

# Primary care

## Cluster randomised controlled trial to compare three methods of promoting secondary prevention of coronary heart disease in primary care

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### Abstract

**Objective** To assess the effectiveness of three different methods of promoting secondary prevention of coronary heart disease in primary care.

**Design** Pragmatic, unblinded, cluster randomised controlled trial.

**Setting** Warwickshire.

**Subjects** 21 general practices received intervention; outcome measured in 1906 patients aged 55-75 years with established coronary heart disease.

**Interventions** Audit of notes with summary feedback to primary health care team (audit group); assistance with setting up a disease register and systematic recall of patients to general practitioner (GP recall group); assistance with setting up a disease register and systematic recall of patients to a nurse led clinic (nurse recall group).

**Main outcome measures** At 18 months' follow up: adequate assessment (defined) of 3 risk factors (blood pressure, cholesterol, and smoking status); prescribing of hypotensive agents, lipid lowering drugs, and antiplatelet drugs; blood pressure, serum cholesterol level, and plasma cotinine levels.

**Results** Adequate assessment of all 3 risk factors was much more common in the nurse and GP recall groups (85%, 76%) than the audit group (52%). The advantage in the nurse recall compared with the audit group was 33% (95% confidence interval 19% to 46%); in the GP recall group compared with the audit group 23% (10% to 36%), and in the nurse recall group compared with the GP recall group 9% (-3% to 22%). However, these differences in assessment were not reflected in clinical outcomes. Mean blood pressure (148/80, 147/81, 148/81 mm Hg), total cholesterol (5.4, 5.5, 5.5 mmol/l), and cotinine levels (% probable smokers 17%, 16%, 19%) varied little between the nurse recall, GP recall, and audit groups respectively, as did prescribing of hypotensive and lipid lowering agents. Prescribing of antiplatelet drugs was higher in the nurse recall group (85%) than the GP recall or audit groups (80%, 74%). After adjustment for baseline levels, the advantage in the nurse recall group compared with the audit group was 10% (3% to 17%), in the nurse recall group

compared with the GP recall group 8% (1% to 15%) and in the GP recall group compared with the audit group 2% (-6% to 10%).

**Conclusions** Setting up a register and recall system improved patient assessment at 18 months' follow up but was not consistently better than audit alone in improving treatment or risk factor levels.

Understanding the reasons for this is the key next step in improving the quality of care of patients with coronary heart disease.

### Introduction

Patients with established coronary heart disease are at serious risk of subsequent vascular events (non-fatal myocardial infarction, non-fatal strokes, and vascular deaths).<sup>1</sup> This risk can be reduced by effective clinical and preventive care.<sup>2</sup> Evidence also exists that the quality of such care in hospitals and general practices is inadequate. Assessment of risk is often incomplete, and many patients whose risk could be reduced are not receiving optimal treatment.<sup>3-4</sup>

Last year the national service framework for coronary heart disease set as a target in England that general practitioners and primary care teams should aim to identify all people with established cardiovascular disease and offer them comprehensive advice and appropriate treatment to reduce their risks.<sup>5</sup> This will require important changes in clinical practice and in the systems of care. Methods of achieving quality improvement and change in clinical practice vary in their effectiveness, and these have recently been reviewed.<sup>6</sup> Audit and feedback, the provision of guidelines (and facilitation to assist their adoption), record systems, improved communications between primary and secondary care, patient reminders, and nurse led clinics in general practice have all been advocated and tested as methods of producing change in practice for patients with established coronary heart disease.<sup>7-12</sup> They have not been compared directly and have different potential costs.

We aimed to compare the effectiveness of three different interventions for improving the secondary preventive care of patients with coronary heart disease delivered at the level of general practice: audit and

feedback; recall to a general practitioner; and recall to a nurse clinic. The intervention was assessed in a pragmatic, unblinded, cluster randomised controlled trial that attempted to include all general practices in Warwickshire.

## Participants and methods

### Recruitment of practices

In June 1997 we invited all 79 general practices in Warwickshire to participate in the study and eventually recruited 21 practices. The practices that had expressed no interest in the study were smaller, less likely to employ practice nurses, and less likely to be involved in training than others.

### Identification of patients

All paper and computer records of patients aged 55-75 years were hand searched by six external auditors, and patients with established coronary heart disease were identified.<sup>15</sup> Coronary heart disease was defined as a previous diagnosis of myocardial infarction, stable angina, or revascularisation by percutaneous transluminal coronary angioplasty or coronary artery bypass. Patients who had single episodes of chest pain diagnosed as possible angina but who did not continue to take any antianginal drugs were not included. In all, 2142 patients were identified as having coronary heart disease.

### Interventions

*Audit and feedback (audit group)*—Practices were given summary audit results at a practice meeting (one practice requested written material only). The results presented were the number of patients with myocardial infarction, angina, and revascularisation; the prevalence of identified coronary heart disease in the practice; and the proportions of patients with “adequate assessment” (see “Study outcomes” for definition) and treatment with antiplatelet drugs, hypotensive agents, and lipid lowering drugs. Anonymised data from other practices in the study were given for comparison. Practices were asked to provide usual care and were given no further support during the trial.

*Recall to general practitioner (GP recall group)*—Practices were given the same patient information as was given to the audit group but were also given the names of patients identified as having coronary heart disease. MM discussed and agreed guidelines for secondary prevention with the practice doctors and gave ongoing support in setting up a register and recall system for regular review of patients with coronary heart disease by their general practitioner.

*Recall to nurse clinic (nurse recall group)*—Practices were given the same patient information as was given to the GP recall group. The trial’s nurse facilitator (LW) gave ongoing support to the practices in setting up a register and recall system for systematic review of patients with coronary heart disease in a nurse led clinic. After discussion and agreement of guidelines for secondary prevention, the practice doctors and nurses agreed the clinic protocol, and the nurses received education to implement it.

**Table 1** Characteristics at baseline of the 1906 patients alive and registered with the practice at follow up, by trial group. Values are numbers (percentages) of patients unless stated otherwise

	Audit group (n=559)	GP recall group (n=682)	Nurse recall group (n=665)
Mean (SD) age (years)	66.1 (5.4)	66.4 (5.6)	65.8 (5.8)
Men	373 (67)	457 (67)	469 (71)
Original diagnosis:			
Myocardial infarction (with or without angina)	294 (53)	342 (50)	320 (48)
Angina only	265 (47)	340 (50)	345 (52)
Mean (SD) No of years since original diagnosis	7.9 (6.1)	8.5 (7.7)	8.5 (7.1)
Complications:			
Coronary artery bypass grafting	92 (16)	109 (16)	109 (16)
Percutaneous transluminal coronary angioplasty	43 (8)	84 (12)	77 (12)
Diabetes	80 (14)	77 (11)	66 (10)
Heart failure	44 (8)	65 (10)	61 (9)
Smoking status:			
Current smoker	94 (17)	116 (17)	126 (19)
Non-smoker	367 (66)	442 (65)	424 (64)
Not recorded	97 (17)	122 (18)	115 (17)

### Study outcomes

The primary outcome was adequate assessment at 18 months’ follow up. At the first audit adequate assessment was defined as (a) a record of blood pressure since diagnosis and, if on any occasion this was recorded as exceeding 140 mm Hg systolic or 90 mm Hg diastolic, a record of a follow up blood pressure in the previous two years; (b) a record of serum cholesterol measurement since diagnosis and, if any reading was  $\geq 5.5$  mmol/l, a record of repeat cholesterol measurement in the previous two years; (c) a record of smoking habit and, for smokers, a record of review in the previous two years. At the second audit the same criteria were applied, except that a blood pressure reading in the previous two years was mandatory. The main secondary outcomes were recorded treatment with hypotensive agents, lipid lowering drugs, and antiplatelet drugs.

Adequate assessment and drug treatment were determined at baseline and follow up from an audit of patients’ notes. Characteristics of the patients were similar in the three trial groups (table 1).

After the second audit, patients were invited to attend their practice for a clinical examination. A research nurse who was blind to the patient’s allocation group and had no previous involvement with the trial, carried out the clinical assessment. This included blood pressure measurement (two measurements taken five minutes apart with a digital blood pressure monitor) and blood sampling for serum cholesterol and cotinine estimations. All blood analyses were carried out in the same laboratory. A plasma cotinine level of  $\leq 20$  ng/ml was taken to indicate non-smoking.<sup>14</sup>

## Results

### Adequate assessment

At baseline about 30% of patients were adequately assessed overall; this proportion rose markedly during the trial in all three groups (table 2). The greatest contribution to the overall rise came from the improvement in assessing cholesterol levels, but assessment of smoking status and blood pressure also increased, especially in the GP recall and nurse recall groups.

**Table 2** Patients with coronary heart disease per practice at follow up and percentage of these patients with adequate assessment at baseline and follow up, by trial group. Values are mean (range) percentages unless stated otherwise

	Audit group (n=7)	GP recall group (n=7)	Nurse recall group (n=7)	P value for difference between groups*
Mean No (range) of patients with coronary heart disease per practice	80 (32-140)	97 (25-124)	95 (26-222)	
Adequate assessment (overall):				
Baseline	29 (13-49)	31 (12-49)	29 (17-40)	<0.001†
Follow up	52 (38-73)	76 (54-92)	85 (75-95)	
Blood pressure:				
Baseline	82 (68-92)	84 (64-95)	85 (69-96)	<0.001
Follow up	86 (72-94)	97 (96-100)	96 (85-98)	
Cholesterol:				
Baseline	42 (28-64)	48 (41-56)	44 (30-65)	0.001
Follow up	67 (46-85)	83 (71-95)	88 (77-97)	
Smoking status:				
Baseline	73 (50-91)	71 (47-96)	71 (46-85)	0.001
Follow up	78 (56-92)	92 (77-100)	95 (88-98)	

Mean percentages are weighted by number of patients with coronary heart disease in each practice.

\*Based on means adjusted for baseline.

†Nurse recall group v audit group: difference 33% (95% confidence interval 19% to 46%; P<0.001); GP recall group v audit group: difference 23% (10% to 36%; P=0.002); nurse recall group v GP recall group: difference 9% (-3% to 22%; P=0.13).

At follow up the groups differed substantially in the proportions of patients being adequately assessed overall (85% (566/665) in the nurse recall group; 76% (521/682) in the GP recall group; and only 52% (293/559) in the audit group). After adjustment for baseline levels, the absolute increase in the proportion of patients adequately assessed overall, compared with the audit group, was 33% (95% confidence interval 19% to 46%) in the nurse recall group and 23% (10% to 36%) in the GP recall group. Adequate assessment was higher in the nurse recall group than the GP recall group, but the difference (9% (-3% to 22%)) was not significant. The three components of adequate assessment all followed a similar pattern.

### Drug treatment

The much higher levels of adequate assessment at follow up in the GP and nurse recall groups were not matched by similar differences in drug treatment (table 3). Prescribing of hypotensive drugs showed minimal change in all three groups, but over two thirds (68%; 1290/1906) of patients were already being treated with hypotensive drugs at baseline. Among the 1782 patients adequately assessed for blood pressure at follow up, raised blood pressure (>160 mm Hg systolic or >100 mm Hg diastolic at the most recent

measurement) was observed in 18% (84/478) of patients in the audit group, 17% (113/663) in the GP recall group, and 13% (86/641) in the nurse recall group. Of the 283 patients in all groups with this higher blood pressure, 55 (19%) were not being treated with hypotensive drugs.

All groups showed an increase in prescribing of lipid lowering drugs, but this increase was no greater in the GP and nurse recall groups than in the audit group. This lack of difference could not be attributed to lower cholesterol levels among the additional patients assessed in the GP and nurse recall groups. Of the 371 patients in all groups with a cholesterol level of >6.0 mmol/L, 46% (172) were not being treated with lipid lowering drugs.

Information about antiplatelet treatment is confined to prescriptions, as we did not have a comprehensive record of self medication with these drugs. Prescribing of antiplatelet drugs was examined only in the 1754 patients with no recorded contraindication at either audit. Prescribing increased in all groups, and after adjustment for different baseline levels across the groups, the prescribing rates for antiplatelet drugs were 76%, 78%, and 86% in the audit, GP recall, and nurse recall groups respectively.

### Clinical examination

Of the 1824 patients invited for assessment, 74% (1342) attended. Attendance rates for each group were similar. Table 4 shows that mean blood pressure, serum cholesterol (total and high density lipoprotein) level, and smoking status did not differ significantly between the three groups.

### Discussion

We already know from studies of other chronic conditions that high quality care needs to be systematic and that outcome tends to be better when quality assurance is introduced on the basis of registration and planned follow up.<sup>15 16</sup> This trial shows that the simple expedient of setting up a patient register for a general practice markedly increases the probability of planned follow up taking place. It also shows that this benefit can be achieved whether responsibility for follow up lies with

**Table 3** Mean (range) percentage of patients with coronary heart disease treated with specified drugs at baseline and follow up, by trial group

	Audit group (n=7)	GP recall group (n=7)	Nurse recall group (n=7)	P value for difference between groups*
Hypotensive:				
Baseline	67 (54-84)	71 (56-80)	65 (54-71)	0.35
Follow up	70 (61-83)	73 (64-83)	66 (58-75)	
Lipid lowering:				
Baseline	25 (14-37)	24 (17-48)	23 (17-27)	0.63
Follow up	37 (9-64)	41 (26-68)	40 (38-45)	
Antiplatelet†:				
Baseline	62 (44-77)	73 (57-85)	66 (48-74)	0.017‡
Follow up	74 (55-84)	80 (68-92)	85 (81-89)	

Mean percentages are weighted by number of patients with coronary heart disease in each practice.

\*Based on means adjusted for baseline.

†Among the 1754 patients with no contraindication recorded at baseline or follow up.

‡Nurse recall group v audit group: difference 10% (95% confidence interval 3% to 17%; P=0.009); GP recall group v audit group: difference 2% (-6% to 10%; P=0.61); nurse recall group v GP recall group: difference 8% (1% to 15%; P=0.031).

**Table 4** Mean blood pressure and cholesterol, and percentage of coronary heart disease patients assumed not smoking at follow up, by trial group. Values are means (range) unless stated otherwise

	Audit group (n=7)	GP recall group (n=7)	Nurse recall group (n=7)	P value for difference between groups
Blood pressure (mm Hg):				
Systolic	148 (136-153)	147 (135-153)	148 (142-153)	0.82
Diastolic	81 (75-82)	81 (75-83)	80 (74-87)	0.82
Cholesterol (mmol/l):				
Total	5.5 (5.2-6.1)	5.5 (5.0-5.9)	5.4 (5.2-5.5)	0.61
High density lipoprotein	1.2 (1.2-1.3)	1.2 (1.2-1.3)	1.2 (1.1-1.3)	0.83
% (range) of assumed non-smokers*	81 (69-86)	84 (75-88)	83 (73-100)	0.58

Means are based on number of patients with coronary heart disease with clinical measurements: blood pressure, n=1341; total cholesterol, n=1286; high density lipoprotein cholesterol, n=1264; cotinine, n=1271.

Overall means and mean percentages are weighted by number of patients in each practice with the relevant measurement.

\*Plasma cotinine  $\leq 20$  ng/ml.

the general practitioner or with the practice nurse, and indeed follow up by nurses seems to be more effective. The only significant treatment benefit we observed was an improvement in the prescribing of antiplatelet drugs in the nurse recall group, although in the absence of complete information on self medication we cannot be sure that this reflects a genuine increase in use of such drugs. As increasing demands are being made on primary care to deliver systematic care for patients with chronic disease—without the prospect of a similar increase in the number of general practitioners—this is an important finding.

The trial also showed a lack of difference between the GP and nurse recall groups in clinical outcome. This is entirely consistent with previous trials of secondary prevention of coronary heart disease in general practice that have reported objective measurements of patient risk factors.<sup>8-10</sup>

#### Lack of clinical benefit

Why are we managing consistently to improve the process of care without achieving any apparent clinical benefit? We suggest several hypotheses, some of which were advanced by the medical and nursing staff in par-

ticipating practices in informal interviews and discussions after the trial had ended.

Firstly, each intervention was predefined and allocated randomly to practices without assessment of need. To influence clinical outcome it may be important to focus more precisely on the staff training needs and clinical competencies of each practice.

Secondly, room for improvement may be limited in certain areas of care. For example, in our study population previous smoking cessation advice was widespread (over 70% of patients had their smoking habit recorded in their notes at baseline). Many of the residual smokers must have failed to stop smoking despite this advice in the motivating context of a myocardial infarction. Moreover, even at baseline, over 80% of patients had had their blood pressure adequately assessed and over two thirds were receiving hypotensive treatment.

Thirdly, in the management of raised cholesterol levels, the prescribing of lipid lowering drugs was substantially suboptimal, even after intervention. Several factors may explain this apparent reluctance to initiate the necessary prescribing changes. Not all medical staff were involved in the practice meetings held after randomisation to discuss and agree guidelines for secondary prevention, so commitment to implement change may not have permeated the practice. The impact of prescribing lipid lowering drugs on cash limited prescribing budgets was also mentioned in some practices. Another factor may be a dislike of polypharmacy by both professionals and patients. Minimising the risk of major coronary events often requires five or more drugs in those with diabetes or hypertension, but the need for polypharmacy and sustained behaviour change emphasises the chronic and progressive nature of the disease.

#### Conclusions

The lessons to be learned from this trial are threefold: helping practices to set up a practice register of eligible patients increases follow up and adequate assessment; care by nurses is as effective as, and possibly more effective than, systematic care by doctors; and adequate assessment does not necessarily translate into better care or clinical outcome. Understanding why this is, and what we should do about it, is the key next step in improving the quality of care of patients with established coronary heart disease.

The ASSIST Trial Collaborative Group also includes G Fowler, E Fullard, K Johnston, A Gray, M Murphy, A Neil, S Thompson, F Wells, Wiles R, and L Youngman.

#### What is already known on this topic

Effective preventive care of patients with any chronic disease requires planned and quality assured follow up on the basis of an up to date register

Strategies for changing clinical practice in primary care have been of limited effectiveness

#### What this study adds

Setting up a coronary heart disease register for a practice substantially increases follow up and adequate assessment of patients at risk

Improved assessment and follow up does not necessarily improve clinical outcome

Follow up by nurses is as effective as, and may be more effective than, follow up by doctors

Patients are being followed up and adequately assessed without the recommended preventive drugs being prescribed

We thank the patients and staff in each of the participating general practices. Names of some of the participating staff can be found in the full version of this paper on the *BMJ's* website.

Contributors: MM contributed to the study protocol and was medical coordinator of the trial. PY contributed to the study protocol, gave ongoing research leadership, and was responsible for the statistical analysis. LW designed and implemented the nurse led intervention and was nursing coordinator of the trial. RT made an important contribution to the statistical analysis and interpretation. TS initiated and was responsible for the study protocol. DM discussed core ideas and gave intellectual stimulus. MM, PY, TS, and DM drafted the text of the paper with the support of the other authors. TS is guarantor for the study.

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Competing interests: LW has been reimbursed by Pfizer, the manufacturer of atorvastatin, for attending a conference.

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## Pre-mortals provision

When you get into your 80s you are likely to experience intimations of mortality; and, for that mortality, some provision should perhaps be made. I have developed a growth in my pancreas, which is as deep seated as mischief can get, but must emphasise that my own decisions were made some years ago. There are two specific ways in which a good lawyer can be of help—a "living will" and a "delayed power of attorney."

The living will gives legal force to whatever stipulations you may wish to make in relation to your medical care during the period of illness that is likely to precede death—unless, of course, that is mercifully (but selfishly) sudden. Such stipulations must themselves be within the law: you cannot empower a lawyer to bid a doctor to kill you. However, you can enjoin legal sanction against specific procedures or, more generally, against the prolongation of semi-mortality which disfigured the last days of Franco and Tito.

The delayed power of attorney gives some safeguard against mental or physical incompetence to "manage one's affairs." In essence it enables a lawyer, often in conjunction with an available relative or relatives, to take over that responsibility. The knowledge that a provision of this kind is in being can be a consolation to those aware of diminishing powers; and its activation could tangibly benefit their relicts.

The best way to discover what people really think is not to consider what they say or write (though that can help), but to observe what they actually do. In my case I have made a delayed power of attorney, but not a living will. Even healthy doctors may not be brilliant at managing their affairs—there are so many more interesting things to do—but the duty remains.

The decision (for it was a decision) not to make a living will perhaps needs some justification. It is not

pleasant or indeed possible for a healthy person to predict the character of his or her final illness; nor is it possible to be sure that convictions will remain unchanged. The care of terminal illness is taxing enough; and it can certainly not be simplified by being constrained by a set of legally enforceable requirements. I am happy to trust myself, as occasion arises, to regular medical and nursing care, free of legal intervention.

So, what is the answer? Find a good doctor and trust him or her. You might not guess from reading, listening, or watching the media that good doctors can be found, but in the real world, they greatly outnumber the ignorant, careless, and maladjusted, let alone the rare lethal criminals. I have suggested elsewhere (POM + EBM = CPD? *Journal of Medical Ethics* 2000;26:229-30) that the most important part of lifelong professional training is not formal instruction or particular methods of information retrieval and display, but the development of justified trust through "the build up of experience in the responsible and sensitive care of numbers of actual patients."

Douglas Black *retired consultant physician, The Old Forge, Whitchurch-on-Thames*

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.