The cost-effectiveness of lipid lowering in patients with ischaemic heart disease: an intervention and evaluation in primary care

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SUMMARY

Background. *There has been a major revolution in the recommended treatment of hyperlipidaemia in patients with ischaemic heart disease following the publication of the Scandinavian Simvastatin Survival Study. This was the first major study to demonstrate that lipid-lowering drugs reduced mortality and morbidity in patients with ischaemic heart disease.*

Aim. *To evaluate the feasibility and cost-effectiveness of screening and treating hyperlipidaemia in patients with ischaemic heart disease in primary care.*

Method. *A study conducted in a rural dispensing training practice on the border of Nottinghamshire and Lincolnshire involving 327 patients with ischaemic heart disease who were registered with the practice on 1 January 1996.*

Results. *Eighty per cent of patients with ischaemic heart disease were considered eligible for screening and 80% of those attended for screening. The majority of patients who were screened had hyperlipidaemia that persisted after dietary advice. Despite lipid-lowering drugs, few patients had serum lipid concentrations in the target range at the end of six months. The costs of identifying and treating 83 patients with lipid-lowering drugs over five years is estimated at £105 318 at 1996 prices, or £94 257 assuming a 6% discount rate per annum. Two-thirds of this is owing to the cost of lipid-lowering drugs. The discounted cost per coronary event prevented would be £17 138 (95% CI = £12 568–£26 183). The discounted cost per coronary death prevented would be £32 502 (95% CI = £23 564–£55 445). There were no important adverse effects of lipid-lowering drugs on quality of life or mood.*

Conclusion. *Such a programme is feasible and acceptable within primary care, although the ongoing cost implications need to be considered against the costs and benefits of other interventions.*

Keywords: ischaemic heart disease; hyperlipidaemia; primary care costs.

Introduction

THERE has been a major revolution in the recommended treatment of hyperlipidaemia in patients with ischaemic heart disease following the publication of the Scandinavian Simvastatin Survival Study (4S).[1] This was the first major study to demonstrate that lipid-lowering drugs reduced mortality and morbidity in patients with ischaemic heart disease, i.e. secondary prevention. Subsequently, the CARE study[2] showed the effectiveness of pravastatin in secondary prevention for ischaemic heart disease patients with 'normal' serum lipid concentrations. When all the clinical effects are considered in isolation, the case for lipid lowering in patients with vascular disease seems overwhelming.[3] This conclusion has substantial implications for the organisation and delivery of care within general practice.[4] While there is some evidence regarding the cost-effectiveness of primary prevention of ischaemic heart disease in primary care,[5,6] the implications of secondary prevention in primary care are yet to be determined.[7,8]

We set out to determine the costs and benefits of screening and treating hyperlipidaemia in patients with ischaemic heart disease in one general practice. The rationale and events that prompted the practice to undertake the venture have already been described.[9] This paper evaluates the effectiveness of the programme for patients with ischaemic heart disease.

Method

Identification of patients with ischaemic heart disease

The study was conducted in a rural dispensing training practice on the Nottinghamshire–Lincolnshire border. The practice has a clinical database that has been shown to have high standards of data completeness and accuracy.[10] All patients registered on 1 January 1996 with recorded evidence of ischaemic heart disease (i.e. a Read code relating to ischaemic heart disease or current prescription for nitrates) were identified from the computerised database. The patients' usual general practitioner (GP) was asked to confirm the diagnosis and to exclude patients who were unsuitable for this study. The exclusion criteria were current treatment with lipid-lowering drugs, old age (more than 90 years), terminal illness or dementia. All eligible patients were invited by letter for a fasting lipid test.

The intervention

A protocol for the management of hyperlipidaemia was drawn up in conjunction with a local consultant chemical pathologist and a local cardiologist using published evidence available in late 1995.[1] A patient was considered to have hyperlipidaemia if their fasting low density lipoprotein cholesterol level (LDL) was greater than 3.5 mmol/l or if their triglyceride level was greater than 3 mmol/l. Patients with hyperlipidaemia were given dietary advice and a diet sheet by the practice nurse. All patients with persistent hyperlipidaemia after a three-month trial of diet were asked to see their usual GP to discuss lipid-lowering drugs. Patients with pure hypercholesterolaemia were recommended for a statin, whereas those with a mixed picture were recommended for a fibrate.[9] Patients who did not attend for follow-up were sent a reminder.

The following variables were collected: age; sex; presence of hypertension; presence of diabetes mellitus; height; weight; smoking status; family history of ischaemic heart disease; use of

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aspirin (prescribed or over-the-counter); and current prescriptions for anti-anginal drugs. There were too few coronary events and deaths during the initial 12-month study period to allow meaningful analysis. Blood test results were entered on the computer each day by a receptionist.

The evaluation: measuring costs

The following practice costs were collected over a 12-month period:[5,6] administration costs of identifying and inviting patients for screening; data entry time; number of GP consultations; number of nurse consultations; costs of all the blood tests as specified in protocol; and costs of lipid-lowering drugs. The cost of an average ten-minute consultation with a GP in 1995/1996 was estimated at £6.90 (SD = £2.73).[11] Others have estimated that it takes five minutes to take a blood test, five minutes to take a dietary history, and 15 minutes to give dietary advice.[12] It was assumed that each blood test resulted in one telephone call for the results. The cost of lipid-lowering drugs was taken from *British National Formulary (BNF)* (1996). The cost of blood tests was obtained from the local pathology laboratory. Other assumed costs (syringes etc.) are listed in Table 3.

The evaluation: measuring benefits

The benefit of the programme was estimated according to the number of patients who needed treatment to prevent cardiac events and deaths, based on outcome data from the 4S study.[1] This method was chosen as it was derived from a population of both men *and* women with established cardiovascular disease and was based on the effect of lipid-lowering drugs. We chose not to discount the benefit of treatment, which may be a limitation to our study.

Assessment of the effect of treatment on mood and quality of life

Two questionnaires were administered to cases before starting lipid-lowering drugs and after six months to detect any changes in mood or quality of life. The Hospital Anxiety and Depression Scale (HAD) was used to rate changes in anxiety and depression.[13] The Short-Form Health Survey (SF-36) was used to rate changes in quality of life.[14] A control group was identified to account for any general shift in mood or quality of life during the study period that was not due to the intervention. The controls were identified by choosing the first patient of the same age and sex as the index case from an alphabetic list of patients with a diagnosis of osteoarthritis. Since patients with ischaemic heart disease could not act as controls on ethical grounds, we chose osteoarthritis as another chronic condition that causes pain on exercise.

Statistics and sample size

We used paired *t*-tests for changes in normally distributed data, the Wilcoxon matched pairs test for changes in paired data that were not normally distributed, and the Mann–Whitney test for changes in unpaired data.

We had an empirical sample size determined by the number of eligible patients in the practice population. A post-hoc power calculation using GPOWER showed that 48 paired responses gave the study a 95% power at the 0.05 significance level to detect a change of three units in depression score. This is based on a standard deviation of the change in depression score of 4.1 units.

Results

The practice population and outcome of screening

Figure 1 shows the outcome of the screening programme. Of the 5623 registered patients, 327 (5.8%) had a confirmed diagnosis of ischaemic heart disease. There were 259 patients in the target group invited for screening, of whom 223 (86%) attended. Overall, 95 patients with ischaemic heart disease began treatment with lipid-lowering drugs — 68 with a statin and 27 with a fibrate. Eighty-three patients were still taking medication at the end of 12 months. The baseline characteristics of the 259 patients in the target group are shown in Table 1.

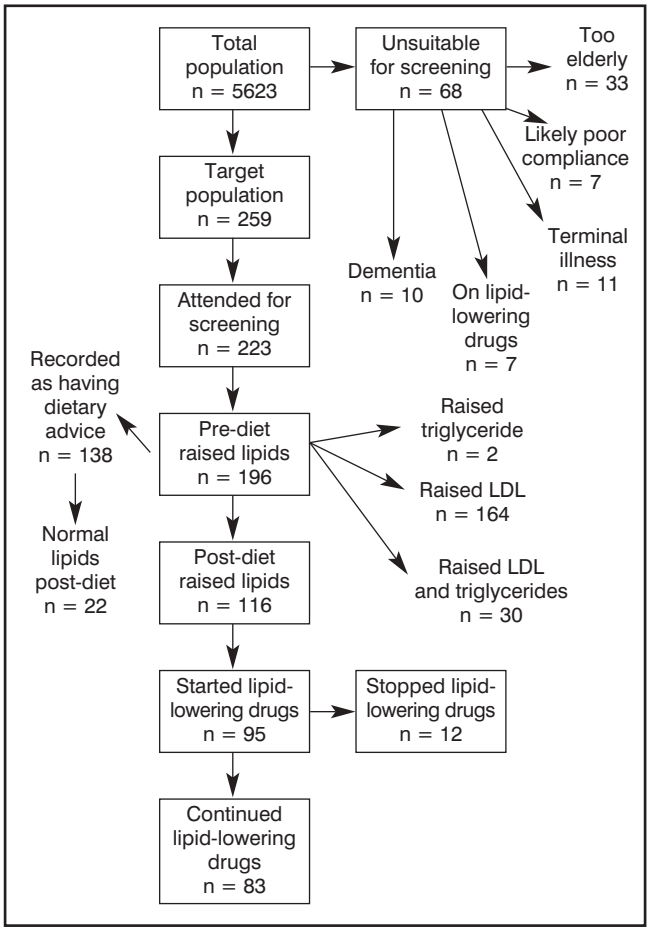

Figure 1. The outcome of hyperlipidaemia screening.

Changes in serum lipid concentrations after diet and after lipid-lowering drugs

Table 2 shows the effect of dietary advice and lipid-lowering drugs on serum lipid concentrations and body mass index. Of the 196 patients with hyperlipidaemia, 138 (70%) were recorded on the computer as having been given dietary advice. There was a 10% reduction in mean LDL from 5.7 mmol/l to 5.1 mmol/l. After dietary advice, 22 patients (16%) had normal serum lipid concentrations according to parameters defined in the protocol. There was no significant change in body mass index.

Paired data before and after treatment with lipid-lowering drugs were available for 73 patients. Twelve patients did not have a repeat test, as they had stopped drug treatment, and 10 patients were due to return for a repeat test after the end of the study period. There were highly significant mean reductions in mean LDL concentrations (21%, $P<0.0001$) and triglyceride concentrations (20%, $P = 0.001$). Despite this, the mean LDL of 4.7 mmol/l was still above our target level. Of the 73 patients with a post-drug blood test result, only 18 (25%) achieved a normal lipid profile.

Table 1. Baseline characteristics of 259 patients in the target population.

	Number of patients (n = 259)	Percentage
Male	159	61.4
Previous myocardial infarction	111	42.9
Diabetes mellitus	34	13.1
Hypertension	94	36.3
Current or ex-smoker	89	34.4
Recorded family history of ischaemic heart disease	104	40.2
	Mean	SD
Age (years)	68.9	9.6
Body mass index (kg/m^2)	27.0	4.2
Systolic blood pressure (mm Hg)	153.3	25.6
Diastolic blood pressure (mm Hg)	85.9	14.5
Medication	Number of patients	Percentage
Nitrate	83	32.0
Beta-blocker	78	30.1
Calcium channel blocker	60	23.2
Three anti-anginal agents	30	11.6
Record of prescribed aspirin	109	42.1
Record of over-the-counter aspirin	94	36.3
All patients on aspirin	203	78.4
Warfarin	12	4.6
Thiazide	15	5.8
Frusemide	22	8.5
Angiotensin-converting enzyme inhibitor	23	8.9

Table 2. The effect of dietary advice and lipid-lowering drugs on serum lipid concentrations and body mass index.

	Number with paired data	Mean (mmol/l)	SD	Percentage change in mean value	P-value[a]
The effect of diet					
LDL					
Pre-diet	136	5.69	2.21	-10.0	0.03
Post diet	-	5.12	2.2	-	-
Triglyceride					
Pre-diet	136	2.19	1.09	-6.4	0.39
Post-diet	-	2.05	1.89	-	-
Body mass index (kg/m^2)					
Pre-diet	149	28.12	4.00	-0.4	0.55
Post-diet	-	28.00	4.65	-	-
The effect of lipid-lowering drugs					
LDL					
Pre-drug	71	5.91	2.35	-21.2	<0.0001
Post-drug	-	4.66	4.66	-	-
Triglyceride					
Pre-drug	69	2.03	0.82	-19.7	0.001
Post-drug	-	1.63	0.90	-	-
Body mass index (kg/m^2)					
Pre-drug	92	28.00	4.60	-0.8	0.64
Post-drug	-	27.78	4.38	-	-

[a]P-value for the change before and after intervention, calculated using the paired t-test (two-tailed).

Twenty-one patients with hyperlipidaemia despite dietary advice did not start lipid-lowering drugs. Such patients were three times more likely to be female (odds ratio = 3.1, 95% CI = 1.4–6.7, P = 0.005) and tended to have lower LDL concentrations (Mann–Whitney U = 1126, P = 0.009). There was no difference in other risk factors, such as age, diabetes, smoking status, hypertension, and body mass index.

Of the 95 patients who started treatment with lipid-lowering drugs, 62 (65%) returned the adverse effects questionnaire. Of these, 22 (34%) patients reported adverse effects and 12 discontinued treatment. The most common adverse effects reported were nausea and/or abdominal pain (11 patients), headache (five patients), and muscular pain (five patients).

The cost of identifying and treating hyperlipidaemia in ischaemic heart disease patients

Initial costs incurred during the first 12 months. Table 3 shows the actual costs of screening and treating hyperlipidaemia in patients with ischaemic heart disease in our practice during the 12-month study period. Note that these actual costs differ from the estimated costs for screening the whole practice population (including patients without ischaemic heart disease) as described

Table 3. The initial hyperlipidaemia programme costs for 12 months.

Potential costs of the screening	Number of hours	Cost (£) per hour	Total cost (£)
GP time to supervise programme	20.0	30.00	600
Practice manager time	12.0	15.10	181
Receptionist time	60.0	6.68	401
Secretarial time	14.5	8.38	122
Data entry for blood test results	48.0	6.69	321
Nurse time to organise patient recall and review case notes	80.0	11.59	927
10-minute nurse appointment for 430 blood tests and to take dietary history	71.7	11.59	831
15-minute nurse appointment for lifestyle advice for 223 patients	55.8	11.59	646
10-minute GP appointment for 232 patients at £6.90 per consultation	38.7	41.40	1601
Subtotal			5629
Items	**Number of items**	**Cost (£) per item**	**Total cost (£)**
Patient invitation by letter	259	0.25	65
Phone calls to and from patients[a]	430	0.10	43
Syringes (20 ml)	430	0.06	26
Needles	430	0.01	5
Test tubes (10 ml)	885	0.09	84
Laboratory cost per lipid blood test	430	4.80	2064
Thyroid function test	105	4.24	445
Urea and electrolytes	105	2.91	306
Liver function test and creatinine kinase	105	2.92	307
Subtotal			3344
Total cost of screening and identifying subjects			8973
Drugs	**Number of patients on drug**	**Cost (£) per patient per month[b]**	**Total annual cost (£)**
Fluvastatin 40mg daily	57	14.90	10 192
Fenofibrate 200mg daily	23	24.40	6734
Simvastatin 20mg daily	3	31.09	1119
Subtotal	83	70.39	18 045
Overall total			27 019

[a]Assume that every blood test resulted in a phone call; [b]drug costs as per *BNF* 1996. Note: salary costs include superannuation and national insurance.

previously.[9] The total cost of screening, identifying, and treating with lipid-lowering drugs was £27 019. It cost £8973 (33%) to screen the 259 patients in the target group — approximately £35 per patient screened.

Of the 95 patients with ischaemic heart disease who started lipid-lowering treatment, 83 were still receiving it at the end of the 12-month study period, 60 patients were on a statin, and 23 on a fibrate. Using *BNF* data, the total cost of the lipid-lowering medication for the first 12 months was £18 045. This represents 67% of the programme costs for the first year. With 83 patients continuing to receive treatment, the cost of treatment was £217 per patient.

The estimated costs for a five-year period for patients with ischaemic heart disease

Assuming 1996 costs (Table 3), over four years there would be 664 blood tests (£3187), 664 nurse appointments (£641), and 332 GP appointments (£2291). This estimate has been based on 83 patients on lipid-lowering drugs each having two lipid blood tests per year, two five-minute nurse appointments per year, and one 10-minute GP consultation. The costs of the lipid-lowering medication for these patients for four years would be £72 180. The total cost of running the programme for the next four years at 1996 prices would therefore be £78 299, or £19 575 per annum. This is equivalent to £235 per person treated per year. If the initial total first year cost of setting up the programme was £27 019 (Table 3) then the total cost to the practice over five years would be £105 318.

Applying a 6% per annum discount rate[15] to the annual cost of running the programme, the total cost for four years would be £67 239. When added to the first year costs (£27 019), the discounted total cost of the programme over five years would be £94 257.

The estimated benefit of treatment

Using outcome data from the 4S, an average of 15 patients (95% CI = 11–23) need to be treated for five years to prevent one coronary event. Twenty-nine patients (95% CI = 20–49) would need to be treated to prevent one coronary death. Assuming 15 patients need to be treated for five years to prevent one event, then treatment of 83 patients for five years would prevent an average of 5.5 events (95% CI = 3.6–7.5). If the cost of running the programme for five years was £105 318 (based on 1996 costs), then the average cost per coronary event prevented would be £19 149 (95% CI = £14 042–£29 255). Based on a 6% discounted total cost of £94 257, the average cost per coronary event prevented would be £17 138 (95% CI = £12 568–£26 183).

If 29 patients (95% CI = 20–49 deaths) need to be treated for five years to prevent one coronary death, then the Collingham programme would prevent 2.9 deaths (95% CI = 1.7–4 deaths). Based on 1996 costs, the average cost per coronary death pre-

Table 4. Baseline characteristics of cases who started lipid-lowering drugs and controls.

	Number of cases (n = 95)	Percentage	Number of controls (n = 95)	Percentage
Percentage				
Male	58	61	58	61
Diabetes mellitus	15	16	1	1
Hypertension	34	36	14	15
Current or ex-smoker	30	32	10	11
Recorded family history of ischaemic heart disease	40	42	3	3
	Mean	SD	Mean	SD
Age (years)	67	8	67	8
Body mass index (kg/m^2)	27.6	3.5	27.0	4.2
Systolic blood pressure (mmHg)	150	21	153	36
Diastolic blood pressure (mmHg)	84	10	87	17

vented over five years would be £36 317 (95% CI = £26 330–£61 952). Based on a 6% discounted total cost of £94 257, the average cost per coronary death prevented would be £32 502 (95% CI = £23 564–£55 445).

The effect of lipid lowering drugs on quality of life

Table 4 shows the baseline characteristics for the 95 cases with ischaemic heart disease compared with the 95 age–sex matched osteoarthritis controls. There were 58 male and 37 female case control pairs with a mean age of 67 years. The groups were well matched for initial body mass index and blood pressure. As expected, cases were more likely to have cardiac risk factors, such as diabetes (χ^2 = 13.38, P = 0.0003), hypertension (χ^2 = 11.15, P = 0.0008), and be current or ex-smokers (χ^2 = 12.67, P = 0.0003).

Seventy-nine cases and 62 controls returned the first questionnaire, giving a response rate of 83% and 65% respectively. Sixty-two (65%) cases and 49 (52%) osteoarthritis controls returned the second questionnaire sent after six months. There was a minimum of 48 paired responses before and after intervention for each of the outcome measures. Table 5 shows the effect of lipid-lowering drugs on quality of life as rated by the SF-36 (higher scores are associated with poorer functioning). The osteoarthritis patients acting as controls were reasonably well matched at baseline for all the domains of the SF-36, except for a borderline difference in physical functioning and general health perception. There were no statistically significant changes in quality of life before and after intervention in cases compared with controls. Given our post-hoc power calculation, this is unlikely to be a type two error.

The effect of lipid-lowering drugs on anxiety and depression

Table 5 shows the effect of lipid-lowering drug treatment on anxiety and depression. At baseline, cases with ischaemic heart disease had higher depression scores compared with our osteoarthritis patients acting as controls (Wilcoxon signed rank test P = 0.004). There was no difference in anxiety scores at baseline. There was no increase in depression scores for cases after treatment.

Of the 95 patients who started lipid-lowering drug treatment, 78 had both a LDL level and a HAD anxiety and depression score before treatment. There was no correlation between pre-treatment LDL concentrations and either anxiety (Spearman's correlation coefficient = 0.01, P = 0.90) or depression (Spearman's correlation coefficient = -0.08, P = 0.50). Similarly, there was no correlation between changes in LDL concentrations and either changes in anxiety or depression scores.

Discussion

This study has evaluated the costs and benefits of screening for hyperlipidaemia in patients with ischaemic heart disease in one general practice. Using a pragmatic approach, we have found that such a programme is feasible in primary care. We have found no evidence that lipid-lowering treatment adversely affects quality of life or mood, which is consistent with the work of Marteau and others.[16]

This type of study is pragmatic — we have taken an intervention that has been shown to work in a large multi-centre double-blind placebo-controlled trial and attempted to evaluate its implementation in ordinary practice. We did not randomise patients to intervention or control because of the ethical difficulty of withholding a proven treatment. We chose the best controls we could think of, although the presence of osteoarthritis may have introduced some bias: osteoarthritic patients may be essentially different or use different medication, for example. Ideally we would have compared the cost-effectiveness of alternative interventions, however constraints on study design prevented us from doing this.

Outcome data from the 4S study were used to calculate the number of patients who need to be treated for five years to prevent one coronary death. Our patients were different from the 4S study population. Our patients had some factors associated with increased coronary risk (older, higher baseline serum lipid concentrations and blood pressure measurements), while others had factors associated with decreased risk (fewer men, fewer subjects with a myocardial infarct, and a higher percentage of patients recorded as taking aspirin), which have been described elsewhere. Any increase or decrease in absolute risk would be associated with a corresponding increase or decrease in absolute benefit.[18] Unfortunately, we were unable to quantify the overall balance of risks. However, if our study patients had a higher absolute risk compared with the 4S study patients, then fewer patients would have needed treatment in order to prevent one coronary event. This would have had the effect of reducing the cost per event prevented.

There was a 10% reduction in LDL concentrations and a 6% reduction in fasting serum cholesterol after dietary advice. These figures are higher than the reduction of 2% found in other studies.[19,20] This could be owing to patients being well motivated and coming from a relatively affluent area.

By contrast, lipid-lowering drugs were less effective than in

Table 5. The effect of lipid-lowering drugs on quality of life (as rated by SF-36) and anxiety and depression (as rated by HAD scale).

	Cases			Controls				
Domain	Number with data (n = 95)	Median	IQR	Number with data (n = 95)	Median	IQR	P-value for baseline[a]	P-value for change[b]
Physical functioning								
Pre-intervention	79	60	40–80	62	75	55–95	0.03	0.39
Post-intervention	62	65	50–80	49	65	50–90	-	-
Role limitation (physical problem)								
Pre-intervention	79	50	0–100	62	75	0–100	0.39	0.09
Post-intervention	62	50	0–100	49	75	25–100	-	-
Bodily pain								
Pre-intervention	78	74	64–94	62	74	54–94	0.40	0.74
Post-intervention	62	74	74–100	49	74	62–100	-	-
Social functioning								
Pre-intervention	79	100	75–100	62	100	75–100	0.31	0.46
Post-intervention	62	100	75–100	49	100	75–100	-	-
Role limitation (emotional problem)								
Pre-intervention	79	100	30–100	62	100	66–100	0.21	0.21
Post-intervention	62	100	0–100	49	100	33–100	-	-
General health perception								
Pre-intervention	79	55	45–72	62	62	50–77	0.05	0.10
Post-intervention	62	57	42–72	49	67	52–87	-	-
Depression								
Pre-intervention	78	4	2–6	62	3	1–4	0.004	0.03
Post-intervention	60	4	2–6	48	4	1–6	-	-
Anxiety								
Pre-intervention	78	6	3–8	62	4	2–7	0.18	0.45
Post-intervention	60	5	2–8	48	4	1–7	-	-

[a]P-value for baseline scores for cases compared with control using Wilcoxon matched pairs signed rank test; [b]P-value for change in score before and after intervention for cases compared with controls using Wilcoxon matched pairs signed rank test.

other studies. There was a 21% reduction in LDL in our study compared with 38% in the 4S study. Similarly, only one-quarter of our patients had normal lipid profiles compared with three-quarters of the 4S patients. We do not have an explanation for this — poor compliance is a possibility, although this is unlikely given the effectiveness of the dietary intervention.

If the practice prescribes lipid-lowering treatment to 83 patients with heart disease for five years, between three and eight coronary events and two to four coronary deaths would be prevented. Assuming a discount rate of 6% per annum, it would cost an average of £19 000 to prevent one coronary event and £32 000 to prevent one death. The total discounted cost to the practice would be approximately £94 000 over five years. These costs would vary according to changes in unit costs per item and could be demonstrated by sensitivity analyses, which we have not done as part of this study. There are many ways such resources could be used — for smoking cessation, treating hypertension in the elderly, improving glucose control for diabetics etc. To make the best use of resources practices need to use clinical audit, scientific evidence, clinical guideline, and analysis of cost-effectiveness before commissioning new strategies of health care.[9] At the moment, it is for individual practices to prioritise their patient's needs, although this will soon be within the remit of primary care groups/trusts in accordance with the National Plan and the National Service Framework for Coronary Heart Disease.

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