

Annals of Internal Medicine

A Case-Management System for Coronary Risk Factor Modification after Acute Myocardial Infarction

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■ **Objective:** To evaluate the efficacy of a physician-directed, nurse-managed, home-based case-management system for coronary risk factor modification.

■ **Design:** Randomized clinical trial in which patients received a special intervention ($n = 293$) or usual medical care ($n = 292$) during the first year after acute myocardial infarction.

■ **Setting:** 5 Kaiser Permanente Medical Centers in the San Francisco Bay area.

■ **Patients:** 585 men and women aged 70 years or younger who were hospitalized for acute myocardial infarction.

■ **Intervention:** In the hospital, specially trained nurses initiated interventions for smoking cessation, exercise training, and diet-drug therapy for hyperlipidemia. Intervention after discharge was implemented primarily by telephone and mail contact with patients in their homes. All medically eligible patients received exercise training; all smokers received the smoking cessation intervention; and all patients received dietary counseling and, if needed, lipid-lowering drug therapy.

■ **Outcome:** Smoking prevalence and plasma low-density lipoprotein cholesterol (LDL) concentrations were measured 2 months after infarction, and functional capacity was measured 6 months after infarction.

■ **Results:** In the special intervention and usual care groups, the cotinine-confirmed smoking cessation rates were 70% and 53% ($P = 0.03$), plasma LDL cholesterol levels were 2.77 ± 0.69 mmol/L and 3.41 ± 0.90 mmol/L (107 ± 30 mg/dL and 132 ± 30 mg/dL) ($P = 0.001$), and functional capacities were 9.3 ± 2.4 METS and 8.4 ± 2.5 METS ($P = 0.001$), respectively.

■ **Conclusion:** In a large health maintenance organization, a case-management system was considerably more effective than usual medical care for modification of coronary risk factors after myocardial infarction.

Systematic modification of coronary risk factors is not integrated into the medical care provided to most of the more than 1 million patients treated annually in the United States for acute myocardial infarction by percutaneous transluminal coronary angioplasty or coronary artery surgery. Most of such patients have lipoprotein abnormalities (1), and nearly one half smoke (2). These risk factors, which contribute to subsequent morbidity and mortality, remain highly prevalent after acute cardiac events. Failure to integrate comprehensive risk factor modification into the standard medical care provided to patients after acute cardiac events primarily reflects the lack of an organizational framework or system. This deficiency in resource allocation for preventive and rehabilitative aspects of care in turn reflects the predominant orientation of the U.S. health care system to the management of acute illness (3).

Several clinical research studies have shown the effectiveness of risk factor modification, especially treatment of lipoprotein abnormalities (4–7), in achieving

SI Units	
Normal Range	Conversion Factor
<i>High-density lipoprotein cholesterol</i>	mg/dL $\times 0.02586 =$ mmol/L
Pre-SI: 30–70 mg/dL (male); 30–90 mg/dL (female)	
SI: 0.80–1.80 mmol/L (male); 0.80–2.35 mmol/L (female)	
<i>Low-density lipoprotein cholesterol</i>	mg/dL $\times 0.02586 =$ mmol/L
Pre-SI: 50–130 mg/dL	
SI: 1.30–3.36 mmol/L	
<i>Total cholesterol</i>	
Pre-SI: <200 mg/dL	mg/dL $\times 0.02586 =$ mmol/L
(<29 years); <200 mg/dL (30–39 years); <225 mg/dL (40–49 years); <245 mg/dL (>50 years); <265 mg/dL	
SI: <5.20 mmol/L (<29 years); <5.85 mmol/L (30–39 years); <6.35 mmol/L (40–49 years); <6.85 mmol/L (>50 years)	
<i>Triglycerides</i>	
Pre-SI: <160 mg/dL	mg/dL $\times 0.01129 =$ mmol/L
SI: <1.80 mmol/L	

Ann Intern Med. 1994;120:721-729.

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regression of coronary artery lesions and reducing the clinical consequences of coronary artery disease (6, 7). However, risk factor interventions shown to be effective in clinical trials may not prove equally effective in clinical practice because of a paucity of resources, especially nonphysician personnel. The lack of effective management systems limits the expected reduction in morbidity and mortality and the corresponding reduction in medical care costs that motivates current efforts to orient the priorities of the American health care system toward preventive and rehabilitative care.

This randomized controlled trial compared the effectiveness of a physician-directed, nurse-managed, home-based case-management system for coronary risk factor modification with that of usual medical care. Outcomes were measured in both groups immediately after the end of the first year after acute myocardial infarction.

The term *case-management system* has been used in various contexts. As used here, it refers to a system in which a nurse case-manager, working with different health care specialists (a psychiatrist, a cardiologist, a lipid specialist, a nutritionist, and a nurse coordinator), managed coronary risk factors.

Methods

Enrollment and Orientation

Program nurses enlisted patients on hospital day 3 or as soon as their medical condition stabilized. Study participants gave written informed consent to be randomly assigned to a treatment group. Immediately after randomization, program nurses introduced patients to the special intervention with the aid of a videotape.

Usual Care

The 585 patients in our study were cared for by 215 internists and 34 cardiologists in the five participating medical centers who were organized into practice groups of 5 to 10 physicians each. Cardiology consultation was often provided during hospitalization, but primary responsibility for follow-up care was generally assumed by internists.

The usual care offered by the Kaiser Permanente Medical Care Program included physician counseling on smoking cessation and nutritionist counseling on dietary change during hospitalization and physician-managed, lipid-lowering drug therapy after hospital discharge. Group outpatient smoking cessation programs were available for a \$50 fee. Group exercise rehabilitation, not generally provided by the Kaiser Permanente Medical Care Program during this study, was available to patients at various community facilities at an average cost of \$1800 to \$2700 for 3 months' participation.

Special Intervention

The behavioral interventions in our case-management system, which were offered to the 293 patients in the intervention group in addition to usual care, were derived from social learning theory (8, 9) and modified for medical problems (10). In this model, persons must learn how to monitor the health habits they seek to change, set attainable subgoals to motivate and direct their efforts, use feedback of progress in ways that promote health, and enlist incentives and social support to sustain the effort needed to succeed (8, 9).

In the hospital, patients were instructed on how to complete self-reports (status reports) of smoking, dietary intake, and exercise. Scheduled interactions between case managers and patients after discharge took three forms: 1) nurse-initiated telephone contacts; 2) computer-generated progress reports mailed to patients based on questionnaires completed by pa-

tients and mailed to the nurses; and 3) visits to the program nurse for treadmill exercise testing, initiation of lipid-lowering drug therapy, if indicated, and a single counseling session after a smoking relapse. The maximum number of treatment contacts during the year, including outcome measurement at 6 and 12 months, was as follows: 14 nurse-initiated telephone contacts, 8 patient visits to the blood chemistry laboratory, and 4 patient visits to the nurse case manager.

Smoking Intervention

Smoking was defined as the use of cigarettes, cigars, cigarillos, pipe tobacco, or any other form of tobacco in the 6 months before admission. Forty-three percent of patients were smokers. Patients who had smoked during the 6 months before hospitalization received the same intensive smoking cessation intervention during hospitalization; this intervention has been described previously (11). Physicians used a written script that enabled them to provide standardized counseling in less than 2 minutes. The hospital-based smoking cessation counseling focused on relapse prevention. Nurses conducted a standardized smoking history to evaluate patients' addiction to smoking. Patients' reported self-efficacy or confidence to resist smoking in each of 28 potentially high-risk situations was measured; patients were then counseled on how to manage the situations in which they reported less than 70% confidence. Patients also received a relapse prevention manual and a relaxation audiotape. They were advised that the nurse would telephone them 48 hours and 1 week after hospital discharge and at monthly intervals for as long as 6 months. Patients who relapsed were offered one additional visit with the nurse for further counseling. Nicotine polacrilex or transdermal nicotine patches were reserved for highly addicted patients who relapsed after hospital discharge.

Nutritional Counseling

A computer-based expert system developed by the investigators was used to provide nutritional counseling on a National Cholesterol Education Program (12) Step 2 diet that was low in cholesterol and saturated fat. A food frequency questionnaire designed by the investigators was scored using the Cholesterol and Saturated Fat Index developed by Connor and colleagues (13). Calculations of cholesterol and saturated fat totals were based on weekly rather than daily average food intakes. Data from the food frequency questionnaires, mailed by patients to the Stanford coordinating center and entered into a microcomputer, were used to generate progress reports that characterized patients' dietary patterns, prioritized dietary change goals, and provided guides for managing difficult situations by directing patients to relevant sections of a nutrition workbook entitled *Good Eating for Good Health* developed by the program nutritionist.

Patients in the intervention group completed a food frequency questionnaire during hospitalization that described their eating habits in the previous month. Patients also completed food frequency questionnaires 6, 11, and 26 weeks after admission. Progress reports were mailed to patients within 48 to 72 hours after the food frequency questionnaires were received. Detailed strategies for maintenance of dietary change were incorporated into the 26-week progress report. Questionnaires to evaluate outcomes were also completed at 36 and 52 weeks.

Lipid-lowering Drug Therapy

The therapeutic goal of a plasma low-density lipoprotein (LDL)-cholesterol value of 2.46 mmol/L (95 mg/dL) adopted for this trial was based on the mean post-treatment level of LDL cholesterol found in patients in the study by Blankenhorn and colleagues (4). Patients with mean plasma LDL cholesterol values (based on measurements in two separate blood samples drawn 75 and 90 days after infarction) that exceeded this value were given initial drug therapy according to the four algorithms shown in Table 1. Patients unable to tolerate bile acid-binding resin or nicotinic acid because of comorbid conditions or potentially adverse interactions with these agents received lova-

Table 1. Initial Drug Therapy*

Lipoprotein Pattern	Drug
LDL-C \geq 2.46 mmol/L (95 mg/dL) Triglycerides < 2.82 mmol/L (250 mg/dL)	Bile acid-binding resin
LDL-C \geq 2.46 mmol/L (95 mg/dL) Triglycerides \geq 2.82 mmol/L (250 mg/dL)	Bile acid-binding resin and nicotinic acid
LDL-C < 2.46 mmol/L (95 mg/dL) Triglycerides \geq 2.82 mmol/L (250 mg/dL)	Nicotinic acid
LDL-C < 2.84 mmol/L (110 mg/dL) Triglycerides < 1.07 mmol/L (95 mg/dL) HDL < 0.91 mmol/L (35 mg/dL)	Nicotinic acid

* HDL = high-density lipoprotein; LDL-C = low-density lipoprotein cholesterol.

statin or gemfibrozil. During a visit 90 days after discharge, the nurses did a brief physical examination and obtained a history relevant to hyperlipidemia. They provided detailed counseling to patients regarding the rationale for lipid-lowering drug therapy and ways to maximize drug efficacy and minimize drug side effects, and they advised patients on the schedule of laboratory visits and nurse-initiated follow-up telephone contacts.

Changes in drug therapy at 120, 150, and 180 days, which were coordinated by nurse-initiated telephone contacts, were based on three types of responses to initial therapy: 1) if lipoprotein levels returned to normal, the effective drug therapy was continued; 2) if the response was incomplete, the dose of the effective medication was increased or another drug was added, or both; and 3) if comorbid conditions worsened or blood chemistry abnormalities or intolerable side effects occurred, drug dosage was reduced or the patient was switched to another agent or both.

A physician lipid specialist and a Stanford-based senior nurse-coordinator provided telephone consultation to the case managers. Before initiating lipid-lowering drug therapy at 90 days and at each subsequent step, nurses reviewed the patients' blood chemistry and lipoprotein values and elicited any symptoms requiring a change in therapy. The nurses telephoned the patients' primary care physicians to obtain permission to add a new drug; changes in drug dosage or discontinuation of a drug therapy did not require permission.

Exercise Training

In the period between hospital discharge and treadmill exercise testing at 21 days, patients were advised to walk briskly at least 20 minutes daily at an intensity that did not cause cardiac symptoms. This moderate-intensity "activity prescription" was designed to overcome the effects of bedrest and physical inactivity during hospitalization (14).

Medical eligibility for symptom-limited treadmill exercise testing, which provided the basis for individual home-based exercise training, was contingent on the absence of congestive heart failure, unstable angina pectoris, atrial fibrillation, left bundle-branch block or physical limitations caused by chronic obstructive pulmonary disease, stroke, severe obesity, or orthopedic or peripheral vascular disease present by the third week or later despite medical treatment. As shown in Table 2, at least 85% of patients in both groups had treadmill exercise testing. The pattern of treadmill testing for usual care patients was generally similar to that of patients receiving the special intervention, that is, one test before hospital discharge and another 3 to 6 weeks after myocardial infarction. Patients having coronary revascularization were considered for exercise testing and subsequent exercise training as early as 1 week after percutaneous transluminal coronary angioplasty or 4 weeks after coronary artery bypass graft surgery. Only patients

eligible for treadmill testing within 4 months of acute myocardial infarction were eligible for exercise training.

The exercise prescription was based on a heart rate range corresponding to 60% to 85% of the peak heart rate achieved during treadmill testing. Patients were instructed to exercise at the prescribed heart rate for 30 minutes per day 5 days per week. Depending on their preferences, patients walked briskly, jogged, rode a bicycle, or swam. After 4 weeks, the ceiling of the heart-rate training range was raised to 100% of the peak treadmill exercise heart rate or 85% of the age-predicted maximal heart rate, whichever was lower (15).

As in our previous studies of home-based exercise training (15, 16), patients were carefully instructed by case managers on how to warm up, how to regulate the exercise intensity within the prescribed heart rate limits, and how to recognize and respond to cardiac symptoms. Patients used a portable heart-rate monitor to regulate their training intensity during the first 8 weeks of exercise training.

Nurses telephoned patients 2 weeks after exercise training began and at monthly intervals thereafter until the sixth month to correct any problems with exercise training and to detect any cardiac symptoms warranting contact with the primary care physician. Patients were given instructions for maintaining their exercise regimen between 6 and 12 months after infarction.

Training and Supervision of the Nurse Case Managers

Before the clinical trial was begun, the program nurses participated in an 80-hour training course directed by specialists in cardiology, psychiatry, lipid therapy, nutrition, and nursing practice. The training focused on exercise testing and training, diet and drug management of hyperlipidemia, and smoking cessation, as well as the requisite psychosocial interventions to achieve these changes.

Nursing Effort

The special intervention involved approximately 9 hours per patient during the first year, allocated as follows: smoking cessation, 2 hours; dietary management, 1.5 hours; lipid-lowering drug therapy, 2.5 hours; exercise training, 1 hour; liaison with the primary care physician and other hospital personnel, 1 hour; and consultation with the Stanford-based staff, 1 hour.

Outcome Determination

Patients' self-reports of nonsmoking at 180 and 360 days were biochemically confirmed by measurement of plasma cotinine and expired carbon monoxide. A plasma cotinine value of 10 ng/mL or lower was required for biochemical confirmation of nonsmoking status. Patients whose plasma cotinine values were 11 to 15 ng/mL were also classified as nonsmokers if their expired carbon monoxide values were below 10 parts per million. Patients stating that they were not smoking who did not return for endpoint determination received reminder letters and telephone calls from the Stanford-based staff. Pa-

Table 2. Management Practice and Medical Outcomes in the Year After Acute Myocardial Infarction*

Variable	Usual Care (n = 292)	Special Intervention (n = 293)
Thrombolysis, %	35.3	37.5
Treadmill exercise testing, %	85.3	86.3
Coronary angiography, %	49.3	47.1
Coronary artery surgery, %	11.3	14.3
Percutaneous transluminal coronary angioplasty, %	11.3	8.5
Cardiac death, %	3.1	3.8
Other death, %	0.3	0.3
Reinfarction, %	6.8	3.4

* No significant differences were noted between groups for any of the variables.

tients who did not return for biochemical confirmation and those who stated that they were smoking or using nicotine replacement therapy at 6 or 12 months were categorized as smokers.

Values of plasma LDL, high-density lipoprotein, and total cholesterol and triglycerides were determined at 90, 180, and 360 days. In addition, lipoprotein levels of patients receiving the special intervention were measured at 120, 150, and 270 days. Plasma lipoproteins were measured by the Friedewald method for indirect beta quantitation of lipoproteins (17) at 180 and 360 days. Plasma samples were collected according to Lipid Research Clinics methodology, frozen in each of the participating hospitals, and transported on dry ice within 1 week to the research laboratory at Stanford, which participates in the Centers for Disease Control and Prevention—National Heart, Lung, and Blood Lipoprotein Standardization Program (18).

Patients in both groups who had no medical contraindications completed symptom-limited treadmill exercise testing 6 months after acute myocardial infarction. Functional capacity was measured by symptom-limited treadmill exercise testing using a combination of Naughton and Balke protocols (15). Functional capacity was expressed in METS or multiples of resting energy consumption, in which 1 MET equaled an oxygen uptake of 3.5 mL/kg per minute.

Follow-up

Nurses documented management practice procedures and medical outcomes. Criteria similar to those used for the initial infarction were used to classify recurrent infarction. Confirmation of nonfatal events was obtained by telephone contact with patients; the circumstances of out-of-hospital deaths were verified by contact with relatives, physicians, or other knowledgeable persons. All cardiac events were confirmed by a cardiologist blind to the randomization.

Randomization and Data Management

Patients were randomly assigned using a computer program that achieved a balanced allocation to the two management conditions within each hospital (19). Randomization was done centrally; nurses were notified of the assignments by telephone calls from the coordinating center staff. Nurses were responsible for computer entry of all demographic and medical data, including laboratory reports, status reports, and data obtained by telephone contact and medical record review for all patients in the intervention group. Usual care was characterized by the nurses through interviews with patients at 180 and 360 days and through medical record review.

Data Analysis

Patients remained in their original groups throughout the study, and analysis was based on intention to treat. For plasma LDL cholesterol concentration, we fit individual regression lines to all available data for each participant to estimate the slope between 90 and 360 days. To assess the differences in smoking cessation between the two groups, we compared survival curves to relapse using the Wilcoxon test. Among patients who died or dropped out, relapse was defined as the point at which they reported a smoking relapse. Among patients who did not relapse before death or dropout, censoring occurred at the last point at which they reported not smoking. Changes in functional capacity were measured only in patients receiving special intervention; a paired *t*-test was used to evaluate this change. An unpaired *t*-test was used to compare functional capacity between the two groups at 6 months. For purposes of statistical description and to allow evaluation of the clinical significance of the results, both the mean values and standard deviations are provided in the text and tables. All confidence intervals are 95%.

Informed Consent

The study was approved by the Committee for the Protection of Human Subjects in Research of Stanford University and the Institutional Review Board for the Protection of Hu-

man Subjects of the Permanente Medical Group of Northern California.

Results

Patients

From 30 November 1988 to 16 April 1991, 894 consecutive men and women ages 70 years or younger who were hospitalized for acute myocardial infarction in five San Francisco Bay area Kaiser Permanente Medical Centers were assessed for eligibility. The diagnosis of acute myocardial infarction was based on the following criteria: characteristic elevation of serum creatine kinase or oxaloacetic transaminase levels, a history of prolonged chest pain consistent with myocardial infarction, and the appearance of new Q waves or evolutionary ST-T segment changes. One hundred eighty-five patients (21%) were excluded: 31 died before randomization, 88 had severe comorbid disease, 13 showed signs of substance abuse or other psychological problems, and 53 could not speak English. Of the remaining 709 eligible patients, 116 (16%) refused to participate, and 8 (1%) were not contacted because their physicians declined participation. Five hundred eighty-five (65%) of all hospitalized patients were randomly assigned to receive special intervention (*n* = 293) or usual medical care (*n* = 292).

Demographic and medical characteristics of study participants, shown in Table 3, were similar for the two groups. Age, sex, and ethnic attributes of study participants were generally similar to those of San Francisco Bay area residents. The Kaiser Permanente Medical Care Program provides care to 2.3 million subscribers—nearly one third of the total population of the San Francisco Bay area. As shown in Table 2, management practice and medical outcomes were similar among patients receiving special intervention and those receiving usual care.

All randomly assigned patients were followed for 1 year after acute myocardial infarction or until death if the patient died before this time. At 6 months, the dropout rates in the special intervention and usual care groups were 11.3% and 9.2%, respectively. Reasons for dropout at 6 months in the special intervention and usual care groups were as follows: death, 3.8% and 3.1%; lost to follow-up, 1.4% and 1.7%; refusal to continue, 4.8% and 3.1%; and other reasons, 1.3% and 0.7%, respectively. The cumulative dropout rates at 12 months among patients in the special intervention and usual care groups were 15.4% and 11.6%, respectively. Reasons for dropout at 12 months in the special intervention and usual care groups were as follows: death, 4.1% and 3.4%; lost to follow-up, 2.7% and 2.4%; failure to return for endpoint analysis, 6.5% and 5.1%; and other reasons, 2.1% and 1%, respectively.

Smoking Cessation

The biochemically determined smoking cessation rates in the special intervention and usual care groups at 6 months were 69% and 55%, respectively. Corresponding rates at 12 months were 70% and 53% (*P* = 0.03). Two percent of patients randomly assigned to the

Table 3. Patient Demographic and Medical Characteristics

Characteristics	Usual Care (n = 292)	Special Intervention (n = 293)
Age, y	57 ± 8	57 ± 8
Male sex, %	79.1	78.5
White, %	75.9	78.0
College education or above, %	61.8	64.9
Occupation, %		
Professional, technician	31.4	33.4
Manager, sales	22.1	20.9
Clerical, service, public safety	19.3	18.5
Trade, assembly	12.5	13.2
Laborer	9.6	9.4
Other	5.1	4.6
Smoker, %	41.4	44.7
Myocardial infarction site, %		
Anterior	23.6	23.3
Inferior	35.6	34.6
Other Q wave	15.1	17.8
Non-Q wave	25.7	24.3
Peak creatine kinase level, μkat/L	1617 ± 1324	1645 ± 1425
Previous myocardial infarction, %	15.8	14.7
Previous angina, %	24.1*	15.2

* $P = 0.007$.

usual care group enrolled in a group outpatient smoking cessation program. Ten percent of the patients in the special intervention group and 2% of the patients in the usual care group reported using nicotine replacement therapy during the year.

Nutritional Management

The baseline food-frequency score of 322 ± 206 for cholesterol and saturated fat among patients receiving the special intervention, reflecting the diet before myocardial infarction occurred, corresponds to a typical American diet. This score decreased to 121 ± 90 by 6 weeks ($P < 0.001$), surpassing a Step 2 diet (score, 160 to 210), and remained low at 11 weeks (score, 125 ± 77), 26 weeks (score, 123 ± 87), 36 weeks (score, 117 ± 72), and 52 weeks (score, 124 ± 84). At baseline, the proportions of patients in the intervention group who had cholesterol and saturated fat scores lower than 160, 160 to 210, 211 to 300, and greater than 300 were 16%, 15%, 23%, and 46%, respectively. At 90 days, the corresponding proportions were 75%, 13%, 9%, and 3%, respectively. Thus, among patients receiving the special intervention, the proportion consuming a diet very low in cholesterol and saturated fat (Step 2 diet or lower) increased from 31% at baseline to 88% at 90 days.

A similar pattern was noted in patients receiving usual care: The baseline food frequency score of 307 ± 255 for cholesterol and saturated fat decreased to 149 ± 95 at 26 weeks ($P < 0.001$) and remained low (140 ± 83) at 52 weeks.

Lipid-lowering Drug Therapy

Between hospital admission and 90 days, total plasma cholesterol values increased to the same extent in both

groups, from 5.33 ± 1.37 mmol/L to 5.60 ± 1.09 mmol/L (an increase of 0.27 mmol/L or approximately 8 mg/dL) in the special intervention group and from 5.05 ± 1.46 mmol/L to 5.50 ± 1.35 mmol/L (an increase of 0.45 mmol/L or approximately 9 mg/dL) in the usual care group, respectively ($P = 0.002$).

At 90 days, 89% of patients receiving the special intervention had plasma LDL cholesterol values that exceeded the project goal level of 2.46 mmol/L (95 mg/dL); 60% had values that exceeded the existing goal level of 3.36 mmol/L (130 mg/dL) set by the National Cholesterol Education Program (12). Lipid-lowering drug therapy was initiated in 83% of patients receiving intervention who failed to meet the project goal level; drug therapy was not given to the remaining 17% of patients for the following reasons: Patients were already taking lipid-lowering drugs (10%), physician refusal (2%), patient refusal (1%), and other reasons (4%). Among intervention patients in whom lipid-lowering drug therapy was initiated, 98% were still receiving the drugs at 6 months, and 90% were still receiving the drugs at 1 year. In contrast, only 17% and 21% of patients in the usual care group were taking lipid-lowering drugs at 6 and 12 months, respectively.

Lipoprotein values in patients receiving usual care and special intervention are shown in Table 4. Plasma LDL and total cholesterol values decreased to a greater extent in patients receiving special intervention than in those receiving usual care ($P < 0.001$ for both comparisons). No significant differences in changes in high-density lipoprotein cholesterol or triglycerides were noted between the two groups. At 360 days, the proportions of patients with plasma LDL cholesterol levels less than 3.36 mmol/L (130 mg/dL), 3.10 mmol/L (120 mg/dL), and 2.59 mmol/L (100 mg/dL) were 82.7%, 69.5%, and 42.4% in patients receiving special intervention and 50%, 32.4%, and 15.2% in patients receiving usual care, respectively. Similar percentages were noted at 180 days.

Exercise Training

Seventy-eight percent of patients in the intervention group had home-based exercise training: 63% began training at 3 weeks, 7% began training after percutaneous transluminal coronary angioplasty an average of 6 weeks after acute myocardial infarction, and 8% began training after coronary artery bypass surgery on average 10 weeks after acute myocardial infarction. The remaining 22% of patients in the intervention group were ineligible for exercise training because of the presence of limiting chronic obstructive pulmonary disease, peripheral vascular disease, stroke, or orthopedic abnormalities or because of atrial fibrillation, left bundle-branch block, high-degree atrioventricular block, or a fixed-rate pacemaker or congestive heart failure that persisted despite medical therapy. No training-induced adverse effects occurred.

Functional capacity measured at 6 months was higher in patients receiving the special intervention than in those receiving usual care: 9.3 METS (CI, 9.0 to 9.6 METS) compared with 8.4 METS (CI, 8.1 to 8.7 METS), respectively. Functional capacity for interven-

Table 4. Lipoprotein Values*

Variable	Lipoprotein Values, mmol/L†			
	Day 90	Day 180	Day 360	Slope (95% CI)
LDL cholesterol	(n = 47)	(n = 248)	(n = 244)	(n = 257)
Usual care	3.52 ± 0.81	3.49 ± 0.90	3.41 ± 0.90	-0.14 (0.29 to 0.00)
Special intervention	(n = 254)	(n = 252)	(n = 243)	(n = 267)
	3.63 ± 0.98	2.85 ± 0.83	2.77 ± 0.69	-0.65 (-0.79 to -0.50)
HDL cholesterol	(n = 49)	(n = 248)	(n = 244)	(n = 257)
Usual care	1.00 ± 0.33	1.08 ± 0.33	1.14 ± 0.48	0.10 (0.02 to 0.18)
Special intervention	(n = 267)	(n = 253)	(n = 243)	(n = 269)
	1.01 ± 0.29	1.15 ± 0.38	1.16 ± 0.36	0.13 (0.10 to 0.16)
Total cholesterol	(n = 49)	(n = 248)	(n = 244)	(n = 257)
Usual care	5.50 ± 1.35	5.45 ± 0.99	5.41 ± 1.05	-0.09 (-0.25 to 0.07)
Special intervention	(n = 268)	(n = 253)	(n = 243)	(n = 269)
	5.60 ± 1.09	4.85 ± 0.94	4.78 ± 0.83	-0.64 (-0.79 to -0.50)
Triglycerides	(n = 49)	(n = 248)	(n = 244)	(n = 257)
Usual care	2.13 ± 1.89	1.96 ± 1.50	1.93 ± 1.41	-0.08 (-0.32 to 0.17)
Special intervention	(n = 268)	(n = 253)	(n = 243)	(n = 269)
	2.11 ± 1.23	1.85 ± 1.06	1.93 ± 1.25	-0.12 (-0.27 to 0.03)

* HDL = high-density lipoprotein; LDL = low-density lipoprotein.

† All values are expressed as mean ± SD. Patient numbers are given in parentheses.

tion patients increased by 2.1 METS (CI, 1.8 to 2.4 METS) between 21 days and 6 months.

Five percent of patients receiving usual care participated in group-based exercise training during the first 6 months after acute myocardial infarction. Among these, functional capacity at 6 months was 9.2 ± 2.9 METS.

Discussion

Our case-management system proved more effective than usual medical care in reducing plasma LDL cholesterol levels, enhancing functional capacity, and increasing smoking cessation among men and women recovering from acute myocardial infarction. The effectiveness of the smoking cessation intervention in our study was similar to that of our previous study done with patients in the Kaiser Permanente Medical Care Program who had had myocardial infarction (11). That patients in the usual care group had higher cessation rates in the present study (53%) than in our previous one (43%) may reflect the effect of hospital smoking bans instituted during the past 3 years. Moreover, the state of California implemented a major smoking cessation campaign that has resulted in lower smoking rates in California (22%) (20) than those in the United States as a whole (29%) (21).

The effectiveness of diet-drug management of hyperlipidemia was substantially greater for the treatment group than for the usual care group. Most of this effect was attributable to lipid-lowering drug therapy. Between admission and 90 days, total plasma cholesterol values increased by 0.23 mmol/L (approximately 9 mg/dL) in patients receiving usual care and by 0.21 mmol/L (approximately 8 mg/dL) in patients receiving intervention treatment. An increase in total plasma cholesterol of this magnitude, which has been previously reported after acute myocardial infarction has occurred (22), may have obscured the effects of nutritional counseling on plasma cholesterol values during this interval. Moreover, all patients, including those in the usual care group, were provided 1 hour of nutritional counseling

while they were in the hospital. This also may have contributed to the lack of difference in total plasma cholesterol values in healthy persons between the two groups at 90 days. Hunninghake and colleagues (23) have documented a much smaller dietary reduction in plasma cholesterol than that expected with a Step 2 diet, which was also used in our study. Dietary efficacy may be particularly limited for patients with ischemic heart disease, especially soon after acute myocardial infarction.

Although concern has been expressed about the high cost of drug therapy for hyperlipidemia (24), general consensus exists that such treatment is of greatest cost-benefit for patients with established ischemic heart disease (25). We selected a therapeutic goal for plasma LDL cholesterol of 2.46 mmol/L (95 mg/dL) because many clinical trials have shown the effectiveness of aggressive diet and drug therapy in producing regression of coronary atherosclerosis (4-6). The mean LDL cholesterol level after treatment was 2.77 mmol/L (107 mg/dL) in our study, which is similar to the mean post-treatment value of 2.92 mmol/L (113 mg/dL) seen in arteriographic regression studies of patients with a similar baseline LDL cholesterol value (26-29). The therapeutic goal of the National Cholesterol Education Program for patients with ischemic heart disease has been revised from a plasma LDL cholesterol value of 3.36 mmol/L (130 mg/dL) to 2.59 mmol/L (100 mg/dL) (29). At 90 days, only 17% of patients in the special intervention group had achieved this more stringent goal by diet alone. Moreover, the existing goal of 3.36 mmol/L (130 mg/dL) was achieved by a substantially higher proportion of patients receiving special intervention than those receiving usual care.

The clinic-based investigations of diet-drug management of hyperlipidemia that have shown regression of coronary atherosclerosis needed extensive resources and required that patients return for six to eight clinic visits annually (4-7). Our case-management system allowed highly effective diet-drug therapy for hyperlipid-

emia to be provided by the nurse case manager in a representative treatment practice setting with only one clinic visit. Subsequent changes in drug therapy were made by nurse-initiated telephone contact, which obviated the need for follow-up visits to the clinic. Moreover, patients scheduled visits to the clinical laboratory at their convenience.

Our previous studies of exercise training after myocardial infarction included only the 50% of patients who were considered eligible to have symptom-limited treadmill exercise testing 2 to 3 weeks after myocardial infarction (15, 16). Our study extends the proportion of patients able to participate in home-based exercise training to 78% of randomly assigned patients. In our study, home-based exercise training was often initiated after coronary revascularization procedures that eliminated or attenuated myocardial ischemia that previously might have warranted group-based exercise training. The risks of home-based exercise training are reduced by appropriate selection, individualized moderate-intensity exercise, careful self-monitoring, and telephone surveillance (15).

Wasson and coworkers (30) reported that frequent telephone contact may achieve a better medical status and medical outcomes for patients than follow-up visits alone. Their study was done in a Veterans Affairs facility with middle-aged patients who had high prevalences of coronary artery disease and other chronic diseases. Four telephone contacts of 15 minutes or less initiated by physicians, physicians' assistants, and nurse practitioners achieved better medical outcomes and reduced inpatient and outpatient medical care costs by nearly 25% during a 24-month period. Much of this savings was attributable to shorter hospital stays and less need for intensive care for patients with chronic diseases. Telephone-based contacts can be used frequently and at convenient periods and can be timed when they are most needed. Our study extends the scope of "telephone therapy" to include nurse-managed modification of coronary risk factors for patients recovering from acute myocardial infarction.

Other researchers have developed systems for nurse-managed hypertension (31) and lipid-lowering drug therapy (32). Our system expands the scope of this approach to include concurrent management of multiple coronary risk factors by a single nurse case manager. The interventions are guided by a set of standardized management algorithms that not only facilitate the training and supervision of the nurses but also permit a well-structured intervention to be provided on an individualized basis to patients of varying health status.

Aided as necessary by telephone consultation with various content experts, a single caregiver, the nurse case manager, can provide at a lower cost a broader range of individualized rehabilitative services to more patients than are currently served by cardiac rehabilitation programs. In our study, nurses spent an average of 9 hours per patient in the year after myocardial infarction, which equates to a per-patient charge of approximately \$500 for nursing salary, office rental, and depreciation of computer and printer and incidental costs. In contrast, cardiac rehabilitation programs in the San Francisco Bay area charge \$1800 to \$2700 to participate

for 3 months. Moreover, the primary emphasis of most cardiac rehabilitation programs is exercise training rather than smoking cessation or diet-drug treatment of hyperlipidemia.

We enlisted nurses as case managers because they are by far the most numerous nonphysician members of the health care delivery system. Moreover, the nurses' experience in coronary care enabled them to provide appropriate guidance to patients participating in home-based exercise training. Their familiarity with drug therapy enabled them to monitor patients' response to lipid-lowering drug therapy. Finally, the nursing role is well integrated into the medical care system.

The support of primary care physicians was crucial to the success of the case-management system. Physicians' support was enhanced by keeping them apprised of their patients' progress through computer-generated reports and personal and telephone contacts with the case managers. This was facilitated by locating inpatient and outpatient care within the same facility.

Physicians' risk factor management after acute myocardial infarction consists primarily of advising patients of dietary changes and smoking cessation and directing nicotine replacement therapy and lipid-lowering drug therapy. These functions were done more effectively by the nurse case managers in our study. Only 2% of smokers in the usual care group received nicotine replacement therapy, compared with 10% in the special intervention group. Only 21% of patients in the usual care group received lipid-lowering drug therapy, even though 60% were eligible for such therapy according to the existing guidelines of the National Cholesterol Education Program (plasma LDL cholesterol values greater than 3.36 mmol/L [130 mg/dL]) (12) and approximately 85% would have been eligible under the revised guidelines (plasma LDL cholesterol values greater than 2.59 mmol/L [100 mg/dL]) (29). Studies done in other health care settings also report a relatively low rate of lipid-lowering drug therapy among patients with ischemic heart disease (33, 34).

Study Limitations

Our findings focus on modification of coronary risk factors rather than on reduction of reinfarction and death, which requires a long follow-up. Patients treated for acute myocardial infarction in the participating Kaiser Permanente Medical Centers had an excellent prognosis: Total first year mortality, including hospital mortality, was 3.4% in the usual care groups and 4.1% in the special intervention groups, respectively. A treatment period of at least 2 years and a follow-up period of as long as 5 to 10 years would be necessary to show a significant reduction in cardiac events in this population. The study was primarily designed to compare the effectiveness of two systems of coronary risk factor management during a fairly long period. Having established the effectiveness of the nurse-implemented system, the next task is to determine how best to tailor the system to reinforce long-term maintenance of health-promoting habits.

We did not include a component for hypertension, which is an important risk factor after acute myocardial

infarction, because the Kaiser Permanente Medical Care Program already provides adequate provisions to treat hypertension. Physicians are more familiar with antihypertensive drug therapy, blood pressure can be measured readily during office visits, and most hypertensive patients receive antihypertensive drug therapy. In contrast, lipid-lowering drug therapy is less familiar to physicians, and the logistics of ordering plasma lipoproteins, obtaining results, and altering therapy accordingly are complex. Consequently, fewer than one quarter of hyperlipidemic patients receive lipid-lowering drug therapy. Our case-management system was designed to address this comparative deficiency in the treatment of hyperlipidemia.

The applicability of our case-management system to other treatment settings such as university, public, and community hospitals and clinics will probably depend largely on the formula for reimbursement and the extent of physician support. Within each of these settings, managed care programs seeking optimal methods for coronary risk factor management should be favorably disposed to a case-management system that provides convenient, individualized, and effective medical care at low cost.

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Acknowledgments: The authors thank research nurses Mary Adornato, RN, MS, Nancy Fitch, RN, MS, Liz Frazier, BSN, MS, Vicki Hacker, RN, MS, Sherry Novak, RN, MBA, Teresa Picchi, RN, BSN, Deborah Senneca, RN, BSN, Sue Swope, RN, MS, and Robin Wedell, RN, BSN for their excellent performance; the medical staffs of the participating Kaiser Permanente Medical Centers for referring patients to the study; the Stanford-based research staff Debi Hooke, BA, Diane Garcia, BS, and Cheryl Leong, BA, for their excellent technical support; and Steven Sidney, MD, for coordination of the project with the Kaiser Permanente Medical Care Program of Northern California.

Grant Support: By HL38874 from the National Heart, Lung, and Blood Institute, Bethesda, Maryland and a Shannon Award from the National Institutes of Health, Bethesda, Maryland. Dr. Thomas participated as a Clinical Scholar of the Robert Wood Johnson Foundation.

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The great possession of any University is its great names. It is not the "pride, pomp and circumstance" of an institution which bring honour, not its wealth, nor the number of its schools, not the students who throng its halls, but the *men* who have trodden in its service the thorny road through toil, even through hate, to the serene abode of Fame, climbing "like stars to their appointed height."

Sir William Osler
Aequanimitas

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