\geq 20% CVD risk over 10 years). Applying these factors results in only 1,000 additional assessments being required per annum from year 6 onwards.

7.2.2 MANAGEMENT OF PATIENTS WITH HIGH CVD RISK

The requirement to manage those identified with a \geq 20% CVD risk equates to approximately 580,000 additional individuals (23% of the population over 40 years of age) who require lifestyle advice and drug therapy over the 5-year programme. This comprises 87,000 patients with established disease and 493,000 asymptomatic individuals.

Of the asymptomatic individuals, approximately 294,000 could be identified from the one million risk assessments carried out every 5 years: the remaining groups are assumed to be currently assessed and comprise: 139,000 asymptomatic individuals with sustained SBP \geq 150mmHg and/or DBP \geq 90mmHg and hence receiving hypertensive therapy, 23,000 asymptomatic individuals who are treated with lipid lowering agents and 37,000 individuals with diabetes.

Assuming all patients with established CVD (87,000) who require additional drug therapy are identified in year one and the asymptomatic individuals at high risk (493,000) are identified at a constant rate over the 5 years, approximately 185,000 patients will require medical management in the primary care sector in year one, with an additional 98,000 patients each year in years 2-5. Table 36 outlines the number of symptomatic and asymptomatic patients who require medical management in years 1-6.

Table 36: Number of patients who require medical management in years 1-6

	Year					
	1	2	3	4	5	6
Symptomatic	87,000	87,000	87,000	87,000	87,000	87,000
Asymptomatic	98,000	197,000	295,000	393,000	492,000	492,000
Total	185,000	284,000	382,000	480,000	579,000	579,000

It was assumed that 25% of high risk asymptomatic individuals will be smokers⁵⁰ and will, therefore, be encouraged to join smoking cessation programmes. An estimated 3.3% (3,000 individuals) will take up the referral per annum over years 1-5 (16,000 individuals in total) and, using rates consistent with those observed by the SEHD⁵⁴ and Department of Health⁵⁵, approximately 20% are likely to successfully stop smoking. It was assumed that all patients with established CVD have previously been offered this service.

Once identified as being at high risk, overweight and obese asymptomatic individuals should receive dietary advice. Assuming that 72% of the Scottish population aged 40 years or over are overweight or obese⁵⁶, and applying this rate to asymptomatic people at high CVD risk, approximately 350,000 individuals should receive dietary advice from their GP or practice nurse in the 5 years after guideline implementation (70,000 people per annum). Assuming 29% of the Scottish population are obese⁵⁶, approximately 145,000 individuals should be referred to a dietician (equating to 29,000 patients per annum).

7.3 CLINICAL BENEFITS AND ASSOCIATED RESOURCE SAVINGS

The main clinical benefits of identifying individuals at high risk are assumed to result from the provision of interventions to change lifestyle and provide drug therapy. The main lifestyle interventions comprise provision of dietary advice and smoking cessation therapies. The advantages of drug therapies are quantified in section 8.3 for statins and section 9.6 for aspirin and blood pressure lowering therapies.

Dietary advice

A Cochrane review⁵⁷ reported an annual 2% reduction in all-cause mortality and 24% reduction in cardiovascular events as a result of dietary interventions to reduce fat intake. No absolute risk rates were presented.

The control arm of ASCOT-LLA⁵⁸ was assumed to capture the underlying absolute risks facing an obese population, but this may understate the actual risks for an obese group. The potential events avoided and associated bed day and cost savings following the provision of dietary advice are presented in Table 37, assuming a mean follow-up period for the trials of three years.

No benefit was assumed from providing dietary advice as a brief intervention to the overweight group. As a sensitivity analysis, if all individuals experienced a similar risk reduction to that assumed for the obese group then the annual mortality benefit could rise from 122 to 500 and potential savings from £1.0 million to £4.1 million.

Table 37: Annual clinical benefit from dietary interventions to 170,000 obese individuals

Event	ARR (%)	RRR (%)	Annual events saved	Annual bed days saved	Annual cost savings (million)
All cause mortality	4.13	2	122	856	£0.3
Unstable angina	0.47	24	71	305	£0.1
Stable angina	1.09	24	166		£0.3
Peripheral artery disease	0.80	24	122	1,011	£0.3
Arrhythmias	0.06	24	9	74	£0.0
Total (excluding mortality benefit)	6.54		368	1,390	£0.7
Total (including mortality benefit)			490	2,246	£1.0
If gain applies to all overweight and obese individuals			2,013	9,216	£4.1

Smoking cessation

Evidence of the benefit of reducing CVD risk by stopping smoking has been taken from a meta-analysis⁵⁹ and a review statement from the American Heart Association⁶⁰. The former reported the relative risk of ischaemic heart disease from smoking 20 cigarettes a day as 1.78, whilst the latter noted that stopping smoking after an infarction reduces the risk of a subsequent event by 50%. 4,000 individuals are forecast to cease smoking following the intervention. Applying these risk rates to the absolute events in Table 35 and assuming a mean follow up period for the trials of five years, gives a mortality benefit of 80 - 130, an absolute reduction in other events of 50 - 75, annual bed day savings of 50 and savings from fewer admissions and deaths of under £0.1 million.

This benefit understates the benefit to NHSScotland from the smoking cessation intervention, by only considering the reduction in CVD events.

7.4 RESOURCE REQUIREMENTS

The analyses assume that one fifth of the asymptomatic population who attend for CVD risk assessment will be assessed in each of the first 5 years, asymptomatic high risk individuals will be identified at a constant rate over this period, and patients with established CVD who require additional drug therapy are identified in the year following implementation.

7.4.1 STAFF REQUIREMENTS

The staffing requirements presented only consider additional individuals, currently 40 years or over and assessed following implementation of the guideline. It does not include additional staff required to assess or manage individuals who are currently under 40 years of age.

Risk Assessment

Assuming 20% of individuals undergo risk assessment with their GP and 80% with a practice nurse^{53,61} during one 15 minute appointment, approximately one additional GP, seven practice nurses and two administrators would be required to assess the extra 50,000 individuals per annum in the 5 years after implementation. As patients at high CVD risk are identified, the resource requirements for risk assessment would fall and as a result there are no additional staff requirements from year 6, as detailed in Table 38. It is assumed throughout this report that an additional 4 minutes administrative time is required per appointment.

Table 38: Additional staffing requirements for CVD risk assessment

	Year 1	Year 2	Year 3	Year 4	Year 5	Years 6+
GP	1.2	1.2	1.2	1.2	1.2	0.0
Practice nurse	6.7	6.7	6.7	6.7	6.7	0.0
Administrator	2.0	2.0	2.0	2.0	2.0	0.0
Total	9.9	9.9	9.9	9.9	9.9	0.0

These additional staff requirements assume that current work practices continue; however extended work hours or re-prioritisation of duties could reduce the number of staff required.

Management of patients with high CVD risk

This assessment of staffing requirements assumes that at present existing patients with CVD, asymptomatic individuals at high risk of CVD who are currently being treated for lipid reduction or hypertension (>150/90), and diabetic patients (40% of additional high CVD risk patients), visit their GP or practice nurse regularly. The additional time required for initiation of additional drug therapy and identification of high CVD risk status is equivalent to two additional appointments per annum; one with their GP and the other with a practice nurse in the year of identification, with an additional 5 minutes per annum with the GP in the years following identification.

All other asymptomatic patients (60%) are assumed to require three appointments for lifestyle advice and drug therapy in the primary care setting in the year of identification, initially with the GP and on consecutive visits with a practice nurse, reducing to one appointment with their GP in the years following identification.

Assuming the above, a total of 22 GPs, 39 practice nurses and 17 administrators would be required in the first year. In year 2 the numbers of GPs increase slightly to 24 while the number of practice nurses and administrators decrease to 26 and 14 respectively. This is because existing patients require less contact time once on optimal drug therapy. The number of GPs, practice nurses and administrators required to manage those secondary patients who initiated additional drug therapy and those primary patients identified in year one (all of whom are on optimal drug therapy in year 2), drop to 12, 0 and 4 respectively. The number of GPs and administrators required then increase until year 6 as more primary patients are identified and receive optimal drug therapy.

However to manage the 98,000 primary patients that are identified each year in years 2-5, there is a requirement for 12 GPs, 25 practice nurses and 10 administrators each year. From year 6 the staffing requirements are stable at 47 GPs and 15 administrators to address the patient demand. It is assumed that an additional 4 minutes administrative time is required per appointment.

Assuming asymptomatic individuals with a body mass index >30 kg/m², are referred to a dietician for advice during two 30 minute appointments, 19 dieticians would be required to meet annual demand in the 5 years after guideline implementation, as detailed in Table 39.

Table 39: Additional staff required to manage patients with high CVD risk

	Year 1	Year 2	Year 3	Year 4	Year 5	Years 6+
GP	22.3	23.7	32.8	41.1	49.7	47.0
Practice nurse	39.4	25.6	25.6	25.6	25.6	0.0
Administrator	17.0	14.1	16.9	19.8	22.8	15.4
Dietician	18.8	18.8	18.8	18.8	18.8	0.0
Total	97.5	82.2	94.1	105.3	116.9	62.4

These additional staff requirements assume that current work practices will continue. However, extended work hours and/or or utilisation of the pharmacy contract (currently under development), in which it is expected that patients could visit their local pharmacist for titration of existing drugs and other services, could reduce the need for additional resources.

Total Additional Staff

Assuming no change in working practices a total of 24 GPs, 46 practice nurses, 19 administrators and 19 dieticians would be required in year 1 (see Tables 36, 37 and 38). The staffing requirements then increase to a maximum of 51, 32, 25 and 19 respectively in year 5, before declining to a stable 51 GPs and 17 administrators in year 6.

The potential implication on laboratory staffing requirements was reviewed as part of this assessment. However due to the small increase (1.7% - 2.9%) in non-urgent workload as a result of these recommendations it was assumed that this could be absorbed within current staffing levels, due to asymmetrical nature of the daily workload profile. This increase was calculated for Dumfries and Galloway and is assumed to apply throughout Scotland⁶². The findings were similar when considering the impact on smoking cessation staff workloads. Table 40 details the overall staffing requirements for years 1-6.

Table 40: Total staffing requirements for CVD risk assessment, management of patients with high CVD risk recommendations

	Year 1	Year 2	Year 3	Year 4	Year 5	Years 6+
GP	23.5	24.9	34.0	42.3	50.9	47.0
Practice nurse	46.1	32.3	32.3	32.3	32.3	0.0
Administrator	19.0	16.1	18.9	21.8	24.8	15.4
Dietician	18.8	18.8	18.8	18.8	18.8	0.0
Total	107.4	92.1	104.0	115.2	126.8	62.4

The staffing requirements to risk assess and manage patients with high CVD risk for year 1, on a national and NHS board levels are presented in Appendices 12 and 13.

7.4.2 CAPITAL REQUIREMENTS

Risk Assessment

In order to accommodate additional staff required for risk assessment 10 extra rooms would be required during years 1-5 reducing to nil in year 6. It was assumed that the additional accommodation required in the 5 years following guideline implementation would be used for other purposes from year 6. As a sunk cost relating to guideline implementation the annual depreciation charge would continue. However, if extended hours were used to meet the additional staffing demand this accommodation requirement would not apply, resulting in no additional capital investment or depreciation charges.

Management of patients with high CVD risk

In order to accommodate the staff and related facilities required to manage the additional high risk individuals, 61 extra rooms would be required in the first year, the accommodation requirements then reduce to 49 rooms in year 2, increasing each year to a maximum of 74 in year 5. However from year 6 only 46 of the 74 rooms would be required. It was assumed that the excess accommodation (28 rooms) would be used for other purposes from year 6, nevertheless as a sunk cost relating to guideline implementation the annual depreciation charge would continue. However, under the pharmacy contract currently under development, it may be that individuals at high risk of CVD could visit their local pharmacist for titration of existing drugs and other services, and thus reduce the short term (years 1-5) requirement for additional accommodation; extended working hours would have a comparable effect.

Total

The total estimated accommodation requirements comprise 71 rooms in year 1, increasing to a maximum of 84 rooms in year 5. In total it is estimated that 46 rooms could be required from year 6 with the 38 excess rooms being utilised in a different capacity. The risk assessment and management of patients with high CVD risk and capital requirements for year 1 are presented on a national and health board level in Appendices 12 and 13.

7.5 COSTS

The analyses assume that one fifth of the asymptomatic population who attend risk assessment appointments will be risk assessed in each of the first 5 years, with asymptomatic high CVD risk individuals being identified at a constant rate over this time period and secondary patients requiring additional drug therapy being identified in the year following implementation.

7.5.1 UNIT COSTS

Table 41 details the unit costs of the resources required to assess and manage CVD risk.

Table 41: Unit cost of resources required to assess and manage CVD risk

Item	Unit Cost	Source
GP	£100,000	Net remuneration 2006/2007 £100,000 assumed
Practice nurse	£30,047	Net 04/05 remuneration £23,355 ²⁸ + salary oncosts of 21.3% ¹⁴ + 3.5% inflation 2005/2006 + 2.5% inflation 06/07
Administrator	£15,765	Assume one WTE for each 25,000 additional appointments (4 minutes per appointment ⁵³ . Average 2006/2007 salary of £13,000 assumed + salary oncosts of 21.3% ¹⁴
Dietician	£36,437	Net 2004/2005 remuneration £28,240 ²⁸ + salary oncosts of 21.6% ¹⁴ + 3.5% inflation 2005/2006 + 2.5% inflation 2006/2007
Smoking cessation clinic	£112.00	NICE ⁶³
Consumables (excluding lab costs)	£2.37*	ISD ² and St Margaret's Health Centre ⁶⁴
Dietary advice leaflet	£0.14*	NICE ⁶⁵ + VAT
Liver function, total and HDL - cholesterol and glucose tests	£7.90†	Dumfries and Galloway ⁶²
Full blood count	£4.99†	Dumfries and Galloway ⁶²
Creatine kinase test	£4.99†	It was assumed that these tests occur on average once after statin treatment for those considered at high risk Dumfries and Galloway ⁶²
Nicotine replacement therapy	£24.87*	NICE ⁶³ + VAT
Consultation rooms (16.5 sq m)	£31,994*	£1,650 per sq m ⁶⁶ (this includes allocation for public spaces)

*VAT inclusive

†VAT exempt

7.5.2 TOTAL COSTS TO IMPLEMENT CVD PREVENTION RECOMMENDATIONS

Tables 42 and 43 outline the annual costs involved in implementing the key recommendations regarding risk assessment and management of patients with high CVD risk. Table 44 shows the total annual costs of implementing all key recommendations within the CVD Prevention guideline (SIGN 97).

Table 42: Total annual cost (including VAT) of implementing risk assessment recommendations

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6+
Direct Staffing	0.4	0.4	0.4	0.4	0.4	0.0
Overheads	0.1	0.1	0.1	0.1	0.1	0.0
Consumables	0.8	0.8	0.8	0.8	0.8	0.0
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0
Total	1.3	1.3	1.3	1.3	1.3	0.0

The estimated total annual cost of implementing the risk assessment recommendation was £1.3 million (including VAT) in years 1-5, falling to approximately £30,000 in year 6. Where VAT is excluded the costs reduce by £18,500 in years 1-5 and £500 in year 6.

A capital budget of £320,000 including VAT (£270,000 excluding VAT) would also be required in the first year to purchase additional accommodation.

Table 43: Total annual cost (including VAT) of implementing management of patients with high CVD risk recommendations

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6+
Direct Staffing	4.4	4.0	5.0	5.9	6.8	4.9
Overheads	1.2	1.0	1.1	1.2	1.3	0.6
Consumables	4.7	4.4	5.4	6.4	7.4	5.9
Smoking cessation	0.7	0.7	0.7	0.7	0.7	0.0
Depreciation	0.1	0.1	0.1	0.1	0.1	0.1
Total	11.1	10.2	12.3	14.3	16.3	11.5

The estimated total annual cost of implementing the management of patients with high CVD risk recommendations was approximately £11 million (including VAT) in year 1, rising to approximately £16 million in year 5. Thereafter annual costs are expected to stabilise at £12 million. Where VAT is excluded the total costs reduce by £0.2 million in years 1-3, £0.3 million in years 4 and 5 and £0.2 million from year 6.

An initial capital budget of £2.0 million would be required in year 1 (£1.7 million excluding VAT), with additional capital budget of £0.2 million in years 4 and 5. Thus, the total capital budget required is £2.4 million over 5 years (£2.0 million excluding VAT).

Table 44: Total annual cost (including VAT) of implementing key risk estimation and prevention of CVD recommendations

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6+
Direct Staffing	4.8	4.4	5.4	6.3	7.2	4.9
Overheads	1.3	1.1	1.2	1.3	1.4	0.6
Consumables	5.5	5.2	6.2	7.2	8.2	5.9
Smoking cessation	0.7	0.7	0.7	0.7	0.7	0
Depreciation	0.1	0.1	0.1	0.1	0.1	0.1
Total	12.4	11.5	13.6	15.6	17.6	11.5

A total capital budget of £2.7 million (including VAT) would be required, an initial budget of £2.3 million in year 1, with additional £0.2 million in years 4 and 5. Excluding VAT a total capital budget of £2.3 million would be required, an initial budget of £1.9 million in year 1, with additional £0.2 million in years 4 and 5.

7.5.3 BREAKDOWN OF TOTAL COSTS REQUIRED TO IMPLEMENT CVD PREVENTION RECOMMENDATIONS

The costs for years 1 to 5 are outlined below and the estimated costs in year 1 for health boards are presented in Appendices 14 and 15. Appendix 14 presents the expenditure for risk assessment, and Appendix 15 details expenditure in relation to the management of high CVD risk patients.

Direct Staffing

The total additional staffing costs for risk assessment approximate to £350,000 per annum in years 1-5, and nil from year 6 onwards. In years 1-5 the costs include: £120,000 per annum for GPs, £200,000 for practice nurses and £30,000 for administrators.

The staffing costs involved in managing patients with high CVD risk were estimated at £4.3 million in year 1 and were predicted to decrease slightly to £4.0 million in year 2, before increasing each year to a maximum of £6.8 million in year 5. Staff costs are then expected to stabilise at £4.9 million from year 6. These figures include GP, practice nurse, administrator and dietician staffing costs of £2.2 million, £1.2 million, £0.2 million and £0.7 million respectively in year 1, and £5.0 million, £0.8 million, £0.3 million and £0.7 million respectively in year 5. The total additional staff costs from year 6 include £4.7 million GP and £0.2 million administrator costs.

Overheads

The total additional overhead costs for risk assessment were estimated at approximately £125,000 per annum in years 1-5, and nil from year 6 onwards. These costs comprised: 81% for practice nurse overhead costs, 10% for GPs and 9% for administrators.

The additional overhead costs for managing patients with high CVD risk were estimated at £1.2 million in year 1, £1.0 million in year 2 rising to £1.3 million in years 5 and £0.6 million from year 6. In year 1 the overhead costs were estimated at: £0.2 million for GPs, £0.6 million for practice nurses, £0.1 million for administrators and £0.3 million for dieticians. In year 5 the costs were estimated at £0.5 million, £0.4 million, £0.1 million and £0.3 million respectively. From year 6 GP and administrator overheads remain at £0.5 million and £0.1 million respectively, with no overhead costs for practice nurses and dieticians.

Consumables

The consumable costs related to the additional CVD risk assessments required were estimated at £805,000 per annum (including VAT) in years 1-5, falling to £16,000 from year 6 onwards. The majority comprised laboratory costs, with a small proportion (0.13%) incurred in the primary care setting. Excluding VAT reduced these costs by £18,500 in years 1-5 and £500 in year 6.

The consumable costs associated with managing high CVD risk individuals were estimated at £4.7 million (including VAT) in year 1, decreasing to £4.4 million in year 2, before increasing annually by £1.0 million in years 3-5. The costs are then estimated to stabilise at £5.9 million per annum in year 6. The majority (80%) of these costs comprised laboratory costs, with a small proportion (0.2%) incurred in the primary care setting. Excluding VAT reduced these costs by reduce by £0.1 million in years 1-3, £0.2 million in from year 4.

Smoking Cessation

Smoking cessation costs were associated with CVD risk management over the first 5 years only, as it was assumed that patients would only receive such treatment when initially identified as at high risk. The estimated cost of this service was £0.7 million per annum (including VAT), comprising £0.4 million for clinic referrals and £0.3 million for nicotine replacement therapy. The total service cost per annum was reduced by £50,000 when excluding VAT.

Capital cost and related annual depreciation charge

The capital cost to accommodate additional staff for risk assessment was estimated at £320,000 including VAT in year 1 (£270,000 excluding VAT); assuming straight line depreciation over 20 years the annual depreciation charge was £14,000.

Capital cost to accommodate additional staff for the management of high CVD risk patients was estimated at £2.0 million (including VAT) in year 1, with additional £0.2 million in years 4 and 5, totalling £2.4 million by the end of year 5. The initial costs reduce to £1.7 million, while the costs in years 4 and 5 remain at approximately £0.2 million, totalling £2.0 million by year 5 when excluding VAT.

Assuming straight line depreciation over 20 years the annual depreciation charge was approximately £85,000 in years 1-3, increasing to £90,000 in year 4 and £100,00 in year 5 then remaining constant. Capital costs and related annual depreciation charges over years 1-5 are detailed in Appendix 16.

Expenditure by NHS Board

The total expenditure (including VAT) for risk assessment and management of high CVD risk individuals are summarised over years 1-6 in Appendices 17 and 18 nationally and by NHS board. Appendix 19 presents the total estimated expenditure of implementing the key recommendations within SIGN guideline 97 for each NHS board. An Excel template that can be used to calculate costs and resource requirements for specific regions or a specific health board population cohort is available on the SIGN website.

7.5.4 COST PER PATIENT

Risk Assessment

The average cost per patient including VAT and excluding capital and related depreciation charges for undertaking CVD risk assessment is £24 in years 1-5 and £15 from year 6. The cost of capital per patient is £1. The depreciation cost per patient is approximately 25 pence in years 1-5, however as patients are identified at high risk this cost increases to £13 per patient from year 6.

Management of patients at high CVD risk

The average cost per patient, including VAT and excluding capital and related depreciation charges, of managing patients with high CVD risk was estimated at £59, £36, £32, £30, £28 in years 1-5 and £20 from year 6. The cost of capital per patient is £4. The depreciation cost per patient is estimated at approximately 45 pence in year 1 reducing annually as more primary patients are identified, the cost per patient stabilises at less than 20 pence from year 5.

These costs include the average cost per patient for all type of expenditure, for example although only a small proportion of patients receive smoking cessation services the cost has been divided by the total number of patients identified each year.

7.6 BED DAYS

Implementing the prevention of CVD recommendations will have no direct impact on bed day requirements in the acute sector, as CVD prevention is a primary care service. However, an estimate of the bed days saved from the resulting fewer hospitalisations is presented in Section 7.3.

7.7 SENSITIVITY ANALYSIS

No sensitivity analyses were undertaken for the prevention of CVD costings.

8 Statin treatment

8.1 BACKGROUND

Previous recommendations (SIGN 40) were that individuals should be considered for lipid lowering drug therapy for primary prevention, usually following a trial of lifestyle measures and other appropriate interventions for at least 3 months, when the total serum cholesterol was ≥ 5.0 mmol/L and the 10 year risk of a major coronary event was $\geq 30\%$. However, the priority for lipid lowering therapy was to target patients with pre-existing cardiovascular disease.

Individuals who had an MI and a total cholesterol ≥ 6.0 mmol/L were recommended to receive drug therapy to reduce cholesterol to under 5.0 mmol/L. If total cholesterol was 5.0-6.0 mmol/L lipid lowering drugs were recommended, if required, to reduce total cholesterol to less than 5.0 mmol/L (SIGN 41).

Updating these recommendations, SIGN 97 recommends treating all patients who have had a CVD event (secondary patients) more aggressively than individuals who are at high risk but remain asymptomatic. This analysis assumes that symptomatic individuals are treated to a minimum total cholesterol level of 5.0 mmol/L (equivalent to a low-density lipoprotein (LDL) cholesterol level of 3.0 mmol/L) using the dosing strategy in Table 45, with those symptomatic patients with total cholesterol level under 5.0 mmol/L receiving simvastatin 40mg. This strategy was adopted as it is consistent with the strategies used by health boards around Scotland.

SIGN 97 also recommends that primary CVD patients (adults over the age of 40 years assessed as having a 10 year CVD risk of $> 20\%$) are treated with simvastatin 40 mg.

Table 45: Assumed statin dosing strategy for secondary patients

Step	Statin therapy prescribed
Start Dose	Simvastatin 40mg
Step 1	Atorvastatin 20mg
Step 2	Atorvastatin 40mg
Step 3	Atorvastatin 80mg

Widening the treatment group to include individuals with a CVD risk $\geq 20\%$, instead of CHD risk $\geq 30\%$ (refer to section 7) will result in increased statin prescription and expenditure. Evidence from the Scottish Health Survey 2003⁵⁰, indicates that not all treated patients currently achieve a total cholesterol level of < 5.0 mmol/L, and this analysis includes the costs of prescribing higher strength statins in such patients to reduce their total cholesterol. As the costs resulting from the implementation of this recommendation are so significant, the topic of statin therapy is covered separately from other medications.

The base case assumed that on implementing the recommendations, secondary patients would follow the above dosing strategy (every 12 weeks) until a level of 5.0 mmol/L or maximum statin dose is achieved with those symptomatic patients with total cholesterol level under 5.0 mmol/L receiving simvastatin 40mg. Consistent with Section 7, it was assumed that 30% of asymptomatic individuals at high CVD risk who are eligible for risk assessment will not be identified due to non-attendance for risk assessment. Of the primary prevention patients identified, it was assumed that all will receive simvastatin 40mg. The base case also assumes discontinuation rates of 22% and 35% (including adverse events (4%)⁶⁷ and contraindications (3%)^{67,68}) after six months for secondary and primary patients respectively^{67,69}.

Sensitivity analyses considered the impact on costs associated with:

- Atorvastatin coming off patent in 2011.
- All patients with PVD currently receive statin therapy.
- Only treating primary patients who are 45-64 years of age, consistent with Prevention 2010.

Scottish Health Survey 2003 data⁵⁰ were used to calculate the total cholesterol distribution for treated and untreated patient groups, and the proportion of individuals achieving target at each step was estimated by combining this data with the efficacy data (see Appendix 20) from the STELLAR trial⁷⁰. The treated cholesterol distributions⁵⁰ were adjusted for changes in prescribing stemming from the operation of the Quality Outcomes Framework (QOF).

The following recommendations refer to the statin therapy target:

9.5 [A] *All adults over the age of 40 years who are assessed as having a ten year risk of having a first cardiovascular event \geq 20% should be considered for treatment with simvastatin 40 mg/day following an informed discussion of risks and benefits between the individual and responsible clinician.*

9.6 [B] *All patients with established symptomatic atherosclerotic cardiovascular disease should be considered for more intensive statin therapy following an informed discussion of risks and benefits between the individual and responsible clinician*

9.7 [GPP] *The existing total cholesterol target of <5 mmol/l in individuals with established symptomatic cardiovascular disease should be regarded as the minimum standard of care.*

8.2 PATIENT GROUP

The results of the risk factor analysis¹² were used in conjunction with mid-2005 population estimates⁵⁰ and total cholesterol (TC) distribution data (Appendix 21) to calculate the additional number of individuals requiring initial or further statin therapy. The TC distribution in Scotland for individuals receiving (treated) and not receiving (untreated) statin therapy was derived from the Scottish Health Survey 2003 data⁵⁰: these were consistent with data from the West of Scotland Coronary Prevention Study⁷¹. In order to adjust the treated TC distribution to incorporate changes in statin prescribing resulting from the operation of the QOF, it was assumed that in 2003 treated individuals were being prescribed Simvastatin 20mg, the TC prior to treatment was then calculated and reduced assuming that Simvastatin 40mg was now prescribed.

It is assumed that currently 92% of both secondary CHD and stroke patients (290,000) receive statin therapy^{53,68,72} and of these approximately 53,000 have not reached the total cholesterol target of 5.0 mmol/L and require more aggressive therapy. The remaining 8% of secondary CHD and stroke patients as well as all peripheral vascular disease (PVD) patients should initiate statin therapy, however, it was assumed that 7% of all patients (25,000) are not prescribed statins⁶⁸, 4% due to adverse effects⁶⁷ and 3% due to contraindications^{67,68}. Thus approximately 42,000 secondary CVD patients require statin therapy, of which it is assumed 15% will discontinue treatment after 6 months^{67,69}. It is expected that all 53,000 secondary patients who require more aggressive statin therapy will continue treatment indefinitely. It is assumed that all secondary patients will initiate or intensify statin therapy in the year following implementation.

It was also assumed that in Scotland 25% of primary CHD prevention patients (43,000) currently receive statin therapy, and of these approximately 8,000 have not reached a total cholesterol level of 5mmol/L. Under SIGN 97 such individuals receive simvastatin 40 mg only so no additional treatment is considered for these patients. Assuming that 7% of individuals are not prescribed statins⁶⁸ (4% due to adverse effects⁶⁷ and 3% due to contraindications^{67,68}), there is current unmet demand of 116,000 primary patients.

The move from treating asymptomatic patients with CHD risk $\geq 30\%$ over 10 years to treating those with a CVD risk $\geq 20\%$ over 10 years will result in more asymptomatic individuals requiring statin therapy. However, as 30% of asymptomatic individuals at high CVD risk who are eligible for risk assessment will not be identified due to non-attendance for risk assessment and that 7% of patients are not prescribed statins⁶⁸, the number of patients estimated to receive statin therapy is 320,000. Therefore the total number of primary patients who are estimated to receive generic statin therapy is 436,000, of which it is assumed 28% will discontinue treatment after 6 months^{67,69}. It was assumed that 20% of primary patients will initiate statin therapy over each of the 5 years following guideline implementation. Appendix 22 details the number of patients initiating and continuing statin treatment over years 1-5.

Table 46 outlines the proportion of patients expected to achieve a target total cholesterol of 5.0 mmol/L, while table 47 details the proportion of secondary patients reaching target at each step. The tables consider primary and secondary patients, and the latter is separated into two patient groups: those who are currently treated with a statin (and require more aggressive therapy) and those who are not currently receiving statins (initiating statin therapy), with each group having a different initial cholesterol distribution profile and thus differing treatment outcomes (Appendix 21).

Table 46: Proportion of patients in which total cholesterol target is achieved

Secondary patients	
Untreated	95.4%
Treated	52.8%
Total	74.1%
Primary patients	
Total	80.8%

Table 47: Proportion of secondary patients achieving a TC target of 5 mmol/L at each dose

	Start Dose	Step 1	Step 2	Step 3	Total
Untreated (Primary start dose only)	80.8%	9.0%	0.0%	5.7%	95.4%
Treated	N/A	0.0%	52.8%	0.0%	52.8%

8.3 CLINICAL BENEFITS AND ASSOCIATED RESOURCE SAVINGS

Benefits from treating asymptomatic individuals to prevent CVD

The evidence base for using statins as primary prevention for CVD has been taken from a meta-analysis⁷³ of seven randomised trials with 42,848 patients of whom 90% had no history of CVD. Mean follow up was 4.3 years. Table 48 presents the results of the meta-analysis.

Table 48: Observed event rates in relevant trials of primary prevention of CVD

Event	Absolute risk statin arm	Absolute risk placebo	Absolute risk reduction
Major coronary	4.3%	5.7%	1.4%
Major cerebrovascular	2.1%	2.4%	0.3%
All cause mortality	6.1%	6.6%	0.5%

The reported major coronary and cerebrovascular events did not identify separately mortality rates from CHD and strokes. These were estimated using data from the Cholesterol Treatment Trialists' Collaborators study⁷⁴ that reported a ratio of 57:43 between vascular and non-vascular deaths and the West of Scotland Coronary Prevention Group⁷⁵ that reported a ratio of 77:23 between CHD and stroke deaths. These estimates were combined with the results of the meta-analysis to derive an indicative number of vascular events avoided.

The meta-analysis did not consider individual diagnoses within the CVD grouping. The events recorded in the CARDS⁷⁶ and ASCOT-LLA⁵⁸ trials were used to derive a weighted average bed days (11.8 days) and associated costs saved (£4,060) from each major CVD event. The estimated potential events avoided and potential annual resource savings from treating 435,000 asymptomatic patients with statins are presented in Table 49.

Table 49: Potential events avoided and related resources saved from treating 435,000 asymptomatic individuals at high CVD risk with a statin

Event	Clinical benefit over 4.3 years	Annual bed days saved	Annual cost savings (million)
Major vascular	6,217	17,050	£5.9
All cause mortality	2,303		
Total	8,520	17,050	£5.9

Benefits from treating symptomatic individuals with statins to prevent further CVD events

The benefit of prescribing statins to symptomatic individuals is derived from two sources, the Heart Protection Study (HPS) Group⁶ and the Treating to New Targets (TNT) study⁷⁷. Of the 95,000 additional patients requiring treatment, 53,000 already take a statin but under the recommendations will be treated more aggressively; the remaining 42,000 are statin naive. The first group may achieve a benefit similar to that seen in the TNT study, whilst the latter are assumed to achieve benefit corresponding to that seen in participants in HPS.

TNT reported no overall mortality benefit and a 5.4% reduction in any CVD event. HPS reported a 1.8% absolute risk reduction for all cause mortality, a 7.4% reduction in major vascular events and a 5.4% reduction for other vascular events. Applying these data to the two patient groups achieves the potential savings presented in Table 50. This analysis uses the same assumed bed days saved and cost avoided per CVD event as for asymptomatic people.

The HPS trial also reported a 2.6% absolute risk reduction in other nonvascular events but no resource benefits were attributed to such reductions.

Table 50: Potential events and resources saved from treating 95,000 symptomatic individuals with a statin

Event	Events avoided	Annual bed days saved	Annual cost savings (million)
Major vascular	9,437	19,770	£6.8
All cause mortality	718		
Total	10,155	19,770	£6.8

8.4 RESOURCE REQUIREMENTS

The additional staff and capital resources required to prescribe statins in primary care, were considered in Section 7.3. It was assumed that primary care patients who do not achieve target cholesterol levels do not need to see a specialist, except for those with heterozygous hypercholesterolaemia as per current practice. Therefore, no additional costs were assumed for primary care patients not reaching the total cholesterol target.

8.5 COSTS

8.5.1 UNIT COSTS

The British National Formulary⁵² and Scottish Drug Tariff were used to calculate the annual cost of the respective statin therapies², including a prescription charge of 91.7 pence per item¹³. While the pharmacist contract is currently under review, it is assumed that the cost to NHSScotland health boards will be similar to current levels.

The annual costs of statin therapy in year 1 and subsequent years are presented in Appendix 26. The costs per annum varied between year 1 (i.e. the year that the patient was identified at high CVD risk or as requiring initiation of more aggressive statin therapy) and subsequent years, because some patients will be treated after the first year with a higher and more expensive statin dose throughout the year (ie. no titration as patient on optimal dose).

The costs in the year of identification have been reduced by 50% to reflect, the likelihood of patients initiating statin therapy throughout the year, ie. not all patients will be identified and start statin therapy at the beginning of the year. While this has not been done with other drugs it has such a large impact on costs (particularly in year 1) that it was deemed necessary in this section.

The costs for years 1-6 are based on current prices and do not take into account when branded drugs come off patent, for example atorvastatin in 2011. The dosing strategies and costs should be reviewed when this occurs, however a sensitivity analysis has been done assuming atorvastatin costs are as per current generic prices.

8.5.2 TOTAL COSTS

The total estimated cost of treating secondary patients to a total cholesterol level of 5.0 mmol/L and primary patients with simvastatin 40mg is approximately £115 million excluding VAT (£135 million including VAT) over 5 years, with the costs in years 1-5 detailed in Table 51. The annual costs remain stable from year 6 and are estimated at £32 million excluding VAT (£38 million including VAT). Appendix 22 details both the drug and prescription charges per annum.

Table 51: Total estimated annual cost of statin treatment in Scotland (including discontinuation rates)

	Cost (£ million)*						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total (Years 1-5)	Year 6+
Costs excluding VAT							
Secondary	8.2	16.8	16.8	16.8	16.8	75.3	16.8
Primary	1.9	5.0	8.1	11.3	14.4	40.6	15.6
Total	10.0	21.8	24.9	28.0	31.2	115.9	32.4
Costs including VAT							
Secondary	9.6	19.7	19.7	19.7	19.7	88.3	19.7
Primary	2.2	5.8	9.4	13.0	16.6	47.0	18.1
Total	11.7	25.4	29.1	32.7	36.3	135.2	37.8

* Totals may not add due to rounding

Although 18% of all patients have established CVD, they accrue 82% of costs in year 1 reducing to 52% in the steady state, with two main cost drivers. Firstly, 55% of secondary care patients already receive statin therapy but require more aggressive therapy. It is assumed that 70%⁶ of these patients currently receive simvastatin at a weighted average dose using ISD prescribing data for year end 31 March 2006² while 30% receive atorvastatin at a weighted average dose for the same period. Most require prescribing statins with a higher efficacy (and cost) in order to reduce their total cholesterol levels to under 5.0mmol/L. This group of patients (treated secondary patients) accrue 75% of the costs for secondary prevention.

Secondly, the assumption that at the start of year 1 there are 16% 'new' statin naïve secondary prevention patients (42,500 PVD patients), who require treatment as a result of the widening of the disease group to CVD rather than CHD. Such patients will start on first-line therapy using the least expensive statin.

No discontinuation of prescriptions

The values in Table 51 assume discontinuation rates for prescriptions of 15% and 28% respectively for symptomatic and asymptomatic individuals at 6 month: Table 52 provides the estimated cost of statin therapy where no discontinuation occurs.

In comparison, the base case total cost over the first 5 years were £116 million (excluding VAT), some £19 million lower and the annual cost from year 6 was £33 million, £13 million lower. The estimated discontinuation rates are for those receiving statin therapy, and therefore do not consider the 7% of patients who are not prescribed statins due to adverse effects and contraindications.

Table 52: Total annual cost of statin treatment in Scotland assuming no discontinuation

	Cost (£ million)						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total (Years 1-5)	Year 6+
Excluding VAT	10.6	24.5	28.9	33.2	37.6	134.8	39.7
Including VAT	12.4	28.6	33.7	38.7	43.7	157.1	46.2

8.5.3 COST PER PATIENT

The average cost per patient per annum is shown in Table 53 where year 1 is the year the patient initiates or intensifies therapy and year 2+ represents subsequent years where no titration is required as patients are maintained at optimal or maximum dose.

Table 53: Average statin cost per patient per annum

	Cost £ excluding VAT		Cost £ including VAT	
	Year 1	Year 2+	Year 1	Year 2+
Secondary	85 (170)	175	100 (200)	205
Primary	21 (43)	36	25 (50)	41

The figures in brackets are the annual estimated cost per patient. However as it was assumed that the annual costs to health boards reduced by 50% as a result of identification of individuals on average mid-year in year 1, then the figures without brackets reflect the costs outlined in section 8.5.2.

The annual cost of treatment per patient at each optimum dose is outlined in Appendix 23.

8.6 BED DAYS

Implementing the prevention of CVD recommendations will have no direct impact on bed days in the acute sector, as the CVD prevention occurs as a primary care service. However, the intervention will save almost 37,000 bed days in the acute sector as a consequence of avoided clinical events as discussed in Section 8.3.

8.7 SENSITIVITY ANALYSES

8.7.1 SENSITIVITY ANALYSIS 1

ATORVASTATIN OFF PATENT AND SOLD AT CURRENT GENERIC PRICES

Given atorvastatin will come off patent in 2011, the estimated additional costs in the later years of the base case are unlikely to materialise. This sensitivity assumes that atorvastatin (all doses) will be sold at the current annual price of simvastatin 40mg; £44 excluding VAT and £52 including VAT². It was also assumed that 70% of secondary patients currently receiving statin therapy currently receive simvastatin (weighted average for the year ended 31 March 2006)⁷, while 30% receive atorvastatin, at the average of the assumed generic price of atorvastatin (as above). The patient numbers and clinical benefits do not change and the discontinuation rates from the base case were also assumed in this analysis.

The cost of treating primary patients does not change, however the cost of treating secondary patients changes significantly, as the 55% of secondary patients who currently receive statin therapy and require more aggressive therapy do so at a lower cost per annum; £44 compared to £370 excluding VAT and £52 compared to £430 including VAT. The total costs were estimated at £51 million over the first 5 years (£59 million including VAT), with stable costs of £18 million from year 6 (£21 million including VAT). Table 54 details the estimated costs for both primary and secondary patients in years 1-6.

Table 54: Total annual cost of statin treatment in Scotland at generic prices

	Cost (£ million)*						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total (Years 1-5)	Year 6+
Costs excluding VAT							
Secondary	1.1	2.2	2.2	2.2	2.2	9.9	2.2
Primary	1.9	5.0	8.1	11.3	14.4	40.6	15.6
Total	3.0	7.2	10.3	13.5	16.6	50.5	17.8
Costs including VAT							
Secondary	1.3	2.6	2.6	2.6	2.6	11.7	2.6
Primary	2.2	5.8	9.4	13.0	16.6	47.0	18.1
Total	3.5	8.4	12.0	15.6	19.2	58.7	20.6

* Totals may not add due to rounding

8.7.2 SENSITIVITY ANALYSIS 2

PVD PATIENTS CURRENTLY RECEIVE STATIN THERAPY

In the base case it was assumed that 92% of both secondary CHD and stroke patients (290,000) currently receive statin therapy^{53,68,72}. This sensitivity analysis assumes that 92% of PVD patients (39,000) also currently receive statin therapy, of which approximately 20% (7,000 patients) require more aggressive therapy to achieve a TC target of 5.0mmol/L. The primary patient numbers do not change and the discontinuation rates from the base case were also assumed in this analysis.

Although fewer secondary patients are initiating statin therapy, the costs increase for those secondary patients who require more aggressive (and expensive) therapy, as a result the cost of treating secondary patients decrease slightly. The cost of treating primary patients remains as per the base case. The total costs were estimated at £110 million over the first 5 years (£128 million including VAT), with stable costs of £31 million from year 6 (£36 million including VAT). Table 55 details the estimated costs for both primary and secondary patients in years 1-6.

Table 55: Total annual cost of statin treatment in Scotland

	Cost (£ million)*						
	Year 1	Year 2	Year 3	Year 4	Year 5	Total (Years 1-5)	Year 6+
Costs excluding VAT							
Secondary (new)	7.5	15.4	15.4	15.4	15.4	69.3	15.4
Secondary (base)	8.2	16.8	16.8	16.8	16.8	75.3	16.8
Saving	0.7	1.4	1.4	1.4	1.4	6.0	1.4
Cost including VAT							
Primary	1.9	5.0	8.1	11.3	14.4	40.6	15.6
Total (new)	9.4	20.4	23.6	26.7	29.8	109.9	31.1
Cost including VAT							
Total (new)	10.9	23.9	27.5	31.1	34.7	128.1	36.2

* Totals may not add due to rounding

8.7.3 SENSITIVITY ANALYSIS 3

COSTS OF TREATING PRIMARY PATIENTS WHO ARE 45-64 YEARS OF AGE, IN LINE WITH PREVENTION 2010, AS PER BASE CASE PROPORTIONS

Baseline practice assumed that secondary patients are treated to a minimum total cholesterol level of 5.0 mmol/L and that all high risk individuals were prescribed simvastatin 40mg. This sensitivity analysis assumes that only primary prevention patients aged 45-64 years of age receive statin therapy, consistent with the Prevention 2010 programme.

It was estimated that 56% of the primary patient population are 45-64 years of age, therefore approximately 245,000 primary patients would receive statin therapy. The proportion of patients achieving a total cholesterol level of 5.0 mmol/L would remain as per base case, as the total cholesterol distribution in patients aged 45-64 and those 65 and over is equivalent to that for all Scottish patients aged 40 and over. It is also assumed that discontinuation rates are as per the base case for this age group.

The cost of primary prevention reduces by 44% to approximately £23million (excluding VAT) over years 1-5 and £9 million from year 6: including VAT the costs were estimated at £26 million over years 1-5 and £10 million from year 6.

9 Other medications

9.1 BACKGROUND

Where the guidelines specified a change in current baseline drug prescribing practice, the additional costs or savings were estimated for each applicable recommendation. The total resource implications of changes in prescribing practices and in the number of patients affected were summarised. Where it was anticipated that patient numbers or prescription levels would change over time this was also considered.

The British National Formulary 52²⁵ and Scottish Drug Tariff (November 2006)² were used to calculate the annual cost of each drug therapy. Where the drug dose was dependent on patient weight, the average patient weight was assumed as 80kg. A titration period of 4 weeks was assumed where titration occurred.

Where the number of prescriptions changed as a result of a recommendation, prescription charges were included in the costs or savings, as a fee of 91.7 pence per item (the standard fee stated in the Scottish Drug Tariff, September 2006)¹³. Its inclusion gives a more complete cost estimate, though prescription charges are changing and details of the new pricing system have not been confirmed. This fee is also added to drugs prescribed in the acute setting, as it was assumed that there are additional costs involved with this process.

Additional clinical benefits, measured in terms of events saved were estimated for all recommendations where the additional cost exceeded £0.1 million per year. These were estimated by applying the absolute risk reductions reported in relevant trials to the number of individuals assumed to take the drug following implementation. The resultant savings in bed days and costs in the acute sector were calculated using ISD data³ (see Table 3).

9.2 TOTAL CLINICAL BENEFITS AND RESOURCE SAVINGS

The total clinical benefits and associated bed days saved and savings from events avoided that might be realised on implementation of these recommendations to change prescribing practice are presented in Table 56.

Table 56: Analyses of clinical benefit and annual resource savings by guideline

Guideline	Mortality avoided over 5 years	Other events avoided over 5 years	Annual bed days saved	Annual savings from events avoided (million)
ACS	391	176	305	£0.1
Heart failure	122	128	400	£0.1
Prevention	975	3,532	12,805	£3.7
Total	1,488	3,836	13,510	£3.9

9.3 TOTAL MEDICATION CHARGES

The total estimated costs relating to the recommended changes in medication in the SIGN CHD guidelines (excluding and including VAT) are presented in Tables 57 and 58.

Table 57: Estimated total medication costs (excluding VAT) of implementing key CHD guideline recommendations

	Total cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
ACS	0.6	0.6	0.6	0.6	0.6	0.6
Heart failure	0.8	0.8	0.8	0.8	0.8	0.8
Prevention	2.4	4.6	6.3	7.9	9.5	9.5
Total	3.8	6.0	7.7	9.3	10.9	10.9

Table 58: Estimated total medication costs (including VAT) of implementing key CHD guideline recommendations

	Total cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
ACS	0.7	0.7	0.7	0.7	0.7	0.7
Heart failure	0.9	0.9	0.9	0.9	0.9	0.9
Prevention	2.6	5.3	7.0	8.8	10.7	10.7
Total	4.2	6.9	8.6	10.4	12.3	12.3

The total Acute Coronary Syndromes medication costs detailed include those estimated for recommendation 6 (Section 9.4.6), which were also made in the Chronic Heart Failure guideline (Section 9.6.3). The baseline value of this recommendation was estimated at £2.1 million excluding VAT (£2.4 million including VAT).

9.4 ACUTE CORONARY SYNDROMES (SIGN 93)

The medications assumed to be prescribed for each Acute Coronary Syndromes recommendation (SIGN 93) are listed in Appendix 24, which outlines the cost per patient, per annum where long term therapy is required (including and excluding VAT). These costs were used to calculate the change in the Scottish medication budget as described below.

The following recommendations related to medications used to manage acute coronary syndromes.

9.4.1 RECOMMENDATION 1

3.5.5 [A] *In the presence of ischaemic electrocardiographic changes or elevation of cardiac markers, patients with an acute coronary syndrome should be treated immediately with fondaparinux or low molecular weight heparin.*

3.5.5 [GPP] *Anticoagulant therapy should be continued for eight days, or until hospital discharge or coronary revascularisation.*

Savings

Low molecular weight heparin is currently used to treat this patient group therefore if this continued there would be no change in the Scottish drug budget. However, if fondaparinux was used for all patients there would be an estimated annual saving of approximately £200,000. Of the 17,000 acute coronary syndrome patients treated each year¹⁶ 6,590 have non-ST elevation acute coronary syndrome^{17,18}. Assuming that 5% of these have contraindications to fondaparinux, 6,260 patients previously treated with low molecular weight heparin would now receive fondaparinux. The resulting annual saving was estimated at £207,000 (excluding VAT), where contraindications were assumed at 10% and 0% the savings were £196,000 and £218,000 per annum, respectively. Including VAT the minimum, baseline and maximum savings were £231,000, £244,000 and £257,000.

This saving was not included in the Acute Coronary Syndromes total, as it may not materialise due to the treatment choice offered by the recommendation.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as it suggests clinical equivalence for the two treatment options.

9.4.2 RECOMMENDATION 2

3.5.5 [B] *Patients with an ST elevation acute coronary syndrome who do not receive reperfusion therapy should be treated immediately with fondaparinux.*

3.5.5 [GPP] *Anticoagulant therapy should be continued for eight days, or until hospital discharge or coronary revascularisation.*

Savings

Of the 17,000 acute coronary syndrome patients treated each year¹⁶ 3,295 have ST elevation acute coronary syndrome^{17,18} and of these it is assumed that 35% (1,150) do not receive pPCI within 90 minutes (refer to appendix 3 for details). Assuming that approximately 15% of these 1,150 patients (5% of all ST elevation acute coronary syndrome patients) have contraindications to thrombolytic therapy, 165 patients previously treated with low molecular weight heparin should now receive fondaparinux. The resulting annual saving was estimated at approximately £5,000 (excluding VAT), where thrombolytic therapy contraindications were assumed at 5% and 20% the savings were £2,000 and £8,000 per annum, respectively. Including VAT the minimum, baseline and maximum savings were £2,000, £6,000 and £9,000.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as the annual costs are under £0.1 million.

9.4.3 RECOMMENDATION 3

3.6 [B] *In the absence of bradycardia or hypotension, patients with an acute coronary syndrome in Killip class I should be considered for immediate intravenous and oral beta-blockade.*

Costs

Of the 17,000 acute coronary syndrome patients treated each year¹⁶ 14,450 are estimated to be in Killip Class 1⁷⁸. Of patients in Killip Class 1, 95% (13,730) do not have bradycardia or hypotension⁷⁸ and previously received oral beta-blockade only. Assuming that 5% of these 13,730 patients have contraindications to intravenous beta-blockade, approximately 13,000 will receive intravenous treatment at an annual cost of £24,000 (excluding VAT and including prescription charges). Where contraindications were assumed at 10% and 0% the costs were £23,000 and £26,000 per annum, respectively. Including VAT the minimum, baseline and maximum costs were £25,000, £27,000 and £28,000.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as the annual costs are under £0.1 million.

9.4.4 RECOMMENDATION 4

4.2.5 [B] *Thrombolysis should be conducted with a fibrin-specific agent.*

Costs

Of the 17,000 acute coronary syndrome patients treated each year¹⁶ 3,295 have ST elevation acute coronary syndrome^{17,18} and of these 35% (1,150) will not receive pPCI within 90 minutes. Assuming that approximately 15% of these have contraindications to thrombolytic therapy, the resulting 990 patients who were previously treated with streptokinase should now receive a fibrin-specific agent. Assuming alteplase is used the annual additional costs were estimated at approximately £515,000 (excluding VAT), where thrombolytic therapy contraindications are assumed at 20% and 5% the additional costs were £480,000 and £570,000 per annum, respectively. Including VAT the minimum, baseline and maximum costs were £562,000, £602,000 and £668,000.

If tenecteplase or reteplase were used for all patients the baseline costs would increase to £525,000 and £580,000 excluding VAT (£616,000 and £679,000 including VAT).

Clinical benefits and resource savings

Section 4.2.5 of the Acute Coronary Syndromes guideline (SIGN 93) notes a potential mortality benefit of 1.1% associated with using fibrin-specific thrombolysis compared with streptokinase. Treating 1,100 patients with a fibrin specific thrombolysis rather than streptokinase could reduce annual mortality by 13 patients.

9.4.5 RECOMMENDATION 5

7.1.2 [B] *In addition to long term aspirin, clopidogrel therapy should be continued for three months in patients with non-ST elevation acute coronary syndromes.*

Savings

Of the 17,000 acute coronary syndrome patients treated each year¹⁶ 6,590 have non-ST elevation acute coronary syndrome^{17,18}. It is assumed that these patients previously received clopidogrel for 1 year in accordance with NICE recommendations⁷⁹. However some physicians in Scotland may not be following the NICE advice, in part because SIGN consulted on a shorter 3-month treatment duration in September 2005. On implementation of the recommendation non-ST elevation acute coronary syndrome patients should be prescribed clopidogrel for 3 months, except for those who have undergone pPCI where drug eluting stents were used, in which case they should receive clopidogrel for 6 months.

Assuming that 10% of these 6,590 patients have contraindications to clopidogrel and 9% of the remaining 5,930 non-ST elevation acute coronary syndrome patients undergo pPCI with drug eluting stents, the annual savings were estimated at £2.01 million (excluding VAT), including the reduction in prescription charges. Where contraindications to clopidogrel were assumed at 15% and 5% the savings were £1.90 million and £2.12 million per annum, respectively. Including VAT the minimum, base line and maximum savings were £2.23 million, £2.36 million and £2.49 million.

Clinical benefits and resource savings

Section 7.1.2 of the Acute Coronary Syndromes guideline (SIGN 93) describes the absolute risk reduction, with associated 95% confidence intervals for treating patients with clopidogrel beyond 3 months. The absolute risk reductions are very small (range 0.0-0.2%) and the confidence intervals all include 100%, therefore no clinical benefit was assumed from continuing therapy after 3 months.

9.4.6 RECOMMENDATION 6

7.7 [B] *Patients with clinical myocardial infarction complicated by left ventricular dysfunction (ejection fraction < 0.40) in the presence of either clinical signs of heart failure or diabetes mellitus should be commenced on long term eplerenone therapy.*

Costs

Of the 10,000 acute MI patients treated each year¹⁷ it was assumed that 3,750 have complications associated with left ventricular dysfunction in the presence of either heart failure or diabetes mellitus.

Assuming that 2% of these 3,750 patients have contraindications to eplerenone, the additional annual cost of treatment was estimated at £2.07 million (including VAT and prescription charges). Where contraindications were assumed at 5% and 0% the additional costs were £2.01 million and £2.11 million per annum, respectively. Including VAT the minimum, baseline and maximum costs were £2.36 million, £2.43 million and £2.48 million.

Clinical benefits and resource savings

Section 7.7 of the Acute Coronary Syndromes Guideline (SIGN 93) notes that the main clinical benefits reported in the relevant RCTs^{80,81} are associated with reductions in all cause mortality and hospitalisation. Applying the observed absolute risk reductions to the forecast patient numbers gives the estimates of clinical benefit presented in Table 59.

Table 59: Clinical benefit of eplerenone compared with placebo

Clinical endpoint	Absolute risk: eplerenone	Absolute risk: placebo	ARR	Benefit from treating 3,750 patients
Mortality	14.4%	16.7%	2.3%	88
AMI	2.3%	2.8%	0.5%	19
Heart failure	3.1%	3.8%	0.7%	27
Stroke	0.8%	0.9%	0.1%	3
Hospitalisation				
AMI	6.7%	6.9%	0.2%	7
Heart Failure	10.4%	11.8%	1.4%	53
Stroke	2.1%	1.5%	-0.6%	-21

The savings associated with these reductions in events translate to 305 annual bed days saved and annual cost savings of £0.13 million.

9.5 ARRHYTHMIAS (SIGN 94)

None of the arrhythmia drug recommendations (SIGN 94) result in significant change from current prescribing practice and thus no additional costings are included in this report.

9.6 CHRONIC HEART FAILURE (SIGN 95)

The medications assumed to be prescribed for each Chronic Heart Failure (SIGN 95) recommendation are listed in Appendix 24, which outlines the cost per patient, per annum where long term therapy is required (including and excluding VAT). These costs were used to calculate the change to the Scottish medication budget as described below.

The following recommendations related to medications used to manage heart failure:

9.6.1 RECOMMENDATION 1

4.3 [B] *Patients with heart failure due to left ventricular systolic dysfunction who are still symptomatic despite therapy with an angiotensin converting enzyme inhibitor and a beta-blocker may benefit from the addition of candesartan, following specialist advice.*

Costs

There are approximately 36,000 heart failure patients in Scotland, of whom 4,000 are prescribed both an angiotensin converting enzyme inhibitor and a beta-blocker⁸². It was assumed that 1,200 patients with moderate to severe heart failure remain symptomatic and would benefit from additional therapy with candesartan.

Table 60 presents the assumed minimum, baseline and maximum contraindication rates, and the optimal candesartan maintenance dosages (where titration occurs every 4 weeks) during treatment. The addition of candesartan to the current treatment regimen was estimated to cost £140,000, £170,000 and £205,000 in year 1 (excluding VAT and including prescription fees) using minimum, baseline and maximum values. Including VAT increased the costs to £165,000, £200,000 and £240,000 respectively.

Treatment costs for subsequent years will increase due to an increased number of patients affected and a rise in the annual cost for existing patients if titration of dose proves necessary. However the data required quantifying the increase was not available.

Table 60: Values assumed for contraindication rates and treatment doses during estimation of candesartan treatment cost

		Patients (%)		
		Minimum level	Baseline level	Maximum level
Contraindication rates		30%	20%	10%
Dose	4 mg	10%	5%	0%
	8 mg	20%	10%	5%
	16 mg	30%	25%	15%
	32 mg	40%	60%	80%

Clinical benefits and resource savings

The trials^{83,84} that support this recommendation did not show a consistent absolute risk reduction for mortality (range 3.5% to -0.4%), but both report an absolute risk reduction for heart failure hospitalisation of about 4%. Taking a midpoint estimate of mortality benefit gives an estimate of 8 deaths avoided per year: the fewer hospitalisations could realise annual savings of 330 bed days and costs of £0.1 million.

9.6.2 RECOMMENDATION 2

4.4 [GPP] Eplerenone can be substituted for spironolactone patients who develop gynaecomastia.

Costs

Of the 36,000 heart failure patients in Scotland⁸² 11,000 are estimated as being prescribed spironolactone⁸⁵, of whom 9% (975) develop gynaecomastia⁸⁶. Assuming that 2% of these 975 patients have contraindications to eplerenone the additional annual treatment cost was estimated at £540,000 (excluding VAT and including prescription fees). Where contraindications

were assumed at 5% and 0% the additional costs were £525,000 and £550,000 per annum, respectively. Including VAT the minimum, baseline and maximum costs were £615,000, £630,000 and £645,000.

Clinical benefits and resource savings

The clinical benefit estimates were taken from the main eplerenone trial⁸¹. With a mean follow-up of 16 months, the absolute risk reduction was 2.3% for death and benefits were also found in terms of fewer hospitalisations for cardiovascular events other than stroke. The benefits for the estimated 956 Scottish patients with a contraindication to spironolactone but able to take eplerenone were estimated to avoid 23 deaths and 13 heart failure events, with NHSScotland accruing 75 annual bed day savings and £0.03 million in associated costs.

9.6.3 RECOMMENDATION 3

4.4 [B] *Patients who have suffered a myocardial infarction and with LVEF < 40% and either diabetes or clinical signs of heart failure should be considered for eplerenone unless contraindicated by the presence of renal impairment or a high potassium concentration.*

Costs/Savings

This was comparable to Acute Coronary Syndromes recommendation 6 (SIGN 93), considered in Section 9.4.6. To avoid double counting the costs and benefits were included under the total cost summary for the Acute Coronary Syndromes guideline.

Clinical benefits and resource savings

This was comparable to Acute Coronary Syndromes recommendation 6 (SIGN 93), considered in Section 9.3.6. To avoid double counting the costs and benefits were included under the total cost summary for the Acute Coronary Syndromes guideline.

9.6.4 RECOMMENDATION 4

4.9 [A] *African-American patients with advanced heart failure due to left ventricular systolic dysfunction should be considered for treatment with hydralazine and isosorbide dinitrate in addition to standard therapy.*

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Costs

African Americans comprise 0.2% of the Scottish population⁸⁷. Assuming that this rate can be generalised to advanced heart failure patients, the cost implications of this recommendation are insignificant reaching an estimated maximum value of £1,000 per annum.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as the annual costs are under £0.1 million.

9.6.5 RECOMMENDATION 5

4.8 [B] *Patients who are intolerant of an angiotensin converting enzyme inhibitor or an angiotensin II receptor blocker due to renal dysfunction or hyperkalaemia should be considered for treatment with a combination of hydralazine and isosorbide dinitrate.*

Costs

Of the 36,000 heart failure patients in Scotland⁸², it is assumed that 725 are intolerant to both angiotensin converting enzyme inhibitors and angiotensin II receptor blockers. Assuming that 30% of these patients have contraindications to hydralazine and isosorbide dinitrate, the annual additional costs resulting from this treatment were estimated as £50,000 (excluding VAT and including prescription charges). Where contraindications were assumed at 50% and 10% the additional costs were £20,000 and £115,000 per annum, respectively. The minimum, baseline and maximum costs (including VAT) were £25,000, £60,000 and £135,000.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as the annual costs are under £0.1 million.

9.7 PREVENTION OF CARDIOVASCULAR DISEASE (SIGN 97)

The medication assumed to be prescribed for each CVD Prevention recommendation is listed in Appendix 24, which outlines the cost per patient per annum where long term therapy is required (including and excluding VAT). These costs were used to calculate the change to the Scottish medication budget as described below.

The following recommendations related to medications used to prevent CVD.

9.7.1 RECOMMENDATION 1

3.4 [D] *Individuals at high cardiovascular risk warrant intervention with lifestyle changes and consideration for drug therapy to reduce their absolute risk.*

Costs

The only drug costs included under this recommendation are antihypertensive therapy for individuals at high risk of CVD and with blood pressure $\geq 140/90$ mmHg, as statin therapy is covered in Section 8 and aspirin therapy in Section 9.7.3. The patient group affected by this recommendation is detailed in Section 7.2. All symptomatic patients and asymptomatic individuals with blood pressure $\geq 150/100$ mmHg are assumed to be receiving adequate antihypertensive therapy. The number of individuals expected to initiate antihypertensive therapy over years 1-6, in accordance with these Guidelines is presented in Table 61. GPs are assumed to use therapeutic strategies that are consistent with the British Hypertension Society (BHS) algorithm⁸⁸ and NICE Hypertension: management of hypertension in adults in primary care guidance (June 2006)⁸⁹. These recommended two strategies, A/B therapies (ACE inhibitor plus a beta blocker if required) or C/D (being calcium channel blockers plus a diuretic if required).

Table 61: Numbers of patients requiring antihypertensive therapy

	Number of patients					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Eligible patients	40,000	80,000	120,000	160,000	200,000	200,000
Currently prescribed	24,000	48,000	72,000	96,000	119,000	119,000
Additional patients	16,000	32,000	48,000	64,000	80,000	80,000
Drug class split according to the BHS algorithm						
A/B	7,000	14,000	21,000	28,000	35,000	35,000
C/D	9,000	18,000	27,000	36,000	45,000	45,000

The assumed drug class split for non-black patients younger than 55 years of age is detailed in Table 62. The drug class split for black patients of any age and non-black patients 55 years or older is assumed to be 30% calcium channel blockers and 70% diuretics. Table 62 also defines the assumed contraindication rates for the minimum, baseline and maximum costing scenarios.

While the use of beta-blockers has been down-graded in the new NICE guidance⁸⁹, it is assumed that they will continue to be prescribed for a small proportion of hypertensive patients. In line with the SIGN guideline 97 recommendations that patients receive treatment for their global risk and not individual risk factors. It is assumed those who are not currently receiving antihypertensive treatment will only receive a single line therapy, with no addition of a second drug.

Table 62: Values assumed for drug class split and contraindication rates during estimation of antihypertensive therapy cost

		Patients (%)		
		Minimum level	Baseline level	Maximum level
Contraindication rates		2%	1%	0%
Dose	Angiotensin converting enzyme inhibitor	81%	76%	72%
	Angiotensin II receptor blocker	9%	14%	18%
	Beta-blocker	10%	10%	10%

The additional cost (excluding VAT and including prescription charges) associated with antihypertensive therapy over years 1-6 are summarised in Table 63, for minimum, baseline and maximum costing scenarios. Table 64 presents the same information including VAT.

Table 63: Estimated additional annual cost (excluding VAT) of antihypertensive therapy

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Maximum level	0.6	1.2	1.8	2.4	3.0	3.0
Baseline level	0.6	1.1	1.7	2.2	2.8	2.8
Minimum level	0.5	1.0	1.5	2.1	2.6	2.6

Table 64: Estimated additional annual cost (including VAT) of antihypertensive therapy

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Maximum level	0.7	1.4	2.1	2.8	3.5	3.5
Baseline level	0.6	1.3	1.9	2.5	3.2	3.2
Minimum level	0.6	1.2	1.8	2.4	3.0	3.0

Clinical benefits and resource savings

The clinical benefit of treating drug naïve patients with antihypertensive therapy has been estimated using data from a meta-analysis of ACE inhibitors and calcium channel blockers, compared with placebo⁹⁰. The absolute risk reductions for various clinical endpoints are set out in Table 65, together with the estimated clinical benefits for the 80,000 individuals to be treated in Scotland. The events avoided total 3,711 of which 950 are deaths avoided. The associated annual savings in bed days and costs are 9,108 and £2.5 million, respectively.

Table 65: Clinical benefit of ACE inhibitors and calcium channel blockers for patients with hypertension

Event	Absolute risk (%)		ARR (%)	Absolute risk (%)		ARR (%)	Benefit of treating 80,000 patients
	ACE inhibitor	Placebo		Calcium channel blocker	Placebo		
Mortality	9.2	10.4	1.2	6.3	7.1	0.8	950
Heart Failure	2.7	3.3	0.6	3.1	2.7	-0.4	39
Stroke	5.2	7.2	2.0	2.0	3.2	1.2	1,501
Other CHD	4.9	6.2	1.3	0.6	1.9	1.3	1,221

9.7.2 RECOMMENDATION 2

8.1 [A] *Individuals with a history of stroke, or transient ischaemic attack, and who are in sinus rhythm should be considered for low dose aspirin (75–300 mg daily) and dipyridamole (200 mg twice daily) to prevent stroke recurrence and other vascular events. If aspirin is contraindicated, or there are side effects, clopidogrel 75 mg daily is an alternative.*

Costs

Annually 0.5% of the Scottish population over 16 years of age experience stroke⁹¹, equating to approximately 20,000 strokes per year⁹¹. A total of 13,300 stroke patients survive⁹² with 50% (6,660) remaining in sinus rhythm⁹³. Currently these 6,660 patients are treated with aspirin. The assumed contraindication rates to dipyridamole M/R and the annual cost of treatment (excluding VAT and including prescription charges) in year 1 and from year 2 are summarised in Table 66. Annual costs are likely to remain stable from year 2, as it is predicted that the incidence of stroke will remain constant. Table 67 presents the annual cost of treatment (including VAT) in year 1 and from year 2.

Table 66: Estimated additional annual cost (excluding VAT) of dipyridamole/clopidogrel treatment

	Contraindication rate (%)	Cost (£ million)	
		Year 1	From year 2
Maximum cost level	5%	0.68	1.36
Baseline cost level	10%	0.64	1.29
Minimum cost level	20%	0.57	1.14

Table 67: Estimated additional annual cost (including VAT) of dipyridamole/clopidogrel treatment

	Contraindication rate (%)	Cost (£ million)	
		Year 1	From year 2
Maximum cost level	5%	0.79	1.59
Baseline cost level	10%	0.75	1.50
Minimum cost level	20%	0.67	1.33

Clinical benefits and resource savings

The clinical benefit of treating 6,600 patients using dipyridamole M/R has been estimated using data from a systematic review⁹⁴. The absolute risk reductions derived from the Antithrombotic Trialists' Collaboration meta-analysis⁷⁴ are presented in Table 68, with the estimated clinical benefits for patients treated in Scotland. A total of 2,100 bed day savings would accrue annually with an associated £0.55 million in costs, assuming an average follow-up period of 2 years.

Table 68: Clinical benefit of dipyridamole and aspirin for patients with a history of cerebral infarction or transient ischemic attack but in sinus rhythm

Event	Absolute risk: dipyridamole with aspirin	Absolute risk: aspirin only	ARR	Benefit of treating 6,660 patients
Mortality	11.2%	11.0%	-0.2%	-12
Stroke	6.6%	9.6%	3.0%	180
MI	0.7%	1.0%	0.3%	18
Severe bleeds	1.4%	1.0%	-0.4%	-24

9.7.3 RECOMMENDATION 3

8.2 [A] *Asymptomatic individuals without established atherosclerotic disease but with a calculated cardiovascular risk of $\geq 20\%$ over ten years should be considered for treatment with aspirin 75 mg daily.*

8.4 [GPP] *Patients with hypertension should be treated with aspirin if their ten year CVD risk exceeds 20% and only once their blood pressure has been treated to <150/90 mmHg.*

Costs

The patient group affected by this recommendation is detailed in Section 7.2, however the additional patients requiring aspirin is lower than indicated, as it is expected 11.3% of these patients have uncontrolled hypertension^{72,95}. The number of patients to receive aspirin in accordance with the above recommendations, over years 1-6, is presented in Table 69.

Table 69: Numbers of patients with $\geq 20\%$ CVD risk, without established atherosclerosis and with controlled hypertension

	Number of patients					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
High CVD risk patients	98,000	197,000	295,000	393,000	492,000	492,000
Uncontrolled hypertension	14,000	28,000	42,000	55,000	69,000	69,000
Additional patients	84,000	169,000	253,000	338,000	423,000	423,000

Table 70 defines the assumed aspirin contraindication rates and the percentage of patients likely to require gastroprotection for the minimum, baseline and maximum costing scenarios.

Table 70: Values assumed for contraindication rates and gastroprotection requirements during estimation of aspirin therapy cost

	Contraindication rate	Patients requiring gastroprotection
Maximum level	5%	15%
Baseline level	10%	10%
Minimum level	15%	5%

The additional costs (excluding VAT and including prescription) charges associated with aspirin therapy over years 1-6 are summarised in Table 71, for minimum, baseline and maximum cost scenarios. Table 72 presents the same information including VAT.

Table 71: Estimated additional annual cost of aspirin treatment (excluding VAT)

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Maximum level	1.3	2.6	3.9	5.2	6.5	6.5
Baseline level	1.1	2.2	3.3	4.4	5.5	5.5
Minimum level	0.9	1.8	2.7	3.6	4.5	4.5

Table 72: Estimated additional annual cost of aspirin treatment (including VAT)

	Cost (£ million)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Maximum level	1.4	2.9	4.3	5.8	7.2	7.2
Baseline level	1.2	2.4	3.6	4.8	6.0	6.0
Minimum level	1.0	2.0	3.0	4.0	4.9	4.9

Clinical benefits and resource savings

The clinical benefit of treating 423,000 individuals with aspirin was estimated using data from a recent meta-analysis of aspirin in primary prevention⁹⁶. The absolute risk reductions from the meta-analysis are presented in Table 73, the main benefit being from fewer MIs but this gain is at a cost of higher numbers of major bleeds. The associated annual savings comprise 1600 bed days and £0.6 million in costs. If gastroprotection reduced all bleeds the annual bed days saved would increase to 2,650, with resultant savings of £1.0 million.

Table 73: Clinical benefits of aspirin for primary prevention and related clinical benefits

Event	Absolute risk: aspirin	Absolute risk: control	ARR	Benefits for 423,000 patients over 5 years
Mortality	3.4%	3.4%	0.0%	55
Stroke	1.3%	1.3%	0.0%	124
MI	1.4%	1.8%	0.4%	1091
Severe bleeds	0.8%	0.5%	-0.3%	- 879

9.7.4 RECOMMENDATION 4

10.2 [GPP] *For individuals with established CVD and diabetes, chronic renal disease or target organ damage a lower blood pressure threshold of <130/80 mm Hg is recommended.*

Costs

Of the 360,000 Scottish patients with established CVD^{12, 50, 51} it was estimated that 3,600 also have chronic renal disease, diabetes with complications or target organ damage⁹⁷. Most patients with renal disease and treated hypertension have target organ damage⁸⁸. It is assumed that 1,800 of this patient group have blood pressure $\geq 140/90$ mmHg and receive antihypertensive therapy. Implementing the lower blood pressure treatment threshold of 130/90mmHg will result in an additional 710 patients requiring antihypertensive treatment as per the NICE guidelines⁸⁹.

According to the British Hypertension Society AB/CD algorithm⁸⁸ and the NICE guidelines⁸⁹ 45% of patients receive an angiotensin converting enzyme inhibitor, angiotensin II receptor blocker or beta-blocker and 55% of patients a calcium channel blocker or diuretic. Table 63 summarises the contraindication rates and the drug class splits assumed for these patients. While the use of beta-blockers has been down-graded in the new NICE guidance it is assumed that they will continue to be prescribed in a small proportion of hypertensive patients.

The annual additional treatment costs (excluding VAT and including prescription charges), associated with treating this patient group at a lower blood pressure threshold were estimated at £27,000, £25,000 and £23,000 assuming maximum, baseline and minimum costing parameters, respectively. Including VAT increased these costs to £31,000, £28,000 and £26,000.

Clinical benefits and resource savings

Clinical benefits were not estimated for this recommendation as the annual costs are under £0.1 million.

10 Report Development

10.1

AUTHORS

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10.2 AUTHORS' ACKNOWLEDGEMENTS

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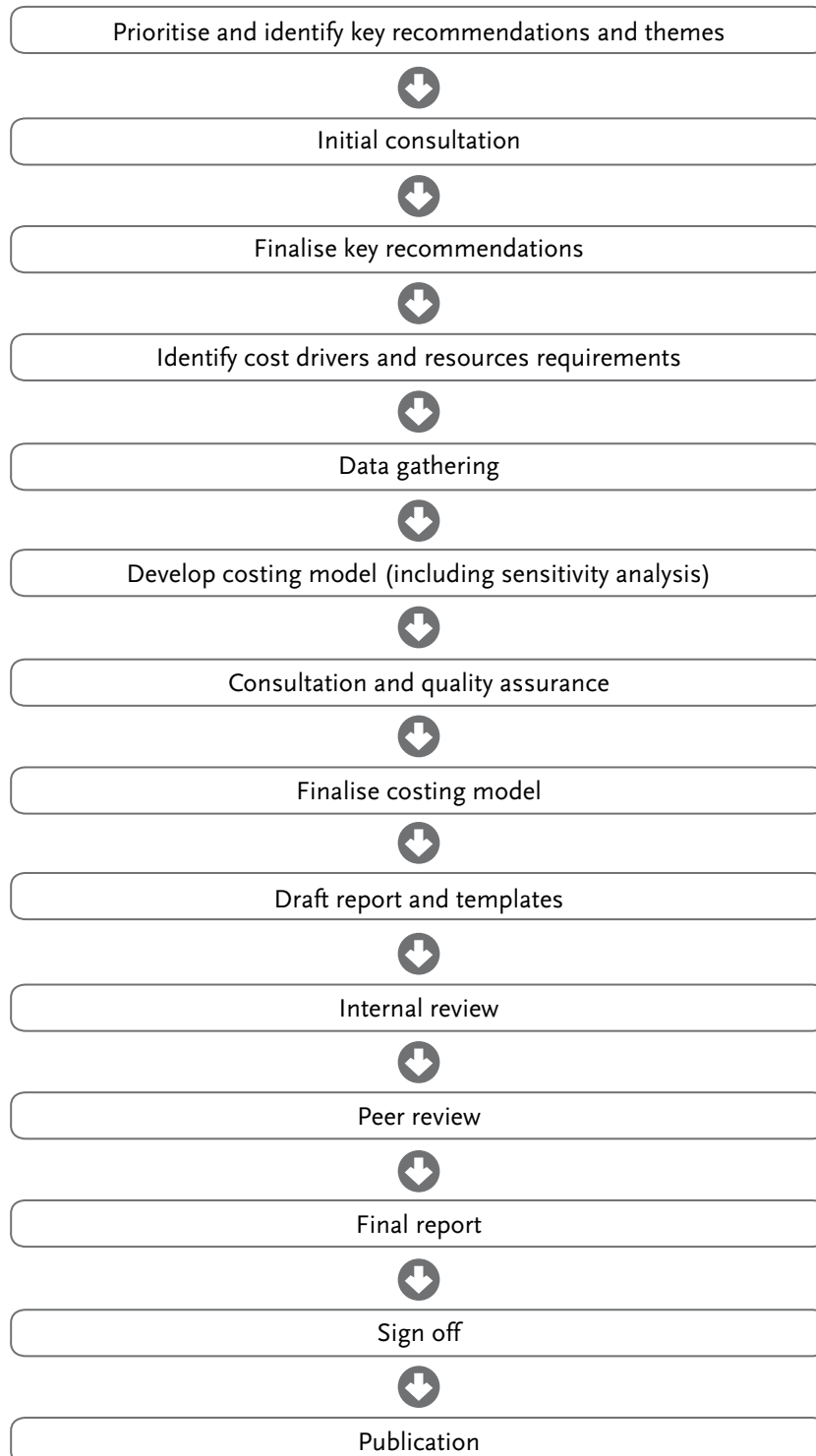
Abbreviations

A&C	Administration and clerical
A&E	Accident and Emergency
ACE	Angiotensin converting enzyme
AB/CD	Angiotensin converting enzyme; beta blockers/calcium channel blocker; thiazide-type diuretic
ACS	Acute coronary syndrome
AMI	Acute myocardial infarction
ARB	Angiotensin-II receptor antagonist
ARR	Absolute risk reduction. The absolute arithmetic difference in rates of outcomes between experimental and control participants in a trial
ASSIGN	ASSessing cardiovascular risk using SIGN guidelines
BCS	British Cardiac Society
BHS	British Hypertension Society
BMI	Body mass index
BNF	British National Formulary
BP	Blood pressure
CABG	Coronary artery bypass graft
CCB	Calcium channel blocker
CHD	Coronary heart disease
CI	Confidence interval
CK	Creatine kinase
CRT	Cardiac resynchronisation therapy
CRT-D	Cardiac resynchronisation therapy with defibrillator
CSBS	Clinical Standards Board for Scotland
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
DGH	District general hospital
DM	Diabetes mellitus
ESC	European Society of Cardiology
FBC	Full blood count
GP	General practitioner
GRACE	Global registry of acute coronary events
HDL	High density lipoprotein
HTA	Health technology assessment
ICD	Implantable cardiac defibrillators
IHD	Ischaemic heart disease
ISD	Information Services Division Scotland

IT	Information technology
JBS2	Joint British Societies' Guideline on Prevention of Cardiovascular Disease in Clinical Practice
LDL	Low density lipoprotein
LFT	Liver function test
LOS	Length of stay
LVEF	Left ventricular ejection fraction
MCN	Managed clinical network
MI	Myocardial infarction
MINAP	Myocardial infarction national audit project
M/R	Modified release
MTO	Medical technical officer
NAC on CHD	National Advisory Committee on Coronary Heart Disease
NHS	National Health Service
NHS QIS	National Health Service Quality Improvement Scotland
NI	National insurance
NICE	National Institute for Health and Clinical Excellence
NNT	Number needed to treat being the number
NSTEMI	Non ST elevation myocardial infarction
NRT	Nicotine replacement therapy
OR	Odds ratio
PAD	Peripheral arterial disease
PVD	Peripheral vascular disease
PCI	Percutaneous coronary intervention
pPCI	Primary percutaneous coronary intervention
PHT	Pre-hospital thrombolysis
QALY	Quality adjusted life year
QOF	Quality Outcomes Framework
RCT	Randomised controlled trial
RRR	Relative risk reduction The proportional reduction in rates of outcomes between experimental and control participants in a trial
SBP	Systolic blood pressure
SHS	Scottish Health Survey
SIGN	Scottish Intercollegiate Guidelines Network
STEMI	ST elevation myocardial infarction
tPA	Tissue plasminogen activator
TC	Total cholesterol
TIA	Transient ischaemic attack
VAT	Value added tax
WTE	Whole time equivalent

Appendix 1

Resource impact assessment process



Appendix 2

Risk factor analysis

A study, the 'risk factor analysis' was commissioned from Dr Haq, Consultant cardiologist Royal Victoria Infirmary Newcastle upon Tyne to determine the proportion of the population who might benefit from lipid lowering therapy. This updates an existing study that used risk factor information collected on individuals by the Scottish Health Survey 1995 (Haq et al, Heart 2001;86:289-295).

Objective

The objective of the risk factor analyses study was to determine the proportion of the population aged 40 years or over:

- a) who do not have symptomatic coronary heart disease (CHD) or cardiovascular disease (CVD) but have different thresholds of risk in order to identify who might benefit from statin treatment for primary prevention;
- b) with clinically apparent CHD or CVD who might benefit from statin therapy for secondary prevention.

Methodology

The methodology was to extract risk factor information on these adults from the survey data collected for the Scottish Health Survey 2003 (Bromley et al, Scottish Executive 2005). The survey used a multi-stage stratified probability sampling design, with postcode sectors. Over 8,000 interviews were conducted with individuals over 18 and over 4,250 gave blood samples to be analysed for factors which included total and HDL-cholesterol.

In the Scottish Health Survey 2003, individuals were classified as having a CVD condition if they reported having any of the following conditions confirmed by a doctor: myocardial infarction, angina or stroke. Peripheral vascular disease was diagnosed by a symptom questionnaire for claudication. Only those with 'definite claudication' were included. Diabetes was confirmed based on recall of a doctor's diagnosis. Smoking was defined as those who smoke cigarettes currently or in the past 12 months.

For individuals without clinically overt cardiovascular disease (primary prevention), CHD and CVD risk was calculated using the Framingham risk equations (Anderson et al Am Heart J 1991;121:293-8). These equations use the following risk factors: age, sex, systolic blood pressure, total and HDL cholesterol, and smoking status. People with diabetes were assumed to be at high risk by virtue of their diabetes. Left ventricular hypertrophy was assumed to be absent.

Results

The results are presented for separately for secondary and primary prevention. For primary prevention, the prevalence of risk is reported for those who have CHD risk $\geq 30\%$, or CHD risk $\geq 15\%$, or CVD risk of $\geq 20\%$ (all over 10 years). The prevalence individuals with isolated risk factors of total cholesterol ≥ 7.5 mmol/L or blood pressure $\geq 160/100$ or individuals taking drugs for hypertension is also reported, if they are not already included in attaining the pre-specified risk thresholds.

Results for individuals who have had a CVD event

The total number sampled with any total cholesterol reading was 2966. Table 1 shows the estimates of prevalence of disease in that group for 5 year age bands. Treating all individuals with CVD will result in 14% of the population being offered a statin, compared to 10.6% if treatment is limited to those with myocardial infarction or angina. Angina was the most common condition with a prevalence of 6.1%, compared to 4.5% for myocardial infarction and under 2% for stroke and PVD.

Table 1: Prevalence of CVD in people aged 40 years or over who had a total cholesterol measurement in the Scottish Health Survey

Age (years)	Total numbers sampled	MI	Angina	Stroke	PVD	Total
		N (%)	N (%)	N (%)	N (%)	N (%)
40-44	417	1 (0.2)	3 (0.7)	4 (1.0)	6 (1.4)	14 (3.4)
45-49	367	6 (1.6)	3 (0.8)	1 (0.3)	6 (1.6)	16 (4.4)
50-54	413	6 (1.5)	11 (2.7)	0 (0.0)	7 (1.7)	24 (5.8)
55-59	439	22 (5.0)	14 (3.2)	6 (1.4)	5 (1.1)	47 (10.7)
60-64	354	23 (6.5)	25 (7.1)	9 (2.5)	4 (1.1)	61 (17.2)
65-69	343	23 (6.7)	33 (9.6)	7 (2.0)	7 (2.0)	70 (20.4)
70-74	232	19 (8.2)	29 (12.5)	10 (4.3)	5 (2.2)	63 (27.2)
75-79	227	15 (6.6)	36 (15.9)	9 (4.0)	4 (1.8)	64 (28.2)
80-84	121	7 (5.8)	18 (14.9)	8 (6.6)	6 (5.0)	39 (32.2)
85+	53	10 (18.9)	8 (15.1)	0 (0.0)	0 (0.0)	18 (34.0)
Total	2,966	132 (4.5)	180 (6.1)	54 (1.8)	50 (1.7)	416 (14.0%)

Table 2 shows that women have a slightly lower prevalence of CVD than men with the main difference being women have/survive fewer myocardial infarctions.

Table 2: Prevalence of established CVD by sex

Sex	Total numbers sampled	MI	Angina	Stroke	PVD	Total
Men	1,363	6.7%	6.7%	1.8%	1.2%	16.4%
Women	1,603	2.6%	5.6%	1.8%	2.1%	12.0%

Results for individuals with no established disease

Table 3 shows that adopting different risk thresholds has a profound effect on the numbers classified as 'high risk' and thus eligible for prevention treatments. Assuming all individuals with diabetes are high risk, moving from a CHD risk of 30% over 10 years to CVD risk of 20% increases the eligible population from 7.5% to 32.7%. Adding in individuals not already included with total cholesterol ≥ 7.5 mmol/L increases the numbers to treat by a further 6%, and adding in those with high blood pressure increases the numbers to treat by a further 8%. Thus almost 1 in 2 people with no symptoms of cardiovascular disease could be treated with drugs if global risk (targeted at 10 year CVD $\geq 20\%$) and individual risk factors were each treated.

Table 3: Prevalence of CVD risk in people aged 40 years or over who had a total cholesterol measurement in the Scottish Health Survey and no overt CVD disease in columns

Age (years)	Total numbers sampled	DM	DM+CHD ≥ 30%	DM+CHD ≥ 15%	DM+CVD ≥ 20%	DM+CVD ≥ 20% or TC ≥ 7.5	DM+CVD ≥ 20% or TC ≥ 7.5 or BP ≥ 160/100 or BP Rx
		N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
40-44	400	7 (1.8)	7 (1.8)	8 (2.0)	8 (2.0)	24 (6.0)	35 (8.8)
45-49	347	4 (1.2)	4 (1.2)	14 (4.0)	18 (5.2)	43 (12.4)	67 (19.3)
50-54	387	16 (4.1)	16 (4.1)	44 (11.4)	49 (12.7)	75 (19.4)	113 (29.2)
55-59	390	16 (4.1)	17 (4.4)	83 (21.3)	106 (27.2)	143 (36.7)	187 (47.9)
60-64	291	27 (9.3)	28 (9.6)	105 (36.1)	137 (47.1)	156 (53.6)	191 (65.6)
65-69	270	30 (11.1)	37 (13.7)	125 (46.3)	161 (59.6)	175 (64.8)	210 (77.8)
70-74	166	18 (10.8)	24 (14.5)	82 (49.4)	114 (68.7)	121 (72.9)	134 (80.7)
75-79	160	23 (14.4)	35 (21.9)	93 (58.1)	135 (84.4)	138 (86.3)	145 (90.6)
80-84	78	6 (7.7)	11 (14.1)	33 (42.3)	65 (83.3)	65 (83.3)	68 (87.2)
85+	34	4 (11.8)	10 (29.4)	17 (50.0)	33 (97.1)	33 (97.1)	34 (100.0)
Total	2,523	151 (6.0)	189 (7.5)	604 (23.9)	826 (32.7)	973 (38.6)	1,184 (46.9%)

DM diabetes mellitus TC total cholesterol (mmol/l)

BP blood pressure Rx treated by drug therapy

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Men have a higher prevalence of risk than women as shown in Table 4.

Table 4: Percentage of asymptomatic men and women at different risk strata

	Total numbers sampled	DM	DM+CHD ≥ 30%	DM+CHD ≥ 15%	DM+CVD ≥ 20%	DM+CVD ≥ 20% or TC ≥ 7.5	DM+CVD ≥ 20% or TC ≥ 7.5 or BP ≥ 160/100 or BP Rx
Men	1,129	6.9%	10.3%	41.6%	45.5%	48.9%	54.1%
Women	1,394	5.2%	5.2%	9.6%	22.4%	30.2%	41.1%

Table 5 shows that adopting different cholesterol concentration thresholds does not materially alter the percentage of the population eligible for treatment.

Table 5: Prevalence of CVD risk in people aged 40 years or over who had a total cholesterol measurement in the Scottish Health Survey and no established CVD disease by cholesterol concentration

TC concentration (mmol/L)	Total numbers sampled	DM	DM+CHD ≥ 30%	DM+CHD ≥ 15%	DM+CVD ≥ 20%	DM+CVD ≥ 20% or TC ≥ 7.5	DM+CVD ≥ 20% or TC ≥ 7.5 or BP ≥ 160/100 or BP Rx
All	2,523	6.0%	7.5%	23.9%	32.7%	38.6%	46.9%
TC > 5	2,523	5.2%	6.6%	20.8%	28.5%	34.3%	41.7%
TC > 4	2,523	5.8%	7.3%	23.5%	32.1%	37.9%	46.1%

Appendix 3

ST elevation acute coronary syndrome assumptions

Current Baseline Practice
3% of patients undergo pPCI
82% of ST elevation acute coronary syndrome patients receive thrombolysis (PHT where possible)
15% patients unable to receive thrombolysis due to late presentation or contraindications
30% of thrombolysis patients require rescue PCI
40% of eligible patients receive early revascularisation
55% of eligible patients do not undergo early intervention
5% of eligible patients are unable to undergo early intervention due to co-morbidities
Of patients who receive early revascularisation 75% undergo PCI and 25% CABG
70% of patients are admitted to a DGH and 30% are admitted to a tertiary centre
70% of patients are admitted via the SAS and 30% self present
100% of patients are transferred via the SAS to DGH following primary or rescue PCI
All CABG patients remain in the tertiary centre
The SAS do not transport elective patients to or from the hospital
Post Recommendation
62% of patients undergo pPCI
3% of patients are unable to undergo pPCI due to co-morbidities
30% of ST elevation acute coronary syndrome patients receive thrombolysis (PHT where admitted via the SAS)
5% patients unable to receive thrombolysis due to late presentation or contraindications
Of the 35% of patients unable to receive pPCI within 90 minutes of diagnoses; 20% are due to geographical issues, 10% are due to technical difficulties, and 5% are because the required catheterisation laboratory is unavailable (eg already in use)
30% of thrombolysis patients require rescue PCI
95% of eligible patients receive early revascularisation
5% of eligible patients are unable to undergo early intervention due to co-morbidities
Of patients who receive early revascularisation 75% undergo PCI and 25% CABG
70% of patients are admitted to a DGH and 30% are admitted to a tertiary centre
70% of patients are admitted via the SAS and 30% self present
15% of patients are transferred via the SAS to DGH following primary, rescue or emergency PCI
All CABG patients remain in the tertiary centre
The SAS do not transport elective patients to or from the hospital
All ST elevation acute coronary syndrome patients who require thrombolysis and are admitted by the SAS receive PHT

Appendix 4

ST elevation acute coronary syndrome resource requirements (including VAT)

Region	North	East	West	Total	North	East	West	Total
Regional percentage split	24%	21%	55%	100%	24%	21%	55%	100%
Staff	WTE				Cost			
Cardiologist	0.6	0.5	1.1	2.2	£73,000	£61,000	£133,000	£267,000
Technician	0.4	0.4	0.8	1.6	£15,000	£15,000	£30,000	£60,000
Radiographer	0.4	0.4	0.8	1.6	£15,000	£15,000	£30,000	£60,000
Nurse (E Grade)	0.4	0.4	0.8	1.6	£11,000	£11,000	£22,000	£44,000
Surgeon	0.0	0.0	0.0	0.0	£0	£0	£0	£0
Registrar	0.0	0.0	0.0	0.0	£0	£0	£0	£0
Anaesthetist	0.0	0.0	0.0	0.0	£0	£0	£0	£0
Perfusionist	0.0	0.0	0.0	0.0	£0	£0	£0	£0
Total Staff	1.8	1.7	3.5	7.0	£114,000	£102,000	£215,000	£431,000
Capital	Unit				Cost			
Cath lab	0.3	0.2	0.6	1.1	£423,000	£282,000	£846,000	£1,551,000
Surgery	0.0	0.0	0.0	0.0	£0	£0	£0	£0
Total Capital	0.3	0.2	0.6	1.1	£423,000	£282,000	£846,000	£1,551,000
Bed Days	Days							
Tertiary	(1,109)	(970)	(2,542)	(4,621)				
DGH	292	256	671	1,219				
Total Bed Days	(817)	(714)	(1,871)	(3,402)				
TOTAL COST	£537,000	£384,000	£1,061,000	£1,982,000				

Appendix 5

Non-ST elevation acute coronary syndrome resource requirements (including VAT)

Region	North	East	West	Total	North	East	West	Total
Regional percentage split	24%	21%	55%	100%	24%	21%	55%	100%
Staff	WTE				Cost			
Cardiologist	0.3	0.3	0.8	1.4	£36,000	£36,000	£97,000	£169,000
Technician	0.2	0.2	0.5	0.9	£7,000	£7,000	£18,000	£32,000
Radiographer	0.2	0.2	0.4	0.8	£8,000	£8,000	£16,000	£32,000
Nurse (E Grade)	0.4	0.4	0.8	1.6	£11,000	£11,000	£22,000	£44,000
Surgeon	0.1	0.1	0.2	0.4	£12,000	£12,000	£24,000	£48,000
Registrar	0.0	0.0	0.1	0.1	£0	£0	£9,000	£9,000
Anaesthetist	0.2	0.1	0.4	0.7	£24,000	£12,000	£48,000	£84,000
Perfusionist	0.1	0.1	0.2	0.4	£5,000	£5,000	£10,000	£20,000
Total Staff	1.5	1.4	3.4	6.3	£103,000	£91,000	£244,000	£438,000
Capital	Unit				Cost			
Cath lab	0.1	0.1	0.3	0.5	£141,000	£141,000	£423,000	£705,000
Surgery	0.0	0.0	0.1	0.1	£0	£0	£118,000	£118,000
Total Capital	0.1	0.1	0.4	0.6	£141,000	£141,000	£541,000	£823,000
Bed Days	Days							
Tertiary	416	363	952	1,731				
DGH	186	163	427	776				
Total Bed Days	602	526	1,379	2,507				
TOTAL COST	£244,000	£232,000	£785,000	£1,261,000				

Appendix 6

ST elevation acute coronary syndrome cost summary (including VAT)

Region	Cost (£)			Total
	North	East	West	
Regional percentage split	24%	21%	55%	100%
Additional Annual Costs				
Additional staff	114,000	102,000	215,000	431,000
Travel	312,000	273,000	716,000	1,301,000
Intracoronary stents	243,000	213,000	557,000	1,013,000
Additional depreciation	33,000	22,000	66,000	121,000
Thrombolysis drugs	(312,000)	(273,000)	(715,000)	(1,300,000)
Thrombolysis A&E	(288,000)	(252,000)	(660,000)	(1,200,000)
Thrombolysis LOS	(576,000)	(504,000)	(1,320,000)	(2,400,000)
Other interventional costs	711,000	622,000	1,630,000	2,963,000
Total	237,000	203,000	489,000	929,000
Capital				
Capital	423,000	282,000	846,000	1,551,000
Protocol	29,000	24,000	41,000	94,000

Appendix 7

ST elevation acute coronary syndrome analysis by intervention (including VAT)

	PCI				CABG (Elective)	Angiography (Elective)	Thrombolysis			Total
	Non-Elective		Emergency PCI	Elective			PHT	A&E	No intervention	
	pPCI	Rescue PCI								
Costs (£ million)										
Post implementation	10.5	1.8	0.4	1.6	2.1	0.6	1.7	0.8	0.1	19.6
Current Position	0.5	4.3	1.1	1.8	2.4	0.7	5.5	2.3	0.1	18.7
Variance	10.0	(2.5)	(0.7)	(0.2)	(0.3)	(0.1)	(3.8)	(1.5)	0.0	0.9
Bed Days										
Post implementation	9,194	1,924	371	552	1,840	368	2,249	962		17,460
Current Position	446	5,272	1,114	641	2,140	428	7,573	3,250		20,864
Variance	8,748	(3,348)	(743)	(89)	(300)	(60)	(5,324)	(2,288)		(3,404)

Appendix 8

Non-ST elevation acute coronary syndrome cost summary (including VAT)

Region	Cost (£)			Total
	North	East	West	
Regional percentage split	24%	21%	55%	100%
Additional Annual Costs				
Additional staff	103,000	91,000	244,000	438,000
Travel	17,000	15,000	39,000	71,000
Intracoronary stents	97,000	85,000	223,000	405,000
Additional depreciation	11,000	11,000	38,000	60,000
Other interventional costs	562,000	491,000	1,287,000	2,340,000
Total	790,000	693,000	1,831,000	3,314,000
Capital	141,000	141,000	541,000	823,000
Protocol	41,000	31,000	54,000	126,000

Appendix 9

Non-ST elevation acute coronary syndrome analysis by intervention (including VAT)

	PCI		CABG (Elective)	Angiography (Elective)	Total
	Emergency	Elective			
Costs (£ million)	1.1	0.6	1.0	0.6	3.3
Bed Days	1,057	235	879	335	2,506

Appendix 10

Risk assessment assumptions

Assumption	Source
Current Situation	
The current unmet need of patients who do not have diabetes, or who are not treated for hypertension is 60% this includes 30% of individuals who do not attend appointment/present to GPs	MCN survey (weighted avg), personal communication with Dr Jim Grant and Dr Malcolm Kerr
58% of people have one of the 5 risk factors outlined in SIGN 40	Scottish Health Survey, 2003
Prevalence	
Population (35-69) with established CHD is 6.2%	Risk factor analysis
Population (40 years and over) with established CVD is 14%	
Population (35-69) at high CHD risk is 4.7%	
Population (40 years and over) without diabetes at high CVD risk is 28.4%	Extrapolated from risk factor analysis
Diabetic population over 40 without CVD is 6%	Risk factor analysis
Treated Hypertension	
Hypertensive population over 40 with no CVD 41.5%	QOF data adjusted for non registered patients
Of the above group 6% have diabetes	Assumed as per population ≥ 40 years
58.1% of hypertensive patients treated	QOF assume all patients with SBP > 150 receive treatment
Lipid reduction treatment	
Lipid reduction threshold in those without CVD is 8mmol/l	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Population over 40 with TC > 8 and no CVD is 4.6%	Scottish Health Survey, 2003
Of the above group 6% have diabetes (as per population ≥ 40 yrs)	Assumed as per population ≥ 40 years
85% of patients above treatment threshold receive lipid reduction treatment	BHF 2004
Appointments	
20% of additional risk assessments are carried out by GPs and 80% by practice nurses	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Each risk assessment takes 15 minutes	Personal communication with Dr Jim Grant and Dr Malcolm Kerr

Assumption	Source
Staff	
Weekly working hours GP = 44.7 Practice Nurse = 37 Administrator = 37	Unit costs of health & social care 2005 Unit costs of health & social care 2005 Assumed
Working weeks per annum GP = 46.5 Practice Nurse = 42 Administrator = 46	Unit costs of health & social care 2005 Unit costs of health & social care 2005 Assumed
GP to practice nurse ratio is 10:4 in Scotland	Unit costs of health & social care 2005 and Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Administrators – 1 WTE for each 25,000 additional appointments (ie. 4 min per appointment)	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
There is no spare capacity	Assumed
Other	
70% of patients who are not currently seen by their GP for other reasons (eg. Diabetics, hypertension (SBP>150)) will be assessed ie. expect 30% will not attend/present to GP	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
20% of patients assessed each year	Guidelines – assess once every 5 years
Asymptomatic individuals with sustained systolic blood pressure between 140 and 150 mm Hg and/or diastolic blood pressures \geq 90 mm Hg and whose 10 year risk of cardiovascular disease is calculated to be \leq 20% are assessed once every five years	Personal communication with Dr Jim Grant and Prof Lewis Ritchie
Consultant room is 16.5m ²	Standard - Personal communication with Dr Jim Grant
FBC, LFT, TC, HDL and Sugar taken for each assessment	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Patient numbers and hence costs are split using population figures	

Appendix 11

Management of patients with high CVD risk assumptions

Assumption	Source
Prevalence	
Population (35-69) with established CHD is 6.2%	Risk factor analysis
Population (40 years and over) with established CHD is 10.6%	
Population (40 years and over) with established CVD is 14%	
Population (35-69) at high CHD risk is 4.7%	
Population (40 years and over) at high CHD risk is 7.5%	
Population (40 years and over) at high CVD risk is 32.7%	
Population (40 years and over) without diabetes at high CVD risk is 28.4%	Extrapolated from risk factor analysis
Diabetic population (35-69) without CVD is 4.3%	Risk factor analysis
Diabetic population (40 years and over) without CVD is 6%	
High risk CHD patients	
Different patient groups have different high CHD prevalence and therefore are x times more likely than average to be a high CHD risk. Where x is assumed as below: SBP ≥ 150 : $x = 2$ SBP 140-149: $x = 1.5$ Patients identified through risk assessment: $x = 1$ (average) Patients who are not eligible for risk assessment (ie. no individual risk factors): $x = 0.5$	Assumed
High risk CHD patients	
All groups have similar high CVD prevalence	Assumed
Smoking	
CVD smoking population 40 or over is 2.7% less than non CVD	Scottish Health Survey, 2003
25% of those who quit smoking do so when identified at high risk, and 75% quit post event	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
20% success rate for cessation services	SEHD
NRT – 4 prescriptions per patient	NICE Public Health intervention no. 1
Smoking cessation given once when patient first identified at high risk	Assumed
Assumption	Source

Diet/Exercise	
Overweight = BMI > 25, Obese = BMI > 30	Clinical consensus
Overweight population (40 years and over) is 71.6%	Scottish Health Survey, 2003
Obese population in 40+ is 29.1%	Scottish Health Survey, 2003
Overweight or obese patients receive a leaflet on initial visit	Assumed
Obese patients attend 2 half hour appointment with a dietician	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Exercise costs are out with the NHS (eg local authority)	Assumed
Appointments	
<p>First Year</p> <p>Secondary patients and primary patients treated for lipid reduction or treated hypertension (>150/90) and diabetic patients (40.3%) currently see GP or practice nurse regularly - additional time with patients due to identification of high CVD risk (drug mix) is equivalent to 2 additional visits per annum - 1 appointment with GP & 1 with practice nurse.</p> <p>All other primary patients (59.7%) have 3 additional appointments per annum - 1 appointment with GP thereafter (2) with a practice nurse.</p> <p>Thereafter</p> <p>Secondary patients and primary patients treated for lipid reduction or treated hypertension (>150/90) and diabetic patients (40.3%) require an additional 5 minutes per annum (1/3 appoint) with GP.</p> <p>All other primary patients (59.7%) have an additional annual appointment with GP after first year.</p>	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
<p>Average appointment length 15 minutes (assuming protocol is followed, ie. 3 BP readings)</p> <p style="text-align: center;">Assumption</p>	<p>Personal communication with Dr Jim Grant and Dr Malcolm Kerr</p> <p style="text-align: center;">Source</p>

Staff	
Weekly working hours	
GP = 44.7	Unit costs of health & social care 2005
Practice Nurse = 37	Unit costs of health & social care 2005
Dietician = 37	Unit costs of health & social care 2005
Administrator = 37	Assumed
Working weeks per annum	
GP = 46.5	Unit costs of health & social care 2005
Practice Nurse = 42	Unit costs of health & social care 2005
Dietician = 42	Unit costs of health & social care 2005
Administrator = 46	Assumed
GP to practice nurse ratio is 10:4 in Scotland	Unit costs of health & social care 2005 and Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Administrators – 1 WTE for each 25,000 additional appointments (ie. 4 min per appointment)	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
There is no spare capacity	Assumed
Other	
All secondary patients are identified in the first year of implementation	Assumed – record of secondary patients held
20% of primary patients are identified each year	Guidelines – assess once every 5 years
70% of patients who are not currently seen by their GP for other reasons (eg. Diabetes, hypertension (SBP>150)) will be risk assessed (expect 30% will not attend/present to GP) and therefore a proportion will not be identified with high CVD risk	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Consultant room is 16.5m ²	Standard - Personal communication with Dr Jim Grant
FBC, LFT, TC, HDL and Glucose taken for each assessment	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
CK taken once for all patients	Personal communication with Dr Jim Grant and Dr Malcolm Kerr
Patient numbers and hence costs are split using prevalence figures	
Treating global risk ie all patients at high risk receive statins, antihypertensives and aspirin (where BP treated to <150/90 mm Hg)	As per guideline

Appendix 12

Risk assessment resource requirements Year 1

Health board	Population*	Patient numbers	Staffing requirements			Capital
			GP	Practice nurse	Administrators	
Ayrshire and Arran	7.2%	3,800	0.1	0.5	0.2	1
Borders	2.2%	1,200	0.0	0.1	0.0	0
Dumfries and Galloway	2.9%	1,600	0.0	0.2	0.1	0
Fife	7.0%	3,700	0.1	0.5	0.1	1
Forth Valley	5.5%	2,900	0.1	0.4	0.1	1
Grampian	10.3%	5,500	0.1	0.7	0.2	1
Greater Glasgow and Clyde ¹	23.5%	12,400	0.3	1.6	0.5	2
Highland ²	6.0%	3,200	0.1	0.4	0.1	1
Lanarkshire	11.0%	5,800	0.1	0.7	0.2	1
Lothian	15.5%	8,200	0.2	1.1	0.3	1
Orkney	0.4%	200	0.0	0.0	0.0	0
Shetland	0.4%	200	0.0	0.0	0.0	0
Tayside	7.6%	4,000	0.1	0.5	0.2	1
Western Isles	0.5%	300	0.0	0.0	0.0	0
Scotland	100.0%	53,000	1.2	6.7	2.0	10

* Source: ISD

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 13

Management of patients with high CVD risk resource requirements

Health board	Prevalence*	Patient numbers	Staffing requirements				Capital	
			GP	Practice nurse	Administrators	Dieticians	Accommodation	
Ayrshire and Arran	7.2%	13,300	1.6	2.8	1.2	1.4	4	
Borders	2.7%	5,000	0.6	1.1	0.5	0.5	2	
Dumfries and Galloway	3.0%	5,500	0.7	1.2	0.5	0.6	2	
Fife	6.6%	12,200	1.5	2.6	1.1	1.2	4	
Forth Valley	5.9%	10,900	1.3	2.3	1.0	1.1	4	
Grampian	6.6%	12,200	1.5	2.6	1.1	1.2	4	
Greater Glasgow and Clyde ¹	26.7%	49,400	6.0	10.5	4.6	5.1	17	
Highland ²	5.5%	10,200	1.2	2.2	0.9	1.0	3	
Lanarkshire	13.4%	24,800	3.0	5.3	2.3	2.5	8	
Lothian	13.1%	24,200	2.9	5.1	2.3	2.5	8	
Orkney	0.2%	400	0.0	0.1	0.0	0.0	0	
Shetland	0.2%	400	0.0	0.1	0.0	0.0	0	
Tayside	8.3%	15,400	1.9	3.3	1.4	1.6	5	
Western Isles	0.6%	1,100	0.1	0.2	0.1	0.1	0	
Scotland	100.0%	185,000	22.3	39.4	17.0	18.8	61	

* Source: ISD

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 14

Risk assessment operating expenditure (including VAT) Year 1

Health board	Cost (£,000)										
	Staffing (including related overheads)			Consumables			Depreciation		Total		
	GP	Practice nurse	Administration	Total	Laboratories	Other	Total				
Ayrshire and Arran	11	23	4	38	49	9	58	1	97		
Borders	0	5	0	5	15	3	17	0	22		
Dumfries and Galloway	0	9	2	11	20	4	23	0	35		
Fife	11	23	2	36	47	9	56	1	93		
Forth Valley	11	18	2	31	38	7	45	1	77		
Grampian	11	32	4	47	70	13	83	1	131		
Greater Glasgow and Clyde ¹	33	72	11	116	160	29	189	3	307		
Highland ²	11	18	2	31	41	7	48	1	80		
Lanarkshire	11	32	4	47	75	14	88	1	136		
Lothian	22	50	6	78	106	19	125	1	204		
Orkney	0	0	0	0	3	0	3	0	3		
Shetland	0	0	0	0	3	1	3	0	3		
Tayside	11	23	4	38	52	10	62	1	101		
Western Isles	0	0	0	0	4	1	4	0	4		
Scotland	132	302	43	477	680	125	805	14	1,296		

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 15

Management of patients with high CVD risk operating expenditure (including VAT) Year 1

Health board	Cost (£,000)										
	Staffing (including related overheads)			Consumables			Smoking cessation	Depreciation	Total		
	GP	Practice nurse	Administration	Dieticians	Total	Laboratories				Other	Total
Ayrshire and Arran	176	126	26	71	399	277	64	341	49	5	795
Borders	66	50	11	26	152	104	24	128	19	3	301
Dumfries and Galloway	77	54	11	31	172	115	27	142	21	3	338
Fife	165	117	23	61	367	254	59	313	45	5	730
Forth Valley	143	104	21	56	324	227	52	279	41	5	649
Grampian	165	117	23	61	367	254	59	313	45	5	730
Greater Glasgow and Clyde ¹	660	473	98	260	1,491	1,028	237	1,265	183	23	2,962
Highland ²	132	99	19	51	301	212	49	261	38	4	604
Lanarkshire	330	239	49	128	745	516	119	635	92	11	1,483
Lothian	319	230	49	128	725	504	116	620	90	11	1,447
Orkney	0	5	0	0	5	8	2	9	1	0	15
Shetland	0	5	0	0	5	8	2	9	1	0	15
Tayside	209	149	30	82	469	319	74	393	57	7	926
Western Isles	11	9	2	5	27	23	5	28	4	0	60
Scotland	2,453	1,776	362	959	5,550	3,849	887	4,737	686	83	11,056

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 16

Capital expenditure for the prevention of CVD recommendations Years 1-5

	Cost (£'000)					Total
	1	2	3	4	5	
Risk Assessment						
Capital Investment						
Including VAT	320					320
Excluding VAT	272					272
Depreciation	14	14	14	14	14	70
Risk estimation and subsequent management of high CVD risk patients						
Capital Investment						
Including VAT	1,952	0	0	192	224	2,368
Excluding VAT	1,661	0	0	163	191	2,015
Depreciation	83	83	83	91	101	441

Appendix 17

Total risk assessment expenditure (including VAT) Years 1-6

Health board	Cost (£,000)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Ayrshire and Arran	129	97	97	97	97	3
Borders	22	22	22	22	22	0
Dumfries and Galloway	35	35	35	35	35	0
Fife	125	93	93	93	93	2
Forth Valley	109	77	77	77	77	2
Grampian	163	131	131	131	131	3
Greater Glasgow and Clyde ¹	371	307	307	307	307	6
Highland ²	112	80	80	80	80	2
Lanarkshire	168	136	136	136	136	3
Lothian	236	204	204	204	204	4
Orkney	3	3	3	3	3	0
Shetland	3	3	3	3	3	0
Tayside	133	101	101	101	101	3
Western Isles	4	4	4	4	4	0
Scotland	1,616	1,296	1,296	1,296	1,296	29

Note: Includes operating expenditure (Appendix 14) and capital expenditure (Appendix 16)

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 18

Total management of patients with high CVD risk expenditure (including VAT) Years 1-6

Health board	Cost (£,000)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Ayrshire and Arran	923	734	877	1,064	1,175	832
Borders	365	272	335	384	435	315
Dumfries and Galloway	402	308	374	428	493	346
Fife	858	676	813	938	1,109	761
Forth Valley	777	602	720	839	958	683
Grampian	858	676	813	938	1,109	761
Greater Glasgow and Clyde ¹	3,506	2,739	3,279	3,849	4,424	3,076
Highland ²	700	559	672	820	892	637
Lanarkshire	1,739	1,369	1,645	1,943	2,220	1,548
Lothian	1,703	1,338	1,609	1,904	2,167	1,506
Orkney	15	15	28	30	32	23
Shetland	15	15	28	30	32	23
Tayside	1,086	853	1,018	1,218	1,351	958
Western Isles	60	58	75	81	131	72
Scotland	13,007	10,212	12,283	14,468	16,529	11,541

Note: Includes operating expenditure (Appendix 15) and capital expenditure (Appendix 16)

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 19

Total expenditure including VAT for the prevention of CVD recommendations Years 1-6

Health board	Cost (£,000)					
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Ayrshire and Arran	1,052	832	975	1,162	1,273	835
Borders	387	294	356	406	457	315
Dumfries and Galloway	436	343	408	463	528	346
Fife	983	769	906	1,032	1,202	764
Forth Valley	887	679	798	917	1,035	685
Grampian	1,021	807	944	1,070	1,240	764
Greater Glasgow and Clyde ¹	3,878	3,046	3,586	4,157	4,731	3,082
Highland ²	812	640	752	901	972	640
Lanarkshire	1,907	1,505	1,781	2,079	2,356	1,551
Lothian	1,939	1,542	1,813	2,108	2,371	1,509
Orkney	18	18	31	33	35	23
Shetland	19	18	31	33	35	23
Tayside	1,219	953	1,118	1,319	1,452	961
Western Isles	64	62	79	85	136	72
Scotland	14,623	11,508	13,578	15,763	17,825	11,570

¹ Greater Glasgow HB = Glasgow HB + (Argyll and Clyde HB - Argyll and Bute CA).

² Highland HB = Highland HB + Argyll and Bute CA.

Appendix 20

Statin efficacy

Product	Dose	Mean % reduction from baseline total cholesterol
Atorvastatin	10mg	27.1%
	20mg	31.8%
	40mg	35.8%
	80mg	38.9%
Pravastatin	10mg	14.7%
	20mg	17.2%
	40mg	21.5%
Rosuvastatin	5mg	29.4%
	10mg	32.9%
	20mg	37.6%
	40mg	40.2%
Simvastatin	10mg	20.3%
	20mg	25.7%
	40mg	27.9%
	80mg	32.9%

Appendix 21

Total cholesterol distribution (Scotland)

Untreated population			Treated population		
Cholesterol	%	Mean	Cholesterol	%	Mean
0 - 4	2.1%	3.59	0 - 4	38.3%	3.48
4 - 4.5	4.8%	4.21	4 - 4.5	25.0%	4.28
4.5 - 5	9.8%	4.73	4.5 - 5	18.4%	4.80
5 - 5.5	14.9%	5.21	5 - 5.5	9.7%	5.22
5.5 - 6	18.5%	5.70	5.5 - 6	5.1%	5.70
6 - 6.5	17.7%	6.18	6 - 6.5	1.5%	6.31
6.5 - 7	13.0%	6.69	6.5 - 7	0.5%	6.80
7 - 7.5	9.0%	7.16	7 - 7.5	0.0%	7.25
7.5 - 8	5.7%	7.68	7.5 - 8	1.5%	7.85
8 - 8.5	2.2%	8.20	8 - 8.5		
8.5 - 9	1.2%	8.70	8.5 - 9		
9 - 9.5	0.8%	9.20	9 - 9.5		
9.5 - 10	0.2%	9.67	9.5 - 10		
10 - 10.5	0.0%	10.25	10 - 10.5		
10.5 - 11	0.0%	10.70	10.5 - 11		
11 - 11.5	0.1%	11.20	11 - 11.5		
Total	100.0%	6.01	Total	100.0%	4.33
Max		11.40	Max		7.98
Min		2.60	Min		2.45

Appendix 22

Patient numbers and costs per annum (excluding VAT) Years 1-6

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
PATIENT NUMBERS (excluding any discontinuation)						
Secondary Patients						
Initiate or receive more aggressive treatment	96,000					
Continue treatment		96,000	96,000	96,000	96,000	96,000
Total		96,000	96,000	96,000	96,000	96,000
Primary Patients						
Initiate treatment	87,000	87,000	87,000	87,000	87,000	
Continue treatment		87,000	174,000	261,000	348,000	435,000
Total		174,000	261,000	348,000	435,000	435,000
COSTS (excluding VAT)						
Costs (£ million)*						
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Drug Costs						
Secondary (to 5.0mmol/L)	8.1	16.6	16.6	16.6	16.6	16.6
Primary (Simva 40mg)	1.7	4.4	7.2	10.0	12.8	13.9
Total drug costs	9.7	21.0	23.8	26.6	29.4	30.5
Prescription charges						
Secondary	0.1	0.2	0.2	0.2	0.2	0.2
Primary	0.2	0.6	0.9	1.2	1.6	1.7
Total prescription charges	0.3	0.8	1.1	1.4	1.8	1.9
Total Costs	10.0	21.8	24.9	28.0	31.8	32.4

Appendix 23

Annual statin costs

Treatment strategy	Annual treatment cost per patient (excluding VAT) (£)		Annual treatment cost per patient (including VAT) (£)	
	Year 1	From Year 2	Year 1	From Year 2
Untreated secondary patients				
Start Dose: Simvastatin 40mg	44.32	44.32	52.08	52.08
Step 1: Atorvastatin 20mg	257.48	321.20	302.54	377.41
Step 2: Atorvastatin 40mg	282.60	367.74	332.05	432.09
Step 3: Atorvastatin 80mg	282.60	367.74	332.05	432.09
Treated secondary patients				
Start Dose: Simvastatin 40mg	N/A	N/A	N/A	N/A
Step 1: Atorvastatin 20mg	321.20	321.20	377.41	377.41
Step 2: Atorvastatin 40mg	357.03	367.74	419.51	432.09
Step 3: Atorvastatin 80mg	357.03	367.74	419.51	432.09
Primary patients				
Simvastatin 40mg		44.32		52.08

Appendix 24

Medication assumptions

ACS recommendations

	Basecase proportion	Chemical compound	Pharmaceutical form	Dose	Frequency	Net cost per pack	Cost per patient per annum (excluding VAT)	Cost per patient per annum (including VAT)	Source
Recommendation 1									
Current practice	100%	Enoxaparin sodium	Intravenous	80mg (8,000 units)	2 daily	£5.40	£86.40	£101.60	BNF 52
Post-rec	100%	Fondaparinux	Intravenous	2.5mg	1 daily	£6.66	£53.28	£62.64	BNF 52
Recommendation 2									
Current practice	100%	Enoxaparin sodium	Intravenous	80mg (8,000 units)	2 daily	£5.40	£86.40	£101.60	BNF 52
Post-rec	100%	Fondaparinux	Intravenous	2.5mg	1 daily	£6.66	£53.28	£62.64	BNF 52
Recommendation 3									
Post-rec	100%	Atenolol	Intravenous	5mg (10ml)	Once	£0.96	£0.96	£1.13	BNF 52
Recommendation 4									
Current practice	100%	Streptokinase	Intravenous	1.5 million units	Once	£81.18	£81.18	£95.39	BNF 52
Post-rec alternative	100%	Alteplase	Intravenous	10mg (2 x 50mg)	Once	£300.00	£600.00	£705.00	BNF 52
Post-rec alternative	100%	Retepase	Intravenous	2 x 10 units	Once	£333.00	£666.00	£782.56	BNF 52
Post-rec alternative	100%	Tenecteplase	Intravenous	50mg (10,000 units)	Once	£612.00	£612.00	£719.10	BNF 52



ACS recommendations continued

	Basecase proportion	Chemical compound	Pharmaceutical form	Dose	Frequency	Net cost per pack	Cost per patient per annum (excluding VAT)	Cost per patient per annum (including VAT)	Source
Recommendation 1									
Current practice - 1 year	100%	Clopidogrel	Tablet	75mg	1 daily	£35.31	£460.29	£540.85	BNF 52
Post-rec - 3 months	91%	Clopidogrel	Tablet	75mg	1 daily	£35.31	£114.76	£134.84	BNF 52
Post-rec - 6 months	9%	Clopidogrel	Tablet	75mg	1 daily	£35.31	£230.78	£271.17	BNF 52
Recommendation 6									
Post-rec - 4 weeks	100%	Eplerenone	Tablet	25mg	1 daily	£42.72	£556.89	£654.39	BNF 52
Post-rec - thereafter	100%	Eplerenone	Tablet	50mg	1 daily	£42.72	£556.89	£654.39	BNF 52

Heart failure recommendations

	Basecase proportion	Chemical compound	Pharmaceutical form	Dose	Frequency	Net cost per pack	Cost per patient per annum (excluding VAT)	Cost per patient per annum (including VAT)	Source
Recommendation 1									
Post-rec	5%	Candesartan	Tablet	4mg	1 daily	£8.15	£106.24	£124.83	BNF 52
Post-rec	10%	Candesartan	Tablet	8mg	1 daily	£9.89	£128.92	£151.48	BNF 52
Post-rec	25%	Candesartan	Tablet	16mg	1 daily	£12.72	£165.81	£194.83	BNF 52
Post-rec	60%	Candesartan	Tablet	32mg	1 daily	£16.13	£210.27	£247.06	BNF 52
Recommendation 2									
Post-rec: 4 weeks	100%	Eplerenone	Tablet	25mg	1 daily	£42.72	£556.89	£654.39	BNF 52
Post-rec: thereafter	100%	Eplerenone	Tablet	50mg	1 daily	£42.72	£556.89	£654.39	BNF 52
Recommendation 3									
Post-rec: 4 weeks	100%	Eplerenone	Tablet	25mg	1 daily	£42.72	£556.89	£654.39	BNF 52
Post-rec: thereafter	100%	Eplerenone	Tablet	50mg	1 daily	£42.72	£556.89	£654.39	BNF 52
Recommendation 4									
Post-rec	100%	Hydralazine hydrochloride	Tablet	50mg	4 daily	£7.78	£50.71	£59.58	ISD - Drug tariff (Nov 2006)
Post-rec	100%	Isosorbide dinitrate	Tablet	20mg	4 daily	£6.37	£41.52	£48.78	ISD - Drug tariff (Nov 2006)
Recommendation 5									
Post-rec	100%	Hydralazine hydrochloride	Tablet	50mg	4 daily	£7.78	£50.71	£59.58	ISD - Drug tariff (Nov 2006)
Post-rec	100%	Isosorbide dinitrate	Tablet	20mg	4 daily	£6.37	£41.52	£48.78	ISD - Drug tariff (Nov 2006)

Prevention of CVD recommendations

	Basecase proportion	Chemical compound	Pharmaceutical form	Dose	Frequency	Net cost per pack	Cost per patient per annum (excluding VAT)	Cost per patient per annum (including VAT)	Source
Recommendation 1									
Post-rec	50% of ACE	Lisinopril	Tablets	20mg	1 daily	£1.98	£25.81	£30.33	ISD - Drug tariff (Nov 2006)
Post-rec	50% of ACE	Ramipril	Capsules	10mg	1 daily	£2.79	£36.37	£42.73	ISD - Drug tariff (Nov 2006)
Post-rec	100% of ARB	Candesartan	Tablets	8mg	1 daily	£9.89	£128.92	£151.48	ISD - Drug tariff (Nov 2006)
Post-rec	100% of B	Atenolol	Tablets	50mg	1 daily	£1.25	£16.29	£19.15	ISD - Drug tariff (Nov 2006)
Post-rec	100% of C	Amlodipine	Tablets	5mg	1 daily	£2.14	£27.90	£32.78	ISD - Drug tariff (Nov 2006)
Post-rec	100% of D	Bendroflumet h-iazide	Tablets	2.5mg	1 daily	£1.15	£14.99	£17.61	ISD - Drug tariff (Nov 2006)
Recommendation 2									
Post-rec	100%	Dipyridamole (M/R)	Capsules	200mg	2 daily	£8.38	£101.96	£119.80	BNF 52

Prevention of CVD recommendations continued

	Basecase proportion	Chemical compound	Pharmaceutical form	Dose	Frequency	Net cost per pack	Cost per patient per annum (excluding VAT)	Cost per patient per annum (including VAT)	Source
Recommendation 3									
Post-rec	100%	Aspirin	Dispersible tablets	75mg	1 daily	£0.40	£5.21	£6.13	BNF 52
Post-rec	10%	Lansoprazole	Capsules	15mg	1 daily	£2.42	£31.55	£37.07	ISD - Drug tariff (Nov 2006)
Recommendation 4									
Post-rec	50% of ACE	Lisinopril	Tablets	20mg	1 daily	£1.98	£25.81	£30.33	ISD - Drug tariff (Nov 2006)
Post-rec	50% of ACE	Ramipril	Capsules	10mg	1 daily	£2.79	£36.37	£42.73	ISD - Drug tariff (Nov 2006)
Post-rec	100% of ARB	Candesartan	Tablets	8mg	1 daily	£9.89	£128.92	£151.48	BNF 52
Post-rec	100% of B	Atenolol	Tablets	50mg	1 daily	£1.25	£16.29	£19.15	ISD - Drug tariff (Nov 2006)
Post-rec	100% of C	Amlodipine	Tablets	5mg	1 daily	£2.14	£27.90	£32.78	ISD - Drug tariff (Nov 2006)
Post-rec	100% of D	Bendroflumet h-iazide	Tablets	2.5mg	1 daily	£1.15	£14.99	£17.61	ISD - Drug tariff (Nov 2006)

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