THE PRESIDENT HAS SEEN
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David S. Broder

Health Care: The Cold Truth

When Congress returns next week, it will face a debate on health care that has started on a partisan note and may well end in frustration. For anything useful to be salvaged, politicians will have to recognize a truth few of them are willing to face.

It is defined succinctly in the headline of an article in the April issue of the monthly magazine of the National Conference of State Legislatures: "Government Does, Indeed, Ration Health Care."

The author is a man known for disgorging uncomfortable truths, former Colorado governor Richard Lamm. Speaking of American medicine, Lamm says, "We are inventing the unaffordable and spending the unsustainable. We need to focus limited resources where they will buy the most health for society."

He cites some of the evidence. In this age of medical breakthroughs, health care has overtaken housing as the most expensive item in the family budget—and health care spending is growing faster than anything else in state and federal budgets as well. The trillion-dollar annual medical bill represents one-seventh of the nation's economy.

And yet, the United States has by far the largest share of uninsured citizens of any advanced nation, with 43 million having no coverage now. Of 29 industrial countries, we rank 21st in infant mortality, 17th in life expectancy for women and 21st for men.

Lamm is far from alone in arguing that the current health care system is unsustainable. Health and Human Services Secretary Donna Shalala says the same thing. So do many other experts.

The question, as Lamm writes, is not if we ration—but how. So far, we have chosen to ration by leaving one-sixth of our population uninsured and, increasingly, by trying to let medical organizations "manage" the health care of those with insurance. Since the failure of the Clinton administration's bill for universal health insurance in 1994, efforts to expand coverage have been sporadic, and the number of uninsured has grown by roughly a million a year.

What is almost as worrisome is the fact that the major health care reforms being considered in Washington ignore the fact that society must make hard choices about what it can afford—and how those dollars can best be used. Indeed, they threaten to exacerbate the problem by promising that the privileged will be even better protected.

Consider Medicare. Those over 65 are the only large class of Americans with guaranteed health benefits. A bipartisan commission's effort to slow the cost spiral that threatens bankruptcy of that program foundered on insistence by the White House and most congressional Democrats that every existing benefit be guaranteed. President Clinton even endorsed a politically popular move to add prescription drug benefits to the menu. No one, least of all the president, has proposed a way of financing that level of services—without new cost-sharing measures—for the growing ranks of senior citizens, whose voting power intimidates politicians of both parties.

Or take the "patient's bill of rights" legislation tabbed as a high priority by the White House and Republican congressional leaders. The basic provision would guarantee every patient in managed care all "medically necessary" treatments, determined by his or her physician or, on appeal, by an independent arbiter.

The legislation is being propelled by a flood of emotional anecdotes about individual patients whose lives were jeopardized—or even lost—by the cost-conscious regulations of a managed care company or insurer. The individual stories are so compelling that the social costs are ignored. If every patient is guaranteed every service that could provide even a marginal benefit in someone's judgment, then what will the economic consequences be? The answer, Lamm writes, is that "the dollars we spend on marginal and futile care are no longer available to spend on needed care for someone else in the system or some other equally important social need."

He adds: "The health care system can no more afford to do everything 'beneficial' for every patient than the education system can do everything 'beneficial' for every student . . . or the police department for every citizen. . . . We are funding health care by an unsustainable yardstick."

Writing in this vein sounds coldhearted. But the real cruelty is ignoring these truths. Until we insist that all Americans of all ages—including the retired—contribute to the costs of their health care as far as they are able, until we acknowledge that additional benefits for those with insurance are less vital than providing access to basic care for the uninsured, the political finagling over health care in Washington is likely to do more harm than good.

The Washington Post
Wednesday, April 7, 1999

Government Does, Indeed, Ration Health Care

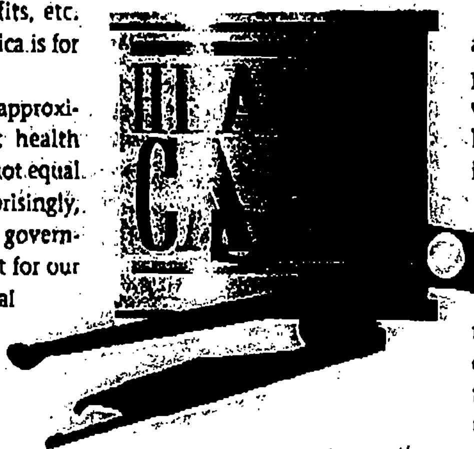
Doctors make decisions based on the good of the individual. When it comes to health care states must make policy based on what is good for the whole population.

By Richard D. Lamm

The largest purchase the average American family will make in their lifetime is no longer their house, but their health care. Over the last 30 years, health care also has been the fastest growing part of the average state, federal, corporate and household budget. National spending on health care averages close to $4,000 per person, more than the per capita earnings of over half the people in the world.

Taxpayers now fund approximately 50 percent of the $1 trillion cost of the American health care system. The funding comes through Medicare and Medicaid, plus state and federal funding of medical schools, public health, employee benefits, etc. One dollar out of every $7 spent in America is for health care.

Yet for all our spending, we still have approximately 43 million Americans without health insurance, and the state of our health is not equal to many other developed countries. Surprisingly, we have spent little time discussing the government's role in health care or what we get for our money. What should a state's role and goal be in funding health care? How do we hold the system accountable for public dollars? Who should the state cover and for what benefits?



PUBLIC POLICY VS. PROVIDERS

Policymakers have not done enough to assert the broader public interest in achieving a healthy state or nation. The public policy of a nation cannot be judged solely by the quality of its medicine or driven simply by the ethics of health providers. Medicine is a key part, but not the only part, of a health care system. Policymakers mostly fund health providers to deliver all "reasonable and necessary" care to covered categories of citizens, and we ask few questions about what is delivered or if we have a just system.

We leave large numbers of medically indigent without health insurance, yet we tell ourselves proudly that we don't "ration" medicine. But every state "rations" taxpayers' money in a process called budgeting. Whenever demand for tax dollars exceeds the supply of those dollars (which is always), a state prioritizes and "rations" the money and services it buys. A state must ask not "if" it rations, but "how."

A state's role and obligations in the health area vary considerably from the role and obligations of health providers. Consider that policymakers view the big picture while providers consider the individual patient: policymakers always consider cost, providers believe cost is not a consideration; policymakers try to maximize good while providers must "do no harm."

Doctors and other medical providers are patient advocates and don't have to deny needed care, but public policymakers' moral universe is not the individual, but all citizens. As Oregon Governor John Kitzhaber, a physician, maintains, "The legislature is clearly accountable not just for what is funded in the health care budget, but also for what is not funded. Accountability is inescapable ..."

Whoever pays for health care rations medicine. An insurance contract is a rationing document in that it limits what is covered and not covered (tattoo removal? Viagra? bone marrow transplants?) and who is eligible for reimbursement (naturopaths? chiropractors?). Rationing is inherent every time we make up a budget.

INFINITE NEEDS, FINITE RESOURCES

Are health professionals in the best position to judge how to keep a state healthy? Clearly they are not. One thoughtful observer points out why this is so:

"Professionals tend to believe that they are the only ones able to make informed choices. In fact, many of them are not trained to see the overall health situation of the whole population, but only the problems of the individual patients. The devotion of the physician to her patient may make it difficult for her not to seek an excessive share of the available resources and to overlook the resulting loss to other patients," says E.O. Attinger, an official with the World Health Organization.

Health providers, as patient advocates, understandably have diffi-

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Richard D. Lamm, a former governor of Colorado, is director of the Center for Public Policy and Contemporary Issues at the University of Denver.

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culty looking at the social context of d[illegible]. They are experts in the human body and disease, but not necessarily in health policy. Government must look at the social context of all problems and decide how to allocate limited funds to buy the most health for those it covers. Doctors can say yes without saying no. In public policy, everything we do prevents us from doing something else. Government can't meet the Hippocratic oath's standard of "do no harm," it must maximize good with always limited money.

As Victor Fuchs has wisely observed, paraphrasing Abraham Lincoln, "A nation can provide all of its people with some of the care that might do them good; it can provide some of its people with all of the care that might do them some good, but it cannot provide all of its people with all of the care that might do them some good."

How do we decide who is covered for what?

ASKING THE HARD QUESTIONS

Ethical health policy must not be the sum total of all individual citizens' "beneficial" medicine. Government could never underwrite the open-ended commitment for reimbursement for every service that the doctor and patient thought "beneficial" to an individual patient. Public policy today has no way to weigh and balance health care spending either within the health care system or against other important priorities.

My generation of public policymakers did not ask enough hard questions of the health care system. We lacked proportion and allowed health care spending to grow out of control. Consequently, we have today many badly maintained public buildings, yet approximately half the hospital beds in America are empty. We have too many doctors (unevenly distributed) and too few teachers. Most American cities have duplicative and redundant medical technology near schools that are without computers for students. We keep people alive in a permanent vegetative state in cities where 20 percent of the population are uninsured, and many kids don't have vaccinations. We pay for marginal end of life care for people, while others don't have meals on wheels, long-term care, respite care or emergency response systems and have no handy senior citizen centers.

The health care system can no more afford to do everything "beneficial" for every patient than the education system can do everything "beneficial" for every student, nor the police department do everything "beneficial" for every citizen, nor every parent do everything "beneficial" for their children. We are funding health care by an unsustainable yardstick.

Nor can a public policymaker "do no harm." Someone must locate the garbage dumps and the one-way streets, must parole prisoners (to make room for this year's crop of new inmates), set speed limits and myriad other tasks which inevitably cause "harm" because public policy can't help but inadvertently do some harm. No public policymaker should ever sign the Hippocratic oath.

What can we not do? We need to start now to discuss what we can morally leave undone. This is "...a dilemma so new that neither our social, legal and religious institutions, nor our health care providers or consumers, have developed a satisfactory way of coping," says Laurene Graig in *Health of Nations: An International Perspective on U.S. Health Reform*. Yet cope we must.

As Dr. David Eddy, policy expert with the Kaiser Permanente Health Care Program has said, "We will need to accept, once and for all, that resources are limited. It's the limitation on resources that both necessitates and justifies the strategy of getting more for less." This is painful but unavoidable. We are inventing the unaffordable and spending the unsustainable. We need to focus limited resources on where they will buy the most health for society.

The price of modern medicine in a high technology society is to decide what and whom to cover. We must find a way to do so and at the same time articulate the trade-offs involved. I suggest that when we deliver futile and marginal care, we are actually being unethical. In the new world of health care, when we overtreat A we take needed care away from B. The unintended end result of current medical ethics is unethical public policy and unethical macro decision making. The dollars we spend on marginal and futile care are no longer available to spend on needed care for someone else in the system or some other equally important social need.

Philosopher Haavi Morreim of the University of Tennessee School of Medicine writes of a new concept, "contributive justice," which changes the rules when making choices for those who contribute to a limited pool. From this viewpoint, my irrational or excessive use of limited funds prevents you or others from getting necessary care. Herein lies a yet undeveloped challenge to society for evaluating modern medicine by a new ethical perspective.

In a world that cannot deliver all the "beneficial" care to everyone, the existing ethics are inadequate to judge a health delivery system. If a system produces more health *for a group*, should we turn against it because it violates ethical standards applicable to an individual (and one which we admit is unsustainable)? In a world of limited resources, what if a group is better off *not* giving all the marginal care to individuals but instead maximizes the health of the group?

HOW DO WE JUDGE A HEALTH CARE SYSTEM?

Does America really have "the best health care system in the world?" It is clear that America has the most technologically advanced medicine, but brilliant medicine does not necessarily make a brilliant health care system. While there is virtually no question that in research, training, facilities and technology no nation tops the United States, most experts agree with Professor Robert Blank's concise analysis of our total system in his book *The Price of Life: The Future of American Healthcare*:

"Although there is no doubt that Americans have the most extensive range of sophisticated medical technology in the world, we fall well short of most other nations in health promotion, preventive medicine and access to primary care. Health outcomes as measured by morbidity and mortality rates fail to reflect the vast expenditure differential with other nations. *Something, therefore, is dreadfully wrong.*" (emphasis added)

It is important to recognize that brilliant doctors and advanced technology alone are not enough to produce an excellent system. Why? Because a system is the sum of its parts, and a weak part anywhere weakens the system overall. What if we were to claim that we had the "best road system in the world," with beautiful, modern freeways, yet traffic movement was paralyzed by congestion, highways missed a significant part of the state and our traffic deaths were among the highest in the world?

A health care system should be evaluated by three criteria: 1) technology and training; 2) access by the entire population; and 3) outcomes and results. While the United States unquestionably excels in

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technology and training, in the other two categories it falls far short of other developed nations.

Despite the enormous amount of resources and talent expended on health care, 50 percent more than any other developed country, America has the most uninsured citizens and the most underinsured citizens in the developed world. Equally upsetting, our citizens are less healthy than those in Europe, Canada or Japan. We are even losing ground compared with other nations. The United States ranks 21 out of 27 countries in infant mortality; 17th for life expectancy of women; and 21st for life expectancy of men of the 29 developed countries.

Health providers can rightly say that those statistics are not their fault, but public policy must take responsibility for them. A doctor can rightly point out that these flow from unhealthy lifestyle, not inadequate medicine, but public policy does have an impact on smoking, alcohol, seat belts, illicit drugs and other non-medical causes of poor health.

CHANGING THE HEALTH ETHIC

If this reasoning is correct, it changes many of our standard yardsticks. We no longer should approve a drug, a new technology or a procedure if it offers only marginal benefits.

Health expert Reinhard Priester at the University of Minnesota says, "...providers should *not* do everything that maximizes benefit in an individual patient, since doing so may interfere with the ability of other patients to obtain basic services; rather, providers should treat each patient with a full range of resources as is compatible with treating patients yet to come. That is an ethical earthquake..."

We must revise our unsustainable health care culture. We are individuals with certain defined rights and duties and also we are members of a society which itself has rights. But when an individual contributes to a limited pool of resources, he enters a new contractual arrangement that cannot be evaluated by the normal standards. Here the system has an ethical duty to the other members of our group not to use limited resources on procedures that have a certain degree of marginal effectiveness. I submit that not only is Oregon's health prioritization ethical, but that it may be unethical *not* to have some system that sets priorities for limited funds. As Governor Kitzhaber has said so often, we must decide both *who* and *what*. It must occasionally consider the health of the group before considering the health of the individual.

A modern system, looking beyond the individual patient, may find as Kaiser has in Southern California that they can save twice as many women for two-thirds of the money by concentrating mammography on women between 50 and 70. Isn't that better than giving mammograms indiscriminately, especially if we use the money saved for other more health producing strategies?

No nation leaves its total defense policy to its generals, nor its educational policy to its teachers, nor its concept of justice to its lawyers. While the state cannot decide what medical care an individual needs, it can and must decide what policies produce the most health, and additionally set up a system to make the best use of the funds it does spend on health care.

Public policy has a broad responsibility and demands a panoramic view. We "ration" health care whenever we leave someone or something out of our health coverage. We can (and have) run from rationing, but we can't hide. We must, sooner or later, better assert the public interest in funding health care.

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APTA's Exclusive PT Weekly

PT BULLETIN

American Physical Therapy Association

MARCH 15, 1999 NATIONAL WEEKLY VOL. 14 NUMBER 11

Legislation Would Allow Exceptions To Annual Cap on Physical Therapy

Sen. Charles Grassley (R-Iowa), chair of the Special Committee on Aging, has introduced legislation to ease the cap on Medicare coverage for outpatient physical therapy and other rehabilitative services.

While APTA maintains its opposition to arbitrary caps on care and supports repeal of the $1,500 cap on outpatient physical therapy services, the association believes this new legislation would provide reasonable relief to seniors and individuals with disabilities who are confronted with the current limitation on coverage.

"Physical therapists across the nation commend Sen. Grassley for his leadership on this important issue," said APTA President Jan K. Richardson, PT, PhD, OCS. "Passage of this legislation would help ensure that patients who are in need of outpatient physical therapy services receive appropriate care in the setting of their choice, without fear of exceeding an arbitrary limit on coverage."

An annual cap of $1,500 on physical therapy and all outpatient rehabilitation services except those provided in hospital outpatient departments was imposed, effective Jan. 1, 1999, under the Balanced Budget Act of 1997. Currently, there are two separate limits: a $1,500 cap on physical therapy and speech-language pathology services, and a $1,500 cap on occupational therapy services.

Sen. Charles Grassley (R-Iowa)

"The cap is arbitrary," Grassley said. "It's based on the bottom line, not on what the patient needs. This legislation would make the patient the priority. It would allow seniors to receive rehabilitative therapy based on their medical conditions, not on arbitrary payment limits."

The caps were imposed as a well-intended, cost-saving step to help preserve Medicare's solvency, Grassley said, but Congress failed to recognize the potentially devastating effects.

The Medicare Rehabilitation Benefit Improvement Act, co-sponsored by Sen. Harry Reid (D-Nev.), would establish exceptions to the $1,500 limit.

Providers would be required to demonstrate medical necessity and the Department of Health and Human Services would implement the exceptions.

Just 31 days after the caps went into effect, Grassley said, an estimated one in four beneficiaries had exhausted half their yearly benefit. According to a recent study, he said, almost 13 percent of Medicare beneficiaries — 750,000 people — will exceed the cap each year.

"Medicare beneficiaries with conditions that require extensive rehabilitation, such as stroke, hip fracture, Parkinson's Disease or cerebral palsy, easily meet and exceed this arbitrary $1,500 limit on coverage that Congress has imposed on outpatient physical therapy services," Richardson said. "Enactment of this legislation would restore reasonable rehabilitation benefits to beneficiaries with illnesses, injuries or disabilities that might typically exceed the $1,500 cap. APTA applauds introduction of this legislation."

(See GRASSLEY on page 6)

Inside News

5 Rep. Adam Smith Speaks At CSM PT PAC Breakfast

Feature Story • 3

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GRASSLEY (Continued from page 1)

The bill establishes certain criteria in order for Medicare beneficiaries to be eligible for an exception to the cap and allows HHS to establish additional criteria if necessary.

The bill's criteria says the beneficiary must:

- Be diagnosed with an illness, injury or disability that requires additional physical, occupational or speech therapy services that are medically necessary in a calendar year; or
- Have a diagnosis that requires such services and an additional diagnosis or incident that exacerbates his condition (such as diabetes) and requires more services; or
- Meet other requirements as determined by HHS.

The legislation also requires HHS to conduct a study and report to Congress two years after enactment of the bill.

The study will include:

- The number of Medicare beneficiaries who received exemptions to the cap;
- The diagnoses of the beneficiaries;
- The types of therapy services that are covered due to such exemptions;
- The settings in which services are provided; and
- The number of beneficiaries who reach the $1,500 cap.

"I hope this bill will assure seniors that Congress wants to preserve their access to medical care," Grassley said. "Physical therapy, occupational therapy and speech therapy aren't luxuries. They're necessary for getting well after someone suffers a stroke or broken hip. Medicare should recognize this with coverage that makes sense."

Richardson agrees.

"As long as services are medically necessary, APTA believes that beneficiaries should not have to fear denial of coverage if they happen to require physical therapy in the spring and then again in the winter of the same year for another condition," she said. ▼

FAX COVER SHEET

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Date: 3/30/99

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REMARKS: Here is a draft fact sheet on the therapy caps.

In addition, when CBO did an analysis last year, they estimated that the limits would cause Medicare payments for therapy to be reduced by about 50%, with over 400,000 people affected annually by the limit.

HEALTH CARE FINANCING ADMINISTRATION
200 Independence Ave., SW
Room 341-H, Humphrey Building
Washington, DC 20201

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Outpatient Therapy Caps

BBA Provision

Section 4541 of the Balanced Budget Act (BBA) established an annual per beneficiary limit of $1500 for all outpatient physical therapy (PT) services (including speech-language pathology services), except for services furnished by hospital outpatient departments. A separate $1500 limit was also established for all outpatient occupational therapy (OT) services except for services furnished by hospital outpatient departments. Therapy services furnished by a physician or incident to a physician's professional services are also subject to the limits. These limits, effective January 1, 1999, replace the current $900 limits, which apply only to services furnished by therapists in independent practice.

Partial Implementation of Policy in 1999

Full implementation of the $1500 limits in 1999 was not possible due to the considerable new programming that would be required, which HCFA cannot undertake simultaneously with the Year 2000 Conversion efforts. HCFA will implement this provision on a limited basis in 1999 with full implementation to begin sometime in 2000.

In 1999, with the exception of therapists in independent practice and SNFs, the limits will be implemented on a per provider basis. That is, each provider, physician, or nonphysician practitioner will be held accountable for tracking incurred expenses for each beneficiary and not billing Medicare for patients who have met the annual $1500 limitation at their facility for each separate limit.

For SNF residents, however, the limits are being fully implemented since SNFs are responsible for billing for all Part B outpatient rehabilitation services for residents no longer covered under a Part A SNF stay. This prevents a beneficiary from getting the services from more than one provider if the cap is exceeded.

For therapists in independent practice, the $900 limits that applied prior to 1999 were increased to $1500. They continue to be applied on an annual per beneficiary basis rather than a provider basis.

Impact on Beneficiaries

HCFA is concerned about the limits and will be monitoring the impact of this provision in the next year, particularly in SNFs, which is where the limits will be most widely felt. The American Physical Therapy Association has estimated the average number of visits required for various diagnoses, indicating that the $1500 caps will leave many beneficiaries without Medicare coverage for medically necessary therapy. Some of the examples of the average number of visits needed are: 35 visits for stroke; 35 visits for brain tumor; 25 visits for fractures with surgery; and 30 visits for lower extremity amputation.

intent is good don't have cost estimates or regulatory criteria now.

Bill Clinton 3-4-99

C Jennings

I have some ideas about this we should discuss —

BC

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C. Jennings
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President of the United States

UNINSURED IN U.S. SPAN MANY GROUPS

Health Coverage Experts Take Further Look at Solutions

By PETER T. KILBORN

WASHINGTON, Feb. 25 — Who are all these 43.4 million Americans, at the Census Bureau's last count, who do not have health insurance? Who runs the least risk in going without it? (Children.) Who runs the most, medical and financial? (Sick people approaching 65.) Who is most likely to have it? (People over 65.) Not to have it? (Adults who work for low wages.) Who doesn't care? (Invincible youth.)

For more than a decade, an average of a million Americans a year have either lost their health insurance or failed to obtain insurance for which they became eligible. The reasons vary: prohibitively priced premiums, reduced employer coverage, the welfare overhaul.

But whatever the causes, the growth in the number of uninsured is a startling anomaly in an economy that has been able to subdue inflation, unemployment and budget deficits. Much to the dismay of advocates for the uninsured, the United States, despite its bounty, stands almost alone among industrial nations in not providing free basic health care for all.

"The number is going in absolutely the wrong direction," said Grace-Marie Arnett, president of the Galen Institute, a conservative health and tax policy organization. "It shows something is wrong with the system."

And with the rise in the cost of insurance and health care outrunning wage gains, said Paul Fronstin,

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Americans Without Health Insurance Run the Gamut

Continued From Page A1

an analyst at the nonpartisan Employee Benefit Research Institute, "this is going to get worse unless something is done about it."

The what to do about it, long primarily the concern of liberals, is now being weighed by officials across the political spectrum. The proposals, still evolving, range from expansion of government insurance programs to tax breaks helping more people buy coverage.

But while there is debate on how to help the uninsured, few experts disagree on who they are.

To begin with, not many are among the elderly or the seriously disabled, most of whom are covered by Medicare. Another group, some five million to six million, have family incomes exceeding $75,000 a year and can usually afford the insurance that, for any number of reasons, they do without.

Almost 11 million are children, from families that range from indigent to well off. But children are a less compelling concern to many health system analysts than are large numbers of the other uninsured. First, they are generally healthier than adults and less expensive to treat. And second, alone among the uninsured, they have already been singled out for help, under a $24 billion, five-year program for non-Medicaid-eligible children approved by Congress in 1997.

That leaves the rest of the uninsured, those who need coverage most: 25 million to 30 million people who have the greatest chance of becoming ill and cannot pay for care when they do. Demographically, they run the gamut.

"Some work, and some don't," said Katherine Swartz, an associate professor at the Harvard School of Public Health. "Some don't work because they're sick. Some are very young adults not covered by their parents' health insurance. They take jobs serving latte in coffee shops that are not likely to have health insurance. They just don't think about the risks."

The income of many is so low that they cannot afford to buy insurance, Professor Swartz said, but not so low that they qualify for Medicaid. Others may qualify but fail to apply, because of ignorance, language barriers or a general sense of intimidation.

Most of the uninsured in the greatest need of coverage "are working adults who are not quite in the middle class," said David B. Kendall, health policy analyst at the Progressive Policy Institute. "They are the folks who don't have a job that's going to be there for a lifetime."

Minority groups account for a disproportionate number of the uninsured, Mr. Kendall said. Hispanic Americans, nearly half of whom under 65 lack insurance, are only 11 percent of the population but 21 percent of all the uninsured. Experts say there are several reasons, among them that Hispanic immigrants tend to be healthy and in addition may be intimidated by language and cultural barriers from applying for Medicaid or other assistance.

The travails of the uninsured are often dismissed because the law assures them the last-resort, safety-net care of emergency rooms, says Drew E. Altman, president of the Kaiser Family Foundation. But by the time they call the ambulance, Mr. Altman notes, many have gone without the preventive care that might have averted the crisis.

A survey of adults under 65 by Kaiser and the Commonwealth Fund found that in a single year, 24 percent of the uninsured declined to fill a prescription that had been given them by a doctor, compared with 6 percent of those who had insurance. Fifty-one percent had encountered difficulty obtaining care, as against 10 percent of the insured. And 42 percent had not seen a doctor during the prior year, compared with 17 percent of the insured.

As a result, the uninsured are sicker than others, according to research last year by the Center for Studying Health System Change, a group supported by the Robert Wood Johnson Foundation. The study found that 16.3 percent of uninsured people under 65 were in fair to poor health, compared with 10.6 percent of all people under 65.

One explanation for the rise in the uninsured is the shift of people from welfare to work. More than six million have left the welfare rolls in the last five years, many for low-wage jobs with employers that do not offer any insurance or that charge a lot for it. For these workers, there is help for a while from Medicaid, the Federal-state insurance program for the poor, which is automatically granted welfare recipients. In most states, families can remain on Medicaid for a year after leaving the cash-assistance rolls.

> **A trend 'going in absolutely the wrong direction.'**

But then, said Ronald F. Pollack, executive director of Families U.S.A., a consumer advocacy group, "their reward is the loss of health insurance."

Another reason for the swelling in the number of uninsured is the rising cost of health care — for hospital stays, visits to the doctor and prescription medicine alike. It is climbing faster than workers' wages, and, on top of the general increase in the cost of care, employers are asking workers to pay a larger share of that cost.

In 1985, nearly two-thirds of all businesses with 100 or more employees paid the full cost of a worker's care, a study by the Kaiser Family Foundation found. A decade later only a third did so. Kaiser also says employers who ask workers to pay part of the cost through payroll deductions had raised the workers' share to 22 percent on average by 1996, from 13 percent in 1988.

As a result, a survey by the Federal Agency for Health Care Policy and Research found, one in four workers who were offered employer-subsidized insurance in 1997 declined to sign up. A decade ago, only one in ten declined.

These changes, analysts say, have spawned the largest segment of the uninsured, the working poor.

Young adults — some poor, some not — are another large group of the uninsured. Of 65 million up to 34 years old, nearly 25 percent are uninsured (compared with 13 percent of the rest of the population), and they account for nearly 40 percent of all the uninsured.

Of the youngest among them, those 19 to 24, the Center for Studying Health System Change says, 30 percent are not offered insurance through their jobs. Of those who are offered it, typically for a few hundred dollars a year, 30 percent turn it down. Some who reject it are working poor and cannot afford it. Others, feeling invincible, simply spend the money on something else.

However much some young adults feel they can do without insurance, the nation has an incentive to help them buy it, analysts say. Like safe drivers who never have accidents and yet are required to buy car insurance, these young people, by paying health insurance premiums, would help defray the cost of care for people who are frailer and older. This process of subsidizing one group whose purchases then serve to subsidize others is called cross-subsidizing.

Among the beneficiaries of cross subsidies would be a not so obviously needy group of the uninsured: the poorer and sicker, often retired and homebound, among the 23 million Americans who, age 55 to 64, are not yet eligible for Medicare.

According to the Center for Studying Health System Change, people in that age group have average family incomes of $45,800 a year, about $4,000 more than the average for all families and enough to permit nearly 90 percent of them to pay the age group's high premiums of close to $3,000 a year, even if the employer pays no share.

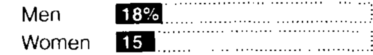
But the three million among them who are uninsured earn an average of only $18,000. The center reports that a third of them are in particularly perilous straits: these one million are in ill health and have average incomes of just $9,600, which puts private coverage far out of reach.

SNAPSHOT

The Uninsured

Percentage of Americans without health insurance in 1997, by ...

SEX



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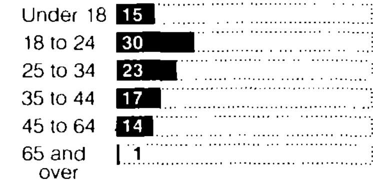
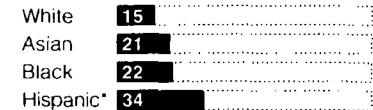


RACE AND ETHNICITY



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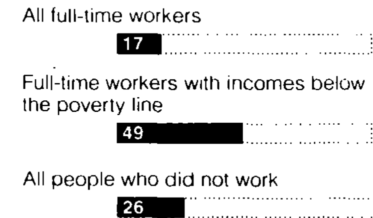

*May be of any race.

Source: Census Bureau

The New York Times

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Testimony of Dean Ornish, M.D.

Committee on Government Reform
Congress of the United States
House of Representatives

Hearing:
"Opening the Mainstream to Complementary and Alternative Medicine:
How Much Integration is Really Taking Place?
An Inquiry into Access to Complementary and Alternative Medicine in Government-Funded Programs"

February 24, 1999
2154 Rayburn House Office Building
Washington, D.C.

INTRODUCTION AND BACKGROUND

Mr. Chairman, members of the Committee, thank you very much for the opportunity to be here today. My name is Dean Ornish, M.D. I am Founder, President, and Director of the non-profit Preventive Medicine Research Institute and Clinical Professor of Medicine at the School of Medicine, University of California, San Francisco (UCSF), where I am also one of the founders of the new Osher Center for Integrative Medicine at UCSF.

The theme of all of my work is simple: if we do not treat the underlying causes of a problem—in this case, heart disease—then the same problem may recur, new problems may emerge, or we may be faced with painful choices. Whenever I lecture, I often show a cartoon of doctors mopping up the floor around an overflowing sink without also turning off the faucet.

During the past 22 years, my colleagues and I have conducted a series of clinical trials demonstrating—for the first time—that the progression of even severe coronary heart disease often can be reversed by making comprehensive changes in diet and lifestyle, without coronary bypass surgery, angioplasty, or a lifetime of cholesterol-lowering drugs. These lifestyle changes include a very low-fat, low-cholesterol diet, stress management techniques, moderate exercise, smoking cessation, and psychosocial support. This was a radical idea when I began my first study; now, it has become mainstream and is generally accepted as true by most cardiologists and scientists.

Within a few weeks after making comprehensive lifestyle changes, the patients in our research reported a 91 percent average reduction in the frequency of angina. Most of the patients became essentially pain-free, including those who had been unable to work or engage in daily activities due to severe chest pain. Within a month, we measured increased blood flow to the heart and improvements in the heart's ability to pump. And within a year, even severely blocked coronary arteries began to improve in 82% of the patients.

These research findings were published in the most well-respected peer-reviewed medical journals, including the *Journal of the American Medical Association, The Lancet, Circulation, The American Journal of Cardiology,* and others. This research was funded in part by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

THE LIFESTYLE HEART TRIAL

In our latest report, published in the December 16, 1998, issue of the *Journal of the American Medical Association,* we found that most of the study participants were able to maintain comprehensive lifestyle changes for five years. On average, they demonstrated even more reversal of heart disease after five years than after one year. In contrast, the patients in the comparison group who made only the moderate lifestyle changes recommended by most physicians (i.e., a 30% fat diet) worsened after one year and their coronary arteries became even more clogged after five years. Also, we found that the incidence of cardiac events (e.g., heart attacks, strokes, bypass surgery, and angioplasty) was 2.5 times lower in the group that made comprehensive lifestyle changes after five years. There has been strong interest in this research in the general public as well. A one-hour documentary of this work was broadcast on *NOVA*, the PBS science series, and was featured on Bill Moyers' PBS series, *Healing & The Mind.*

These research findings have particular significance for Americans in the Medicare population. One of the most meaningful findings in our research was that the older patients improved as much as the younger ones. When I began the research, I believed that the younger patients with milder disease would be more likely to show regression, but I was wrong. Instead, the primary determinant of change in their coronary artery disease was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. No matter how old they were, on average, the more people changed their diet and lifestyle, the more they improved. Indeed, the oldest patient in our study (now 83) showed more reversal than anyone. This is a very hopeful message for Medicare patients, since the risks of bypass surgery and angioplasty increase with age, but the benefits of comprehensive lifestyle changes may occur at any age.

These findings also have particular significance for women. Heart disease is, by far, the leading cause of death in women in the Medicare population. Women have less access to bypass surgery and angioplasty. When women undergo these operations, they have higher morbidity and mortality rates than men. However, women seem to be able to reverse heart disease even easier than men when they make comprehensive lifestyle changes.

MULTICENTER LIFESTYLE DEMONSTRATION PROJECT

The next research question was: how practical and cost-effective is this lifestyle program?

As you know, there is bipartisan interest in finding ways to control health care costs without compromising the quality of care. Many people are concerned that the managed care approaches of shortening hospital stays, shifting from inpatient to outpatient surgery, forcing doctors to see more and more patients in less and less time, etc., may compromise the quality of care because they do not address the lifestyle factors that often lead to illnesses like coronary heart disease.

Beginning five years ago, my colleagues and I established the Multicenter Lifestyle Demonstration Project. It was designed to determine (a) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow this lifestyle program; (b) if this program may be an equivalently safe and effective alternative to bypass surgery and angioplasty in selected patients with severe but stable coronary artery disease; and (c) the resulting cost savings. In other words, can some patients avoid bypass surgery and angioplasty by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

In the past, lifestyle changes have been viewed only as *prevention*, increasing costs in the short run for a possible savings years later. Now, this program is offered as a scientifically-proven alternative *treatment* to many patients who otherwise were eligible for coronary artery bypass surgery or angioplasty, thereby resulting in an immediate and substantial cost savings.

For every patient who chooses this lifestyle program rather than undergoing bypass surgery or angioplasty , thousands of dollars are immediately saved that otherwise would have been spent; much more when complications occur. (Of course, this does not include sparing the patient the trauma of undergoing cardiac surgery.)

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive coronary bypass surgery or coronary angioplasty may result in significant *long-term* cost savings. Despite the great expense of bypass surgery and angioplasty, up to one-half of bypass grafts reocclude after only five to seven years, and 30-50% of angioplastied arteries restenose after only four to six months—an example of mopping up the floor around the overflowing sink without also turning off the faucet. When this occurs, then coronary bypass surgery or coronary angioplasty is often repeated, thereby incurring additional costs.

Through our non-profit research institute (PMRI), we trained a diverse selection of hospitals around the country. The initial sites were Alegent Immanuel Medical Center/Alegent Heart Institute, Omaha, NB; Alegent Bergen Mercy Medical Center, Omaha, NB; Beth Israel Medical Center, New York, NY; Mercy Hospital Medical Center/Iowa Heart Center, Des Moines, IA; Broward General Medical Center, Fort Lauderdale, FL; Palmetto Richland Memorial Hospital, Columbia SC; Mt. Diablo Medical Center, Concord, CA; Beth Israel Deaconess Medical Center/Harvard Medical School, Boston, MA; Scripps Hospitals and Clinics, La Jolla, CA. Additional program sites included the School of Medicine, University of California, San Francisco; California Pacific Medical Center, San Francisco; Franciscan Health System of the Ohio Valley, Cincinnati Ohio; Swedish American Health System, Rockford, IL; and Swedish Medical Center/First Hill, Seattle, WA.

Also, Highmark Blue Cross/Blue Shield of Western Pennsylvania was the first insurer to both cover and to provide this program to its members. Over 40 other insurance companies are covering this approach as a defined program either for all qualified members or on a case by case basis at the sites we have trained. The Technology Assessment Committees of both Blue Cross of California and, separately, Blue Shield of California have evaluated this program and determined it to be reimbursable and non-investigational.

In brief, we found that 77% of people who were eligible for bypass surgery or angioplasty were able to avoid it safely by making comprehensive lifestyle changes in the hospitals we trained. Mutual of Omaha calculated an immediate savings of $29,529 per patient. These patients reported reductions in angina comparable to what can be achieved with bypass surgery or angioplasty without the costs or risks of surgery. These findings were published in the *American Journal of Cardiology* in November 1998. We also found that patients who needed bypass surgery or angioplasty were able to reduce the likelihood of needing another operation by making comprehensive lifestyle changes after surgery.

MEDICARE

Over 500,000 Americans die annually from coronary artery disease, making it the leading cause of death in this country. Approximately 500,000 coronary artery bypass operations and approximately 600,000 coronary angioplasties were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. Much of this expense is paid for by Medicare. Not everyone is interested in changing lifestyle, and some people with extremely severe disease need surgery, but billions of dollars per year could be saved immediately if only some of the people who were eligible for bypass surgery or angioplasty were able to avoid it by making comprehensive lifestyle changes instead.

Unfortunately, for many Americans on Medicare, the denial of coverage is the denial of access. Because of the success of our research and demonstration projects, we asked the Health Care Financing Administration to consider providing coverage for this program. We believe that this can help provide a new model for lowering Medicare costs without compromising the quality of care or access to care. In short, a model that is caring and compassionate as well as cost-effective and competent.

This approach empowers the individual, may immediately and substantially reduce health care costs while improving the quality of care, and offers the information and tools that allow individuals to be responsible for their own health care choices and decisions. It provides access to quality, compassionate, and affordable health care to those who most need it.

I first met with officials from HCFA on June 9, 1994, almost five years ago, and many times since then. Then, as now, concern was expressed that if HCFA were to cover an "alternative medicine" program, then a "Pandora's Box" would be opened. In other words, if HCFA covered this program, then everyone who had any kind of alternative medicine program would demand coverage. Or, even in a more limited way, everyone who had an alternative program for treating coronary heart disease would demand coverage from HCFA.

I understand this concern. In the first meeting with HCFA in 1994, I was accompanied by the medical director of Mutual of Omaha. In response to this issue, he replied that Mutual of Omaha made a decision to provide coverage for this program because it has the scientific data from many years of randomized controlled trials demonstrating safety and efficacy. If other programs develop this scientific evidence of safety and efficacy, then Mutual of Omaha would consider providing coverage for those programs as well. Other insurance companies that are providing coverage for this program in the sites we have trained have expressed similar ideas.

I appreciate very much the leadership and vision of Hon. Nancy-Ann Min DeParle at HCFA. After going back and forth with HCFA for several years during which a variety of options have been considered (including a demonstration project), I am respectfully requesting that HCFA now make a decision to cover this program for selected patients. Another demonstration project would largely duplicate the demonstration project that we have already conducted, it would cost millions of dollars, and it would delay this program for several more years to Americans who may benefit from it.

Coverage from HCFA could be limited to people who are choosing this program of comprehensive lifestyle changes as a direct alternative to bypass surgery or angioplasty. These are the patients in whom the cost savings are the most dramatic and immediate, and it would be the easiest group in which to prevent fraud or abuse. My colleagues and I would be happy to work with an outside group (e.g., the American College of Cardiology) that could provide certification for any comprehensive lifestyle program that has sufficient scientific evidence of medical effectiveness and cost effectiveness to justify coverage. This certification could be offered on a non-exclusive basis and would meet HCFA's understandable need for credentialing of programs to avoid fraud and abuse, thereby making the program available to the people who most need it.

In response to an earlier request from Hon. DeParle's predecessor, Bruce Vladeck, Dr. Claude Lenfant (Director, National Heart, Lung, and Blood Institute, National Institutes of Health) evaluated this program and found it to be safe for Americans in the Medicare population.

Also, bipartisan letters of support were written from President Clinton, former Speaker Gingrich, and ten other U.S. Senators (Republican and Democrat), as well as AARP executive director Horace Deets, former Surgeon General C. Everett Koop, and other medical authorities including Christine Cassel, M.D. (Professor and Chairman, Department of Geriatrics and Adult Development, The Mount Sinai Medical Center, Immediate Past President, American College of Physicians, Chair, American Board of Internal Medicine), Alexander Leaf, M.D. (Jackson Professor of Clinical Medicine, Emeritus, Chairman, Department of Medicine, Emeritus, Chairman, Department of Preventive Medicine & Clinical Epidemiology, Emeritus, Harvard Medical School and Massachusetts General Hospital), Marion Nestle, Ph.D. (Professor and Chair, Department of Nutrition and Food Studies, New York University), and others.

We appreciate very much a recent appropriation from Congress to the Department of Defense to make this comprehensive lifestyle change program available at the Walter Reed Army Medical Center. If heart disease can be reversed, then the implications for prevention are even more important. Increasing evidence links a low-fat plant-based diet with a lower incidence of diabetes, hypertension, obesity, and cancers of the prostate, breast, and colon.

A recent editorial by the editors of *The New England Journal of Medicine* (1998;339(12), p. 839-841) stated, "There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted." This program has been tested rigorously and was found to be reasonably safe and effective. It works. Therefore, I respectfully submit that it should be covered by Medicare for selected heart patients as an alternative to bypass surgery or angioplasty.

Everyone benefits: patients have access to new choices, health professionals have new options to serve their patients, Medicare offers an innovative approach to lowering health care costs without compromising the quality of care, and Congress can demonstrate bipartisan leadership in an area that is important to so many Americans.

Thank you very much for this opportunity to be here today. My colleagues and I are very grateful for your interest in our work.

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February 25, 1999

Flt. Lt. Jerry John Rawlings
President of the Republic of Ghana
Mrs. Nan Konadu Agyeman-Rawlings
c/o Blair House
702 Jackson Place
Washington, DC 20503

attention: Mr. Randy Bumgardner

Your Excellencies,

It was a great pleasure and honor to meet you last night in the receiving line of the State Dinner honoring you, hosted by President Clinton and Mrs. Hillary Rodham Clinton at The White House.

Please accept the enclosed copies of my books. I would be honored to be of service to you at any time.

With best wishes and warm personal regards,

Sincerely,

Dean Ornish, M.D.
Clinical Professor of Medicine
School of Medicine
University of California, San Francisco

American Medical Association
Physicians dedicated to the health of America

News Release

EMBARGOED FOR RELEASE: 3 p.m. (CT) Tuesday, December 15, 1998
Media Advisory: To contact Dean Ornish, M.D., call 800/775-7674, ext. 222.

Long-Term Lifestyle Changes Increase Regression of Coronary Heart Disease

Coronary atherosclerosis continued to progress in those with conventional lifestyle

CHICAGO--Patients in an experimental group who made intensive changes in diet, exercise, stress management, and other lifestyle factors showed greater reversal of coronary heart disease after five years than after one year in the Lifestyle Heart Trial, according to an article in the December 16 issue of *The Journal of the American Medical Association (JAMA).*

In contrast, the authors found that control group patients showed much more progression (continued worsening) in average percent diameter stenosis after five years than after one year, even though more than half of the control group patients were prescribed lipid-lowering medications during the course of the study.

Dean Ornish, M.D., of the Preventive Medicine Research Institute, Sausalito, Calif., and the University of California at San Francisco School of Medicine, and colleagues conducted a five-year follow-up of the Lifestyle Heart Trial. The original trial found that after one year, heart patients who made intensive lifestyle changes had a 37.2 percent reduction in LDL cholesterol, less frequent angina, and a reduction in stenosis. By contrast, patients who made moderate changes reduced LDL cholesterol by only 6 percent, had more frequent angina, and greater narrowing of the blood vessels. Among the 48 patients from the original study, 35 agreed to take part in the follow-up and continued through the entire five years.

Patients in the experimental group were prescribed an intensive program that included a 10 percent fat vegetarian diet, moderate aerobic exercise, stress management training, smoking cessation, and group psychosocial support. Control group patients were asked to follow the advice of their personal physicians regarding lifestyle changes, consistent with the American Heart Association's Step II diet guidelines. No experimental group patients took lipid-lowering drugs, while 60 percent of control patients received lipid-lowering medication. Angiograms were done at the end of five years for the 20 experimental group and 15 control patients who completed the follow-up.

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--more--

Among the findings of the study:

- Experimental group patients had a 91 percent reduction in frequency of angina after one year, and a 72 percent reduction after five years. Control patients had a 186 percent increase after one year, and a 36 percent decrease after five years. Three of the five control patients who reported an increase from baseline to year one underwent coronary angioplasty before year five.
- The reduction in LDL cholesterol levels in the experiment group was comparable with results achieved by lipid-lowering drugs for ambulatory patients.
- In the experimental group, the average percent diameter stenosis (narrowing of the blood vessels)showed a 7.9 percent relative improvement after five years, while the control group showed a 27.7 percent relative worsening.

The researchers also found more than twice as many cardiac events in the control group (45 events, 2.25 events per patient) than in the experimental group (25 events, 0.89 events per patient). Events included heart attacks, coronary angioplasty, coronary bypass surgery, cardiac-related hospitalizations, and cardiac-related deaths.

The authors write: "These findings support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods."

The authors conclude: "In summary, these ambulatory patients were able to make and maintain comprehensive changes in diet and lifestyle for five years and showed even more regression of coronary atherosclerosis after five years than after one year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after five years than after one year, and had more than twice as many cardiac events as patients making comprehensive lifestyle changes."
(*JAMA*. 1998;280:2001-2007)

Editor's Note: The Preventive Medicine Research Institute is a non-profit organization. Major support for this study was provided by grants from the National Heart, Lung, and Blood Institute of the National Institutes of Health, Bethesda, Maryland and numerous other organizations. For a complete listing, please see the *JAMA* article.

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For more information: contact the AMA's Science News Department at 312/464-5374.
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Intensive Lifestyle Changes for Reversal of Coronary Heart Disease

Dean Ornish, MD; Larry W. Scherwitz, PhD; James H. Billings, PhD, MPH; K. Lance Gould, MD; Terri A. Merritt, MS; Stephen Sparler, MA; William T. Armstrong, MD; Thomas A. Ports, MD; Richard L. Kirkeeide, PhD; Charissa Hogeboom, PhD; Richard J. Brand, PhD

Context.—The Lifestyle Heart Trial demonstrated that intensive lifestyle changes may lead to regression of coronary atherosclerosis after 1 year.

Objectives.—To determine the feasibility of patients to sustain intensive lifestyle changes for a total of 5 years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease.

Design.—Randomized controlled trial conducted from 1986 to 1992 using a randomized invitational design.

Patients.—Forty-eight patients with moderate to severe coronary heart disease were randomized to an intensive lifestyle change group or to a usual-care control group, and 35 completed the 5-year follow-up quantitative coronary arteriography.

Setting.—Two tertiary care university medical centers.

Intervention.—Intensive lifestyle changes (10% fat whole foods vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychosocial support) for 5 years.

Main Outcome Measures.—Adherence to intensive lifestyle changes, changes in coronary artery percent diameter stenosis, and cardiac events.

Results.—Experimental group patients (20 [71%] of 28 patients completed 5-year follow-up) made and maintained comprehensive lifestyle changes for 5 years, whereas control group patients (15 [75%] of 20 patients completed 5-year follow-up) made more moderate changes. In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening) ($P = .001$ between groups. Twenty-five cardiac events occurred in 28 experimental group patients vs 45 events in 20 control group patients during the 5-year follow-up (risk ratio for any event for the control group, 2.47 [95% confidence interval, 1.48-4.20]).

Conclusions.—More regression of coronary atherosclerosis occurred after 5 years than after 1 year in the experimental group. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

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THE LIFESTYLE Heart Trial was the first randomized clinical trial to investigate whether ambulatory patients could be motivated to make and sustain comprehensive lifestyle changes and, if so, whether the progression of coronary atherosclerosis could be stopped or reversed without using lipid-lowering drugs as measured by computer-assisted quantitative coronary arteriography. This study derived from earlier studies that used noninvasive measures.[1,2]

After 1 year, we found that experimental group participants were able to make and maintain intensive lifestyle changes and had a 37.2% reduction in low-density lipoprotein (LDL) cholesterol levels and a 91% reduction in the frequency of anginal episodes.[3] Average percent diameter stenosis regressed from 40.0% at baseline to 37.8% 1 year later, a change that was correlated with the degree of lifestyle change. In contrast, patients in the usual-care control group made more moderate changes in lifestyle, reduced LDL cholesterol levels by 6%, and had a 165% increase in the frequency of reported anginal episodes. Average percent diameter stenosis progressed from 42.7% to 46.1%.

Given these encouraging findings, we extended the study for an additional 4 years to determine (1) the feasibility of patients sustaining intensive changes in diet and lifestyle for a much longer time, and (2) the effects of these changes on risk factors, coronary atherosclerosis, myocardial perfusion, and cardiac events after 4 additional years.

METHODS

The design, recruitment, and study population were previously described.[3-5] In brief, we recruited men and women

Table 1.—Baseline Characteristics of Experimental and Control Groups*

Characteristic	Experimental (n = 20)	Control (n = 15)	P Value
Men, No.	20	12	.07
Women, No.	0	3	
Age, mean (SD), y	57.4 (6.4)	61.8 (7.5)	.08
Education, mean (SD), y	15.5 (2.7)	14.5 (3.4)	.29
Employed, No.	14	6	.10
mass index, mean (SD), kg/m²	28.4 (4.1)	25.4 (3.5)	.03
No. with history of myocardial infarction	12	5	.17
Average No. of lesions studied, mean (SD)	5.3 (2.7)	5.3 (3.2)	.93
No. with history of percutaneous transluminal coronary angioplasty	5	4	>.99
No. with history of coronary artery bypass graft	1	0	>.99
Reported angina, No. (%)	11 (55)	6 (40)	.49

*Values are statistics unless otherwise indicated. P values are 2-tailed.

with coronary atherosclerosis documented by quantitative coronary arteriography.

We identified 193 patients as potentially eligible for our study who agreed to undergo quantitative coronary angiography. Following angiography, 93 patients remained eligible and were randomly assigned to experimental or control groups using a randomized invitational design to minimize crossover, ethical concerns, nocebo effects, and dropout. Of these 93 patients who were eligible, 53 were randomly assigned to the experimental group and 40 to the usual-care control group. Patients were then contacted and invited to participate in the study; 28 (53%) and 20 (50%) agreed to participate in the experimental and control groups, respectively. The primary reason for refusal in the experimental group was not wanting to undergo intensive lifestyle changes and/or not wanting a second coronary angiogram; control patients refused primarily because they did not want to undergo a second angiogram. To detect possible selection biases, we collected data on age, marital status, reported angina, history of myocardial infarction, height, weight, number of diseased lesions, and stenosis severity for all patients who were randomized into the study but refused to participate. We did not exclude any experimental group patients who volunteered even if we doubted their ability to adhere to the lifestyle program. All patients who volunteered were followed up using the intention-to-treat principle.

After 1 year, 7 patients did not provide angiographic data, and the reasons for loss to follow-up have been reported.[3] Of the remaining 41 patients at baseline most had severe coronary atherosclerosis: 28 had 3-vessel disease, 12 had -vessel disease, and 1 had 1-vessel disease. Two of these patients whose angiographic data were not usable after) · agreed to undergo quantitative coronary arteriography after 5 years; these results are included in the baseline to 5-year comparisons.

Four experimental and 4 control patients who had an angiogram at 1 year did not have a third angiogram after 5 years. Three of these 4 patients in the experimental group refused a third angiogram (patients only volunteered for a 1-year study that was subsequently extended), and 1 died between years 1 and 4; of the 4 control group patients who did not undergo a third angiogram, 1 died, 2 underwent revascularization of the arterial lesions under study, and 1 developed Parkinson disease and became too ill to be safely tested. Cine arteriograms made in San Francisco, Calif, were sent to the University of Texas Medical School, Houston, for blinded quantitative analyses as previously described in detail.[4]

All results, except lesion changes at 1 year (18 experimental and 15 control subjects) and cardiac events after 5 years (all 28 experimental and 20 control subjects), are based on the total of 35 patients (20 experimental and 15 control subjects) who had both baseline and 5-year angiograms. From these 35 patients, there were 224 lesions studied at baseline, of which 24 were 100% occluded and were excluded a priori from the lesion-change analyses per the study protocol. Of the remaining 200 lesions, 14 were lost to the 4-year follow-up, as follows: in the experimental group, 2 lesions were excluded due to technical failure during the angiogram and 2 had views that did not match; in the control group, views did not match for 3 lesions, 3 lesions were excluded due to technical failure, 1 was excluded due to angioplasty, and 3 were excluded due to coronary artery bypass surgery. Of the 186 lesions available for analysis at 4 years, 109 were from the experimental group and 77 were from the control group.

The 1-year original study and the 4-year extension were approved by the committees on human research at California Pacific Medical Center and University of California, San Francisco, and each patient signed a written consent form after being fully informed of the study requirements.

Patients completed a 3-day diet diary at baseline and after 1 and 5 years to assess nutrient intake and dietary adherence.[6] Methods of lipid assays were the same as previously reported.[3] These 3-day diet diaries were analyzed with a software package (CBORD Diet Analyzer; CBORD Group Inc; Ithaca, NY) using the US Department of Agriculture database. Also, patients were asked to complete a questionnaire reporting the frequency and duration of exercise and of each stress management technique. Information from these sources was quantified into continuous scores using an a priori determined formula. The adherence measure was a continuous score reflecting daily intake of cholesterol (in milligrams), fat (in grams), frequency and duration of exercise, frequency and duration of stress management techniques, and smoking. A score of 1.0 equalled 100% adherence but scores could be greater than 1.0 if participants exceeded the recommended intensive lifestyle changes.

The technicians responsible for performing all medical tests were blinded to patient group assignment. Also, different personnel implemented the lifestyle intervention, conducted the tests, and computed statistical analyses, although the dietitian was made aware of the nutrient analysis to monitor patients' safety and adherence. Quantitative coronary arteriograms were blindly analyzed without knowledge of group assignment.

Program Intervention

Experimental group patients were prescribed an intensive lifestyle program that included a 10%-fat vegetarian diet, moderate aerobic exercise, stress management training, smoking cessation, and group psychosocial support previously described in detail.[3,7-10] Patients were encouraged to avoid simple sugars and to emphasize the intake of complex carbohydrates and other whole foods. Only 1 patient in the experimental group was actively smoking at baseline, and she quit at entry. Control group patients were asked to follow the advice of their personal physicians regarding lifestyle changes.

Statistical Methods

We decided a priori to use percent diameter stenosis as the primary dependent variable. Statistical methods to compare the 2 groups were previously described.[3] Analysis of adherence variables and risk factor levels used time-structured repeated measures in which levels from all 3 measurement times (baseline, 1 year, and 5 years) were in-

Table 2.—Adherence to Exercise, Stress Management, and Dietary Guidelines

	(SEM) at E[illegible]		(SEM) at 1 Year			Mean (SEM) at 5 [illegible]		
	Experimental (n = 20)	Control (n = 15)	Experimental (n = 20)	Control (n = 15)	*P* Value* Baseline-1 Year	Experimental (n = 20)	Control (n = 15)	*P* Value* Baseline-5 Years
Exercise								
Times per week	2.66 (0.84)	2.38 (0.77)	4.97 (0.35)	2.87 (0.70)	.06	4.34 (0.49)	3.57 (0.56)	.64
Hours per week	2.26 (0.85)	2.42 (0.99)	5.02 (0.61)	2.52 (0.70)	.12	3.56 (0.56)	2.90 (0.65)	.50
Stress management								
Times per week	0.70 (0.41)	0.15 (0.10)	8.22 (0.73)	0.49 (0.25)	<.001	4.93 (1.02)	0.74 (0.39)	<.001
Minutes per day	6.01 (3.56)	1.71 (1.19)	87.25 (7.85)	4.47 (2.79)	<.001	48.53 (10.36)	8.44 (6.11)	.001
Fat intake								
Grams per day	63.67 (4.35)	57.42 (5.94)	12.71 (1.06)	52.38 (5.31)	<.001	17.34 (2.30)	44.09 (6.66)	<.001
% of Energy intake	29.71 (1.8)	30.52 (2.9)	6.22 (0.3)	28.76 (2.3)	<.001	8.51 (1.0)	25.03 (2.7)	<.001
Dietary cholesterol, mmol/L [mg/dL]	5.47 (0.672) [211.4 (26.0)]	5.49 (0.908) [212.5 (35.1)]	0.08 (0.002) [3.3 (0.8)]	4.69 (0.636) [181.3 (24.6)]	<.001	0.48 (0.140) [18.6 (5.4)]	3.59 (0.641) [138.7 (24.8)]	.002
Energy intake, J/d	8159 (473)	7159 (489)	7623 (473)	7004 (489)	.64	7724 (485)	6581 (489)	.86
Total adherence score†	0.62 (0.08)	0.60 (0.07)	1.29 (0.08)	0.64 (0.07)	<.001	1.06 (0.08)	0.72 (0.07)	<.001

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.
†Percentage of minimum recommended level of combined lifestyle change: includes all the above plus smoking cessation.

Table 3.—Baseline Levels, 1-Year, and 5-Year Change Scores in Coronary Artery Lesions*

	Mean at Baseline (95% CI)		Change Scores at 1 Year (95% CI)			Change Scores at 5 Years (95% CI)		
	Experimental (n = 20)	Control (n = 15)	Experimental (n = 18)	Control (n = 15)	*P* Value† Baseline-1 Year	Experimental (n = 20)	Control (n = 15)	*P* Value† Baseline-5 Years
Diameter stenosis, %	38.92 (35.29 to 42.54)	42.50 (38.18 to 46.81)	−1.75 (−4.08 to 0.58)	2.28 (−3.0 to 4.86)	.02	−3.07 (−5.91 to −0.24)	11.77 (3.40 to 20.14)	.001
Minimum diameter, mm	1.64 (1.44 to 1.84)	1.74 (1.50 to 1.97)	0.01 (−0.10 to 0.12)	−0.12 (−0.25 to −0.001)	.11	0.001 (−0.11 to 0.11)	−0.34 (−0.66 to −0.02)	.05
Normal diameter, mm	2.65 (2.39 to 2.92)	2.96 (2.64 to 3.27)	−0.06 (−0.16 to 0.03)	−0.10 (−0.27 to 0.06)	.68	−0.13 (−0.26 to 0.01)	0.045 (0.017 to 0.072)	.01

*CI indicates confidence interval.
†All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

cluded in a single regression model. Statistical significances of group differences were obtained for baseline levels, 1-year changes, and 5-year changes using F tests. All repeated measures analyses were implemented using PROC MIXED under SAS version 6.08.[11] Analysis of lesion data used a repeated measures model in which the repeated measures were baseline or change values for multiple lesions within each subject. Change scores were used for the baseline to 1-year and baseline to 5-year follow-up periods, and analysis of baseline levels, 1-year changes, and 5-year changes were done separately. Again, F tests provided by SAS PROC MIXED were used to test significance of differences between groups with respect to baseline levels, 1-year changes, and 5-year changes. The SAS PROC MIXED linear regression, which allowed for dependence in data, was used to determine the relationship between adherence and percent diameter stenosis changes. Relative rates for cardiac events were analyzed and tested by Poisson regression using exact tests (Stata 5.0, College Station, Tex).

RESULTS

Baseline Comparisons of Volunteers With Refusals

Those who declined the invitation to be in the study were similar to those who volunteered in all available data except those who volunteered were more likely to have a history of angina (87% vs 65%; $P = .02$), a greater number of lesions (4.5 vs 3.5; $P = .04$), and slightly more severely stenosed lesions (2.3 vs 2.0 on a 3-point scale; $P = .05$).

Baseline Comparisons of Experimental Group With Control Group

Analyses across the 35 volunteers at baseline for whom 4-year lesion data were available showed no significant differences between the experimental group and the control group in demographic characteristics, history of myocardial infarction, angioplasty, bypass surgery, lesion number, lesion stenosis, dietary fat or cholesterol intake, exercise and stress management practice, blood pressure, exercise capacity, and psychosocial measures (Tables 1-3).

Among the many comparisons, only a few differed significantly ($P < .05$). More women were randomly assigned to the control group (4) than to the experimental group (1); this fact accounted for half the weight difference (10 kg) between the 2 groups and most of the height difference (6 cm).

Experimental group patients had a slightly larger body mass index (measured as the weight in kilograms divided by the square of the height in meters) (28.4 vs 25.4 kg/m^2; $P = .03$) and had lower high-density lipoprotein (HDL) cholesterol levels (1.04 mmol/L [40.1 mg/dL] vs 1.36 mmol/L [52.4 mg/dL]; $P = .04$), which was also reflected in lower apolipoprotein A-I levels (3.45 mmol/L [133.1 mg/dL] vs 4.08 mmol/L [157.5 mg/dL]; $P = .03$). The lower body mass index in the control group may be due to the larger number of women in the control group. Other lipid values, including ratios of total cholesterol to HDL and LDL to HDL, did not differ significantly at baseline (Table 4).

Program Adherence

In the experimental group, adherence to all aspects of the program was excellent during the first year and good after 5 years, whereas control group patients maintained more moderate changes during the 5 years consistent with conventional guidelines (Table 2). The percentage of daily energy (calories) provided by fruits, vegetables, whole grains, soy, other legumes, nonfat dairy, and alcohol was comparable at 1 year and at 5 years. In the experimental group, fat intake decreased from approximately 30% to 8.5%, cholesterol from 211 to 18.6 mg/d, energy from 8159 to 7724 J (1950-1846 cal), protein from 17% to 15%, and carbohydrates increased from 53% to 76.5%. In

Table 4.—Changes in Risk Factors

Risk Factor	Mean (SEM) at Baseline: Experimental (n = 20)	Mean (SEM) at Baseline: Control (n = 15)	Mean (SEM) at 1 Year: Experimental (n = 20)	Mean (SEM) at 1 Year: Control (n = 15)
Serum lipids, mmol/L [mg/dL]				
Total cholesterol	5.83 (0.31) [225.1 (11.9)]	6.42 (0.24) [247.9 (9.4)]	4.22 (0.22) [162.9 (8.4)]	6.33 (0.38) [244.3 (14.7)]
Low-density lipoprotein	3.72 (0.29) [143.80 (11.21)]	4.30 (0.19) [166.40 (7.46)]	2.24 (0.24) [86.56 (9.41)]	4.25 (0.38) [164.13 (14.85)]
High-density lipoprotein	1.04 (0.07) [40.05 (2.78)]	1.36 (0.14) [52.36 (5.54)]	0.94 (0.10) [36.28 (3.81)]	1.34 (0.10) [51.87 (3.81)]
Triglyceride	5.90 (0.69) [227.8 (26.5)]	5.78 (1.63) [223.3 (63.0)]	6.69 (0.75) [258.2 (29.1)]	4.30 (0.40) [166.1 (15.5)]
Apolipoproteins, g/L				
A-I	1.331 (0.046)	1.575 (0.092)	1.308 (0.057)	1.761 (0.121)
B	1.000 (0.054)	1.024 (0.062)	0.7685 (0.046)	1.085 (0.053)
Blood pressure, mm Hg				
Systolic	135.3 (4.0)	137.2 (4.5)	126.4 (3.9)	128.8 (4.5)
Diastolic	81.70 (2.05)	80.27 (3.15)	77.03 (2.01)	75.07 (8.15)
Weight, kg	91.40 (3.42)	75.74 (4.37)	80.64 (2.48)	77.18 (4.73)

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

Table 5.—Reported Angina Symptoms

	Mean (SD) at Baseline: Experimental (n = 18)	Mean (SD) at Baseline: Control (n = 14)	Mean (SD) at 1 Year: Experimental (n = 18)	Mean (SD) at 1 Year: Control (n = 14)	*P* Value* Baseline-1 Year	Mean (SD) at 5 Years: Experimental (n = 18)	Mean (SD) at 5 Years: Control (n = 14)	*P* Value* Baseline-5 Years
Chest pain frequency, times per week	5.8 (14.7)	1.4 (1.8)	0.5 (0.8)	4.0 (9.3)	.08	1.6 (2.7)	0.9 (1.9)	.32
C pain duration, min	3.1 (4.8)	3.2 (8.4)	1.8 (4.7)	7.6 (15.9)	.11	0.9 (1.3)	1.0 (2.7)	.93
C pain severity (1-7 scale)	1.5 (1.5)	0.6 (0.8)	0.7 (1.2)	1.4 (1.2)	<.001	0.9 (1.4)	0.6 (1.1)	.29

*All *P* levels are 2-tailed and each is a result of a test of the null hypothesis that the change between 2 particular visits (eg, baseline and 1 year) does not differ between the experimental and control groups.

the control group, fat intake decreased from 30% to 25%, cholesterol from 212.5 to 138.7 mg/d, energy from 5.49 to 3.59 J (1711-1573 cal), protein from 19% to 18%, and carbohydrates increased from 51% to 52%. Since patients volunteered originally only for a 1-year study, there was a significant decrease in meeting attendance after 1 year for 4 of the patients. Walking was the recommended form of exercise, but some patients jogged or did more strenuous exercise.

Risk Factor Changes

Patients in the experimental group lost 10.9 kg (23.9 lbs) at 1 year and sustained a weight loss of 5.8 kg (12.8 lbs) at 5 years, whereas weight in the control group changed little from baseline. In the experimental group, LDL cholesterol levels decreased by 40% at 1 year and remained 20% below baseline at 5 years. In the control group, LDL cholesterol levels decreased by 1.2% at 1 year and by 19.3% at 5 years. There were no statistically significant differences in LDL levels between the 2 groups at 5 years, primarily because 9 (60%) of 15 control patients took lipid-lowering drugs between year 1 and year 5 of the study. None of the experimental group patients took lipid-lowering drugs during the 5 years of the study. Fourteen patients in the experimental group and 11 patients in the control group took aspirin during the study.

Triglycerides did not change significantly in either group. Apolipoprotein A-I did not change in the experimental group, but it increased in the control group ($P = .04$). High-density lipoprotein levels and blood pressure did not differ between the 2 groups.

Angina Pectoris

Experimental group patients had a 91% reduction in reported frequency of angina after 1 year and a 72% reduction after 5 years (Table 5). In contrast, control group patients had a 186% increase in reported frequency of angina after 1 year and a 36% decrease in frequency after 5 years. The decrease in angina in the control group after 5 years was in large part because 3 of the 5 patients who reported an increase in anginal episodes from baseline to 1 year underwent coronary angioplasty between years 1 and 5. Because of this reduction in angina in control group patients who underwent revascularization, the between-group differences were no longer significant after 5 years (Table 5).

Angiographic Changes

All detectable lesions that matched at baseline and 5-year follow-up and were not 100% occluded at baseline were included in the analyses (n = 186). At baseline, there were no significant differences between the experimental and control groups in any measure of lesion severity (Table 3). In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement). In contrast, the average percent diameter stenosis in the control group increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening). These between-group differences were statistically significant after both 1 year and 5 years ($P = .02$ and $P = .001$, respectively, Figure 1).

Figure 2 shows the experimental group changes in percent diameter stenosis from baseline to 5 years according to tertiles of adherence to the lifestyle intervention. As seen at 1 year,[3] there was also a strong correlation between adherence and percent diameter stenosis after 5 years in a dose-response relationship; the tertile of patients that was most adherent to the program had the most regression, the tertile with intermediate adherence had less regression, and the tertile with the least adherence halted the progression of disease without regression ($P = .04$). Of interest is that this relationship was not related to age or disease severity. There was no significant relationship between adherence and lesion changes in the control group, perhaps because many of these patients began taking lipid-lowering drugs, which may have confounded the ability to detect a possible relationship. Indeed, we found significant correlations between changes in lipid levels (LDL and total cholesterol) and changes

	Mean (SEM) at 5 Years		
P Value* Baseline-1 Year	Experimental (n = 20)	Control (n = 15)	P Value* Baseline-5 Years
.004	4.87 (0.20) [188.0 (7.8)]	5.62 (0.20) [217.0 (7.9)]	.60
.003	2.99 (0.20) [115.35 (7.59)]	3.47 (0.21) [133.80 (8.25)]	.76
.35	0.90 (0.05) [34.75 (2.03)]	1.28 (0.12) [49.27 (4.47)]	.54
.17	6.11 (0.59) [236.1 (22.9)]	5.48 (0.78) [211.5 (30.2)]	.78
.11	1.302 (0.092)	1.839 (0.139)	.04
.004	1.014 (0.072)	0.991 (0.083)	.63
.96	130.0 (3.9)	123.3 (4.7)	.19
.91	76.63 (2.01)	73.61 (3.25)	.74
.001	85.64 (2.88)	77.09 (4.5)	.001

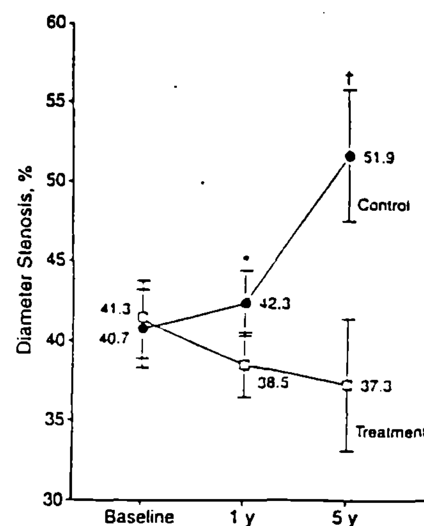

Figure 1.—Mean percentage diameter stenosis in treatment and control groups at baseline, 1 year, and 5 years. Error bars represent SEM; asterisk, $P = .02$ by between-group 2-tailed test; dagger, $P = .001$ by between-group 2-tailed test.

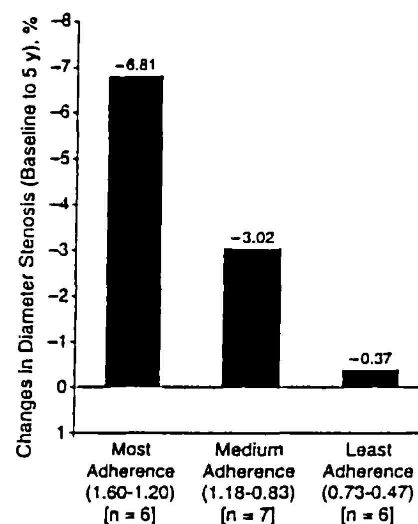

Figure 2.—Changes in percentage diameter stenosis by 5-year adherence tertiles for the experimental group.

in lesions in both groups. These correlations remained significant when examining either the lipid values at 5 years or the change in lipid values from baseline to 5 years.

As a secondary analysis, we examined the results in control group patients who began taking lipid-lowering drugs during the study. Percent diameter stenosis progressed from 45.7% to 51.7%, a change of 6.0 absolute percentage points. In the control patients who did not take lipid-lowering drugs the disease progressed from 40.7% to 59.7%, a much greater change of 19.0 absolute percentage points. (No experimental group patients took lipid-lowering drugs during the study.)

The change in body mass index from baseline to 1 year ($r = -0.85$; $P<.001$) and from baseline to 5 years ($r = -0.72$; $P = .001$) was significantly correlated with the change in percent diameter stenosis in the control group only. In other words, those who gained weight were more likely to show progression of atherosclerosis.

Cardiac Events

Data on cardiac events were obtained from all 48 patients. Cardiac events included myocardial infarction, coronary angioplasty, coronary artery bypass surgery, cardiac-related hospitalizations, and cardiac-related deaths. At 5 years, there were more cardiac events in the control group (45 events for 20 patients, or 2.25 events per patient) than the experimental group (25 events for 28 patients, or 0.89 events per patient) (Table 6). Control group patients were more likely to have undergone coronary angioplasty and bypass surgery and/or to have been hospitalized for cardiac-related problems than were experimental group patients.

COMMENT

The primary end point of this study, chosen a priori, was percent diameter stenosis. On average, there was more reduction (continued improvement) after 5 years than after 1 year in experimental group patients who were asked to make intensive lifestyle changes. In contrast, control group patients showed much more progression (continued worsening) in average percent diameter stenosis after 5 years than after 1 year, even though more than half of the control group patients were prescribed lipid-lowering medications during the course of the study. Although the sample size was relative small,[12] these differences were statistically significant at both 1 year and 5 years. These findings support the feasibility of intensive lifestyle changes in delaying, stopping, or reversing the progression of coronary artery disease in ambulatory patients over prolonged periods.

We found more than twice as many cardiac events per patient in the control group than in the experimental group. These findings are consistent with other clinical trials showing that even small changes in percent diameter stenosis are often accompanied by marked reductions in cardiac events.[13-16] Other studies have demonstrated how quickly the coronary artery endothelium stabilizes in response to lipid-lowering drugs.[17,18]

Although there was some reduction in adherence to the intensive lifestyle intervention between years 1 and 5 in the experimental group, long-term adherence remained remarkably high in this sample of self-selected patients. The level of lifestyle change, even at 5 years, is greater than in any other published study of ambulatory populations. These results are especially encouraging because these patients initially volunteered to participate for only 1 year when they entered the study.

The experimental group reduced LDL cholesterol levels by 40% at 1 year and by 20% after 5 years; these reductions are comparable with those achieved with lipid-lowering drugs in an ambulatory population.[19] In contrast, the Step II diet reduces LDL cholesterol by only 5% or less.[20,21]

High-density lipoprotein levels decreased and triglycerides increased in experimental group patients overall, although the ratio of LDL to HDL was improved. Recent reports assert that this phenomenon, which is often seen in very low-fat diets, may be harmful.[22,23] However, patients in the Lifestyle Heart Trial showed even more regression of coronary atherosclerosis after 5 years than after 1 year as well as significantly decreased cardiac events. Low

Table 6.—Cardiac Events During 5-Year Follow-up

	No. of Events				
	Experimental* (n = 28)	Control† (n = 20)	Risk Ratio	95% Confidence Interval	P Value
Myocardial infarction	2	4	2.74	0.393-30.3	.26
Percutaneous transluminal coronary angioplasty	8	14	2.40	0.939-6.60	<.05
Coronary artery bypass graft	2	5	3.43	0.561-36.0	.14
Cardiac hospitalizations‡	23	44	2.62	1.55-4.55	<.001
Deaths	2	1	0.685	0.012-13.2	.81
Any event	25	45	2.47	1.48-4.20	<.001

*Person-years of observation was 108.04.
†Person-years of observation was 78.81.
‡Includes myocardial infarction, percutaneous transluminal coronary angioplasty, and coronary artery bypass graft.

HDL cholesterol levels due to reduced fat intake are the result of a decreased transport rate rather than the increased catabolism that is responsible for most cases of low HDL cholesterol levels in persons consuming a typical Western diet.[24] Populations consuming low-fat, plant-based diets have low HDL cholesterol levels and low rates of coronary heart disease. Our data provide evidence using quantitative coronary arteriography in this population that diet-induced lowering of HDL cholesterol does not confer the same risk of atherosclerosis as do low HDL cholesterol levels in Americans consuming a high-fat diet.[25] Experimental group patients whose triglycerides increased during the first year were asked to minimize their intake of simple carbohydrates, and triglyceride levels decreased between year 1 and year 5.

The experimental group's marked reduction in frequency, severity, and duration of angina after 1 year was sustained at similar levels after 5 years. This long-term reduction in angina is comparable with that achieved following coronary artery bypass surgery or angioplasty and helps to maintain long-term adherence.[26] Between-group differences in most measures of chest pain were not statistically significant after 5 years because there was a large variability in angina and control group patients who were the most symptomatic underwent revascularization.

When we began this study, we believed that the younger patients with milder disease would be more likely to show regression, but we did not find this to be true. Instead, we found that the primary determinant of change in percent diameter stenosis in the experimental group was neither age nor disease severity but adherence to the recommended changes in diet and lifestyle. This relationship of adherence to percent diameter stenosis in the experimental group was found after 1 year[3] and also after 5 years in a dose-response relationship. Coronary artery minimum diameter remained stable in the experimental group but markedly narrowed in the control group during the 5 years of the study. At 5 years, the differences between the experimental and control groups were statistically significant for both percent diameter stenosis and minimum diameter, even though control group patients reported risk reduction behavior consistent with a Step II diet of the National Cholesterol Education Program and the American Heart Association: they consumed an average of 25% of energy (calories) from fat and exercised an average of 3.5 times per week. These data are consistent with other studies indicating that moderate changes in diet and lifestyle may not be sufficient to stop the progression of coronary atherosclerosis unless combined with lipid-lowering drugs.[27]

After 5 years, the normal diameter (the segment of least narrowing proximal to the minimum diameter) decreased slightly in the experimental group but widened slightly in the control group. A slight decrease in normal diameter, at least up to a point, may improve myocardial perfusion by streamlining flow—decreasing the forward flow losses that occur when going from a larger to a sharply reduced lumen diameter.[4] Conversely, the slight increase in the normal diameter and reduction in the minimum diameter seen in control group patients increased the entry angle, further reducing blood flow. These theoretical considerations are consistent with the substantially increased myocardial perfusion in the experimental group and decreased myocardial perfusion in the control group that we measured using cardiac positron emission tomography scans.[5]

A much earlier study by Morrison[28] found that moderate reductions in fat and cholesterol intake improved cardiac survival: after 12 years, all of the control group patients had died compared with only 62% of experimental group patients in a nonrandomized trial. More recently, an important study by Esselstyn et al[29] reported that a similar diet plus lipid-lowering drugs in 11 patients caused regression of 11 lesions and stabilization in the remaining 14 lesions after 5.5 years. Although there was no control group, those who were adherent to the diet reported substantially fewer cardiac events than those who were not adherent.[29]

Like all clinical trials, our study has limitations. Although the study participants were a diverse group, they may not be representative of the general population of patients with coronary heart disease. Half of the patients who underwent quantitative coronary arteriography in the participatory hospitals did not meet all of the inclusion and exclusion criteria and were not invited to participate in the study. Also, half of the patients who were invited declined to enroll in the study. Nevertheless, it is encouraging that 50% of the patients who were contacted agreed to volunteer despite the requirement for repeated arteriography and that experimental group patients were able to make and maintain comprehensive lifestyle changes. The angiographic measures lost to follow-up may have affected the treatment and control groups differently, although there are no data to suggest that this occurred. In addition, there is a possibility of differential loss of lesions in patients, although no evidence indicates that this occurred; in both groups, there were 14 lesions that were lost to follow-up. Also, 4 lesions were lost in the control group to bypass surgery or angioplasty; since these lesions were worsening sufficiently to require revascularization, the exclusion of these lesions from analysis would make between-group differences more difficult to detect. We recently completed a multicenter demonstration project to assess the practicality and cost-effectiveness of this intervention in a larger sample of economically and geographically diverse patients with coronary heart disease.[30]

Although we did not use lipid-lowering drugs in the experimental group, their value has been demonstrated in studies that have been published since the Lifestyle Heart Trial began. We do not know if experimental group patients may have demonstrated even more improvement by including lipid-lowering drugs.[14-16] Patients in the control group who were not prescribed lipid-lowering drugs during the study showed more than 3 times as much progression in percent diameter stenosis as those who were. No experimental group patients took lipid-lowering drugs during the study, yet they showed better results than control group patients who were taking these drugs. Lipid-lowering drugs are expensive, compli-

ance is difficult to achieve,[31] and long-term safety is unknown.[32] In practice, patients may be offered a range of therapeutic options, including comprehensive lifestyle changes, lipid-lowering drug therapy, and revascularization, either separately or in combination.

In summary, these ambulatory patients were able to make and maintain comprehensive changes in diet and lifestyle for 5 years and showed even more regression of coronary atherosclerosis after 5 years than after 1 year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after 5 years than after 1 year, and had more than twice as many cardiac events as patients making comprehensive lifestyle changes.

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A Symposium: Summit on Cholesterol and Coronary Disease

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Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project

Dean Ornish, MD, for the Multicenter Lifestyle Demonstration Project Research Group

The Multicenter Lifestyle Demonstration Project was designed to determine if comprehensive lifestyle changes can be a direct alternative to revascularization for selected patients without increasing cardiac events. A total of 333 patients completed this demonstration project (194 in the experimental group and 139 in the control group). We found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality. These patients reported reductions in angina comparable with what can be achieved with revascularization. ©1998 by Excerpta Medica, Inc.

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The idea that the progression of coronary artery disease is often reversible was once a radical concept but now has become mainstream, as these proceedings clearly demonstrate. A number of interventions have been shown to arrest or reverse the progression of coronary atherosclerosis, many of which have been detailed in this symposium. These include comprehensive changes in diet and lifestyle,[1–3] lipid-lowering drug therapy,[4–6] partial ileal bypass surgery,[7] and parenteral nutrition.[8]

Approximately 500,000 coronary artery bypass graft (CABG) operations and approximately 600,000 percutaneous transluminal coronary angioplasties (PTCAs) were performed in the United States in 1994 at a combined cost of approximately $15.6 billion, more than for any other surgical procedure. The cost of treatment of coronary artery disease (CAD) in the United States was estimated to be $56.3 billion in 1994.[9] Thus, there is a potential for significant cost savings if safe and comparably effective, but less expensive, alternative interventions can be implemented.

The Multicenter Lifestyle Demonstration Project was designed to determine (1) if we could train other teams of health professionals in diverse regions of the country to motivate their patients to follow a program of comprehensive lifestyle changes; (2) if this lifestyle program may be an equivalently safe and medically effective but more cost-effective alternative to revascularization in selected patients with severe but stable coronary artery disease; and (3) what the resulting cost savings might be. In other words, can patients avoid revascularization by making comprehensive lifestyle changes at lower cost without increasing cardiac morbidity and mortality?

Earlier studies demonstrated that the progression of even severe coronary artery disease often can begin to reverse in many patients by an intensive, multifactorial program of comprehensive lifestyle changes. These lifestyle changes include a very low-fat, low-cholesterol diet (approximately 10% fat, <10 mg/day dietary cholesterol, a whole-foods vegetarian diet high in complex carbohydrates and low in simple sugars), stress management techniques, moderate exercise, and psychosocial support. Endpoint measures included quantitative coronary arteriography to assess coronary artery stenosis and cardiac positron emission tomography to assess myocardial perfusion.[2,10]

In the past, insurance companies, managed care organizations, and Medicare have been reluctant to pay for lifestyle interventions, in part because these have been viewed as prevention—increasing costs in the short run for a possible savings years later. Also, since approximately 20–30% of patients change their insurance plans each year, even if cost savings result from lifestyle interventions, they may accrue to another insurance company.

However, a program of comprehensive lifestyle changes may be offered as a much less costly alternative treatment to revascularization for selected patients who are eligible for CABG or PTCA (under the supervision of the referring physician), thereby resulting in immediate and substantial cost savings.

Also, providing lifestyle changes as a direct alternative for patients who otherwise would receive CABG or PTCA may result in significant long-term cost savings. Despite the expense of bypass surgery and angioplasty, 30–50% of bypass grafts reocclude after only 5–7 years, and 30–50% of angioplastied arteries restenose after only 4–6 months.[11,12] When this occurs, then bypass surgery or angioplasty is often repeated, thereby incurring additional costs.

CABG is effective in decreasing angina and improving cardiac function. However, when compared with medical therapy and 16 years of follow-up, CABG improved survival only in a very small subgroup of patients: those with decreased left ventricular function and stenotic lesions of the left main coronary artery of >59%. Median survival was not prolonged in patients with left main coronary artery stenosis <60% and normal left ventricular function, even if a significant right coronary artery stenosis >70% was also present.[13–16]

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PTCA was developed with the hope of providing a less invasive, lower-risk approach to the management of coronary artery disease and its symptoms. Although widely utilized, PTCA has never been compared with medical therapy in a randomized trial in stable patients with coronary artery disease; therefore, the mortality and morbidity benefits of PTCA are unknown.

The use of various types of stents (the insertion of a mesh brace into the lumen of the coronary artery during angioplasty) may slow the rate of restenosis, but there are no randomized controlled trial data supporting the efficacy of these approaches. The use of the left internal mammary artery in bypass surgery may reduce reocclusion, but vein grafts also must be used when patients have multivessel disease. Thus, in addition to the costs of the original bypass or angioplasty, there are costs of further procedures when restenosis and reocclusion occur.

The majority of adverse events related to coronary artery disease, myocardial infarction, sudden death, and unstable angina are due to the rupture of an atherosclerotic plaque of <40–50% stenosis. This often occurs in the setting of vessel spasm and results in thrombosis and occlusion of the vessel.[17] CABG and PTCA usually are not performed on lesions <50% stenosed and do not affect nonbypassed or nondilated lesions, whereas comprehensive lifestyle changes (or lipid-lowering drugs) may help stabilize all lesions, including mild lesions (<50% stenosis). Also, mild lesions that undergo catastrophic progression usually have a less well-developed network of collateral circulation to protect the myocardium than do more severe stenoses.

Bypass surgery and angioplasty have risks of morbidity and mortality associated with them, whereas there are no significant risks from eating a well-balanced low-fat, low-cholesterol diet, stopping smoking, or engaging in moderate walking, stress management techniques, and psychosocial support.

ASSESSING COSTS OF LIFESTYLE CHANGE

Thousands of dollars are saved immediately for every CABG candidate who can avoid the procedure by making intensive changes in diet and lifestyle. However, cost savings in avoided revascularization will occur only if patients who are trained in this lifestyle program adhere to it over time. If patients do not adhere, costs would increase rather than decrease because insurers would end up paying for both lifestyle training and subsequent revascularization. The missing link, therefore, are the data to demonstrate whether patients will adhere to this intensive lifestyle program. We wanted to determine whether patients who are motivated to make comprehensive lifestyle changes can maintain these changes in an ambulatory setting if given the proper support.

To address this question, we began the Multicenter Lifestyle Demonstration Project in 1993 at 8 sites. Also, we have trained practitioners at.0001 additional sites whose data are not included here. These sites are geographically, socioeconomically, racially, and culturally diverse. Approximately 40 insurance companies are now reimbursing at least part of the cost of this program at these sites for selected patients.

We trained teams of health professionals at each of these clinical sites, including cardiologists, registered dietitians, exercise physiologists, psychologists, chefs, stress management specialists, registered nurses, and administrative support personnel. These teams, in turn, worked with their patients to motivate them to make and maintain comprehensive lifestyle changes.

Patients were selected who had angiographically documented coronary artery disease severe enough to warrant revascularization and who were approved for insurance indemnity to undergo a procedural intervention.

In addition, patients were excluded for any of the following: (1) >50% stenosis in the left main coronary artery; (2) CABG within 6 weeks or angioplasty within 6 months; (3) chronic unresponsive congestive heart failure; (4) malignant uncontrolled arrhythmias; (5) myocardial infarction within 1 month; (6) homozygous hypercholesterolemia; (7) psychosis; (8) hypotensive response to exercise; (9) alcohol or drug abuse; and (10) life-threatening comorbidity.

Patients and staff met 3 times per week for 12 weeks plus once per week for the remaining 9 months. Most sessions were 4 hours long: 1 hour of exercise, 1 hour of stress management techniques, 1 hour of group support, and a 1-hour meal. The cost of the 1-year program averaged $7,000 per person. (Shorter and less-expensive versions of the program are now available for people with less severe coronary artery disease.)

All hospitals sent data directly to the independently funded data coordinating center at the Massachusetts General Hospital. Matched control-group patients were provided by Mutual of Omaha. Patients were matched for age, gender, left ventricular ejection fraction (<25%, 25–40%, or >40%), and cardiac score defined as the sum of the severity score for each of the 3 main coronary arteries rated as 0 (<50% stenosis), 0.5 (50–75% stenosis), or 1.0 (>75% stenosis). All control group patients were within 1 month of having undergone revascularization.

Although a randomized controlled trial intervention comparing comprehensive lifestyle changes with revascularization may seem ideal, it is not feasible in practice. The attitude of someone willing to make comprehensive lifestyle changes is often quite different from that of someone who wants to undergo revascularization. The decision to make comprehensive lifestyle changes requires commitment, discipline, and a willingness to assume personal responsibility for one's health. The decision to undergo revascularization is often made by patients who want the doctor to "fix" them—the other end of the personal responsibility spectrum. This is not a value judgment, only a reflection of different approaches, both of which may be valid. To be randomized, a patient has to be willing to undergo either treatment (revascularization or comprehensive lifestyle changes). Since the mindset is so different, it would be very difficult to find patients

who were willing to accept either choice determined by someone else; most patients want to choose one or the other for themselves.

Baseline demographics: A total of 333 patients completed this demonstration project. Of these, 194 were in the experimental group and 139 were in the control group.

At baseline, there were no significant differences between the experimental group and control group in age, gender, marital status, employment status, or history of hypertension, hypercholesterolemia, diabetes, smoking, or family history of heart disease. In the experimental group, the average age was 58 years, 79% were male, and 77% were married. Of particular note is that 63.5% of these patients were currently working yet were able to find time to adhere to the intervention of comprehensive lifestyle changes. Furthermore, 50% were hypertensive, 62% had hyperlipidemia, 19.6% had diabetes, 66% had smoked cigarettes, and 58% had a family history of heart disease. Finally, 54% of the experimental group patients and 32% of control group patients were taking lipid-lowering drugs.

Angiographic severity of coronary artery disease was comparable in both groups. However, 55% of experimental group patients had a prior myocardial infarction compared with only 28% in the control group; also, experimental group patients had a longer history of coronary artery disease than those in the experimental group. Taken together, these factors may bias toward higher morbidity for the experimental group than the control group during the demonstration project.

Adherence and changes in risk factors: These adherence data, changes in risk factors, and a more detailed description of the demonstration project will be described in greater detail in a forthcoming article. Not all patients completed adherence questionnaires; the validity of our adherence data depends on the assumption that the patients who did not provide follow-up data had the same adherence as those who did. If patients who had low adherence were more likely to avoid follow-up, then the adherence rates that we estimated would be overly optimistic.

RESULTS

In brief, patients exercised an average of 1.6 hours/week at baseline, increasing to 3.9, 3.5, 2.9, and 2.7 hours/week at 3 months, 1 year, 2 years, and 3 years, respectively. Patients practiced stress management techniques an average of 0.19 hours/week at baseline and 4.5, 2.6, and 2.0 hours/week at 1 year, 2 years, and 3 years, respectively.

Based on the results of 3-day diet diaries, the percentage of total calories as dietary fat was 6.5%, 6.8%, 7.4%, and 8.3% after 3 months, 1 year, 2 years, and 3 years. The cholesterol intakes for these 4 time periods were 14.1, 19.0, 22.7, and 25.7 mg/day.

Low-density lipoprotein (LDL) cholesterol levels decreased from a mean of 122.9 mg/dL at baseline to 106.1 mg/dL after 3 months ($p <0.0001$), 104.2 mg/dL after 1 year ($p <0.0001$), 107.5 mg/dL after 2 years ($p <0.0001$), and 101.7 mg/dL after 3 years ($p <0.0001$). Total cholesterol decreased from a mean of 202.0 mg/dL at baseline to 183.7 mg/dL after 3 months ($p <0.0001$), 182.6 mg/dL after 1 year ($p <0.0001$), 187.3 mg/dL after 2 years ($p <0.0001$), and 183.4 mg/dL after 3 years ($p <0.0001$). Thus, reductions in LDL and total cholesterol levels were maintained throughout the 3-year interval, although the lifestyle intervention was only 1 year long.

High-density lipoprotein (HDL) cholesterol levels initially decreased from 36.7 mg/dL to 32.8 mg/dL after 3 months ($p <0.0001$) and to 36.1 mg/dL after 1 year ($p = 0.120$) but increased to 40.1 mg/dL after 2 years ($p <0.005$) and increased to 42.2 mg/dL after 3 years ($p = 0.001$). Triglycerides initially increased nonsignificantly from 229.8 mg/dL to 235.7 after 3 months ($p = 0.494$), but stabilized after 1 year to 228.8 ($p = 0.946$) to 213.0 ($p = 0.607$) to 200.8 after 3 years ($p = 0.339$). These changes in HDL-cholesterol and triglyceride levels are particularly relevant in light of recent controversies in this area.[18]

Mean weight decreased from 187.3 lb at baseline to 178.0 lb after 3 months ($p <0.0001$), to 177.0 lb after 1 year ($p <0.0001$), to 176.6 after 2 years ($p <0.0001$), to 179.9 lb after 3 years ($p = 0.007$). Long-term reductions in weight are unusual.[19] Percent body fat decreased from 25.7% at baseline to 22.9% after 3 months ($p <0.0001$), to 21.3% after 1 year ($p <0.0001$), to 22.4% after 2 years ($p <0.0001$), to 23.4% after 3 years ($p = 0.134$).

Exercise capacity increased from 9.59 METS at baseline to 11.15 after 3 months ($p <0.0001$), to 11.66 after 1 year ($p <0.0001$), to 10.88 after 2 years ($p <0.0001$), to 11.03 after 3 years ($p <0.0001$).

CAN PATIENTS SAFELY AVOID REVASCULARIZATION?

We found that 150/194 of experimental-group patients were able to avoid revascularization and the frequency of adverse cardiac events was not increased. The number of cardiac events per patient-year of follow-up when comparing the experimental group with the control group was as follows: 0.012 versus 0.012 for myocardial infarction (p = not significant), 0.014 versus 0.006 for stroke (p = not significant), 0.006 versus 0.012 for noncardiac deaths (p = not significant), and 0.014 versus 0.012 for cardiac deaths (p = not significant).

As described above, a primary benefit of revascularization is reduction of angina. In the Multicenter Lifestyle Demonstration Project, we used a very conservative measure of angina: no angina at all in during the prior 30 days. For example, if a patient who had frequent angina at baseline—as many as 10 episodes per day—had even 1 episode in the prior 30 days, then the patient was still considered to have angina.

Of the experimental group patients who reported angina at baseline, 49% had no chest pain during the prior 30 days after 3 months, 65% had no chest pain during the prior 30 days after 1 year, 61% had no chest pain during the prior 30 days after 2 years, and 61% had no chest pain during the prior 30 days after 3

years. These reductions in angina are comparable with what can be achieved with revascularization but without the morbidity and costs.

As noted above, the average cost of the 1-year intensive lifestyle intervention was $7,000. The average cost for PTCA (with cardiac catheterization) was $31,000 and for CABG was $46,000. All of the experimental group patients were eligible for revascularization both by medical criteria and by reimbursement criteria from Mutual of Omaha. However, only 31 PTCAs were performed on the 194 experimental group patients (0.064 events per patient-year of follow-up) and 26 CABGs were performed on the 194 experimental group patients (0.053 events per patient-year of follow-up) after entry. Thus, the costs in the experimental group were: (31 × $31,000) + (26 × $46,000) + (194 × $7,000) = $3,515,000, or an average cost of $18,119/patient.

All of the 139 control group patients were selected for having had a recent PTCA or CABG before entry: 66 underwent PTCA, and 73 underwent CABG. In addition, there were 23 PTCAs and 11 additional CABGs in the control group after entry. Thus, the costs in the control group were: (66 × $31,000) + (23 × $31,000) + (73 × $46,000) + (11 × $46,000) = $6,623,000, or an average cost of $47,647/patient.

The average savings per patient, therefore, were: $47,647 − $18,119 = $29,529. This number is a conservative estimate, since 8 experimental group patients who had a PTCA after enrolling had ≥1 additional PTCAs or CABGs during the study. Restenosis within 6 months following PTCA is a failure of the angioplasty rather than intensive lifestyle changes, yet we counted all procedures in this cost analysis, even PTCAs occurring within 6 months after a prior PTCA.

There is no way to know with certainty how many of the patients who were eligible for revascularization actually would have undergone revascularization in the absence of the lifestyle program. Whether or not a patient undergoes revascularization is a function of many factors, including disease severity, patterns of practice in the local community, individual preferences among cardiologists and cardiac surgeons, and method of reimbursement. Revascularization rates tend to be much higher when reimbursed on a fee-for-service basis than on a capitated basis. One of the sites in our demonstration project, for example, performed more angioplasties (17) than the other 7 hospital sites combined (14).

Given the large cost differential between the cost of revascularization and the cost of the year-long lifestyle intervention program, it would have been cost-effective to offer comprehensive lifestyle changes even if only 18% of patients who were eligible for revascularization actually would have had it in the absence of this program.

In practice, we believe that patients with coronary artery disease should be offered a range of therapeutic options, including comprehensive lifestyle changes, medications (including lipid-lowering drugs), angioplasty, and bypass surgery. The physician should explain the relative risks, benefits, costs, and side effects of each approach and then support whatever the patient decides.[20] At this time, however, most third-party payers will cover most of the costs of drug therapy and revascularization but not the costs of training patients in a program of comprehensive lifestyle changes. Approximately 40 insurance companies are covering this lifestyle program in the sites we have trained, but this is still a relatively small number.

Comprehensive lifestyle changes are not for everyone. We do not know how many patients with coronary artery disease in the United States would be interested in choosing to make comprehensive lifestyle changes rather than undergo revascularization. In practice, however, the primary limiting factor has been the lack of widespread insurance coverage rather than a shortage of motivated patients.

This is a particularly rewarding and emotionally fulfilling way to practice medicine, both for patients and the physicians and other healthcare professionals who work with them. Much more time is available to spend with patients addressing the underlying lifestyle factors that influence the progression of coronary artery disease, yet costs are substantially lower. Patients usually show rapid decreases in angina and often report other improvements within weeks; these rapid improvements in well-being sustain motivation and help to explain the high levels of adherence in these patients. The major reason that most stable patients undergo CABG or PTCA is to decrease the frequency of angina, and comparable results may be obtained by making comprehensive lifestyle changes alone. Instead of pressuring physicians to see more patients in less time, this is a different approach that is caring and compassionate as well as cost-effective and competent.

CONCLUSION

In summary, in the Multicenter Lifestyle Demonstration Project, we found that experimental group patients were able to avoid revascularization for at least 3 years by making comprehensive lifestyle changes at substantially lower cost without increasing cardiac morbidity and mortality.

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APPENDIX

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