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THE STANFORD HEART DISEASE PREVENTION PROGRAM

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This afternoon I want to tell you about the results of a major study we have been doing as a part of the Stanford Heart Disease Prevention Program. The Stanford Heart Disease Prevention Program is an interdisciplinary project directed by Dr. John W. Farguhar, Professor of Medicine at Stanford University and I am co-director. This paper was really co-authored by fifteen people as part of an interdisciplinary team. With a group of different people like this, we had to spend a significant amount of time trying to teach each other our respective professional languages. Initially, communication within our group was a terrible problem. We have worked through this stage and now we have, among other things, a post doctoral training program in which both young M.D.'s or young Ph.D.'s can become involved in cardiovascular work in its various aspects. This project has a psychlogical component, a pathological component, a biochemical component, a behavioral component and a communications component. This afternoon I want to talk about our major community study.

The gradual rise in age-adjusted cardiovascular disease mortality in industrialized countries has considerably diminished what would otherwise be seen as striking gains in health in the last 75 years. These gains, due primarily to increased and improved practices in modern medicine, have occurred mainly in the prevention of infant and early childhood mortality and in the improvement in crisis intervention techniques after the onset of disease symptoms. Unfortunately, much cardiovascular disease is apparently unresponsive to

anything but pre-crisis preventive intervention. The U.S. male who has survived to age 45 now has only a slightly greater life expectancy than did his forebear in 1900. Table I shows comparative rates of coronary heart disease, treating the U.S. rate as base 100. That is not the actual figure but shows, by comparison, for example, that Japan and Greece and Yugoslavia have considerably lower rates and that only Finland is worse off than we are.

TABLE I

Coronary Heart Disease in Other Countries as % of U. S. Rate

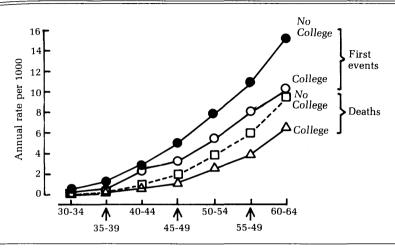
1. Japan	10%
2. Greece	18%
3. Yugoslavia	30%
4. Italy	56%
5. Netherlands	79%
6. U.S.A.	100%
7. Finland	112%

The Japanese, incidently, when they are tested in Hawaii have a higher rate than in Japan and when they are tested in California have a rate almost like ours. This seems to indicate that although genetic factors may play a very important role in the etiology of coronary heart disease, environmental factors also play a very substantial role. Changes in life style in industrialized countries, coupled with a lack of pre-symptomatic preventive medicine have resulted in what can only be described as an epidemic prevalence of cardiovascular disease, principally coronary heart disease and stroke. Three quarters of the annual deaths which occur in the United States before age of 65 are attributable to coronary heart disease alone. The associated costs of medical treatment and lost human productivity are, of course, immense. One of the common misbeliefs about coronary heart disease is that it is something which characterizes well-educated people — the highstrung business executive who undergoes a lot of stress. Stress may play a very important role, but it is not limited to people who are business executives.

You can see in Figure I that the less educated are in no way protected. As in the case with many chronic illnesses which occur in modern society, a number of complex behavioral and environmental factors are implicated in the etiology of cardiovascular disease.

FIGURE I

Incidence of Disabling Coronary Heart Disease ("first events") and Deaths Among Men in the Bell System, 1963–1965, by Age (abscissa) and Education.



Epidemiological studies clearly establish cigarette smoking, high levels of plasma cholesterol and high blood pressure as the principal risk factors in premature cardiovascular disease. These risk factors must be addressed prior to the onset of symptoms if morbidity and mortality are to be reduced. Although there is a genetic component to high plasma cholesterol levels and high blood pressure, both are also strongly influenced by relative body weight and by other variables affected by the environment. It is also clear that these risk factors occur in a broad range of society including the so-called normal range of society, and that behavioral and environmental factors like diet, physical activity, and maladaptive responses to peceived stress of harmful emotional lifestyles are important in determining the level of these risk factors.

We are participating in one such epidemiological study testing whether reduced cholesterol can produce cardiovascular morbidity and mortality. Regardless of the outcome of these clinical trials, previous worldwide epidemiological studies strongly suggest that morbidity and mortality can be readily lowered if risk factors are controlled for long periods.

In view of the exceedingly high cost to society of the epidemic of cardiovascular disease, prudence dictates the urgency of developing efficient methods of teaching large groups of people about risk factors and how they can be reduced. It is our belief that this task can best be done in natural communities. The choice of the family and a

community centered approach—the Community Model—rather than the clinic and physician's office—the Medical Center Model—for the development of new, potentially cost effective, risk reduction strategies stems from three major considerations: (1) There is ample evidence that prior attempts using the Medical Center Model are typically ineffective in overcoming client resistance to change and in preventing rapid returns to the status quo in the areas of exercise habits, smoking cessation, and in weight reduction, despite the use of highly motivated volunteers in such studies. (2) The Community Model provides for the interpersonal and mediated diffusion of information and for a consensus of support for preventive practices more effectively than does a Medical Center Model because information and directions about appropriate behavior become part of the natural environment. (3) The Community Model includes the use of mass media, the reduction in the need for individual instruction and a reliance on a greater proportion of non-medical personnel, all of which suggest considerably greater potential cost effectiveness than that afforded by the Medical Center Model.

In 1972, our group (researchers in the School of Medicine and the Institute for Communication Research at Stanford) began a field experiment in three northern California communities in order to study modification of cardiovascular risk factors through the Community Education Model. Little was then known regarding the effectiveness of this approach in influencing risk related behavior. The major tactical choices for a campaign based on the Community Model are mass-media, face-to-face instruction, or varying combinations of the two. A study of previous mass media campaigns directed at large open populations has established the potential effectiveness of the media in transmitting information and altering some attitudes, and in producing small shifts in behavior such as choices among consumer products. However, it has failed to demonstrate that media alone substantially influence more complex behavior.

The habits influencing cardiovascular risk factors are very complex and of long standing. They are often reinforced by culture, custom, and costly commercial advertising, and are unlikely to be very strongly influenced by mass media alone. Face-to-face instruction and exhortation also have a long history of failure, particularly with respect to recidivism in efforts to influence diet and smoking. Jean Mayer, the distinguished former professor of nutrition of Harvard (now President of Tufts) has described weight reduction as practicing the rhythm method of girth control, which I think points to the problem very succinctly.

After considering the powerful cultural forces which reinforce and maintain the health habits that we wished to change, and in view of past failure of health education campaigns, we designed our initial test of the Community Education Model to include a heretofore untested combination of extensive mass media plus a considerable amount of face-to-face instruction. Other segments of the population were administered treatments via mass media alone. We also chose to include three elements typically ignored in health campaigns: (1) The mass media materials were devised to teach specific behavioral skills as well as to perform the more usual task of offering information and affecting attitudes, and motivation. (Incidentally. we developed our own mass media—in our Department of Communication where we train people to produce film, television, radio and print. We used our own alumni and our own people in conducting formative evaluation to test our materials as we developed them instead of turning the task over to outsiders:) (2) Both the mass media, and in particular the face-to-face instruction protocols, were designed to embody many previously validated methods of achieving changes in behavior and self-control training principles and; (3) The campaign was designed on the basis of careful analysis of the specific needs and the media consumption patterns of the intended audience. Our overall goals were to create and evaluate methods for achieving changes in smoking, exercise, and diet that were both cost effective and applicable to large population groups.

Since our media campaigns were directed at entire communities. random assignment of individuals to treatment or control conditions was not feasible. A rigorous experimental model treating a large number of entire geographically defined populations as single units and randomly assigning them to treatment or control conditions was prohibitively expensive. Thus we concluded that the most realistic compromise between feasibility and rigor is a quasi-experimental research approach on a small number of experimental units. Three roughly comparable communities in northern California were selected. Tracy was selected as a control community because it was relatively distant and isolated from media. The other two communities, Gilroy and Watsonville, share some media channels television and radio, but each town has its own newspaper, Gilrov and Watsonville received different strategies of health education over a period of two years. Gilroy received mass media alone. Watsonville received the same mass media treatment combined with intensive face-to-face instruction for a subset of the sample identified as having higher risks of cardiovascular disease than the remaining members of the sample. In Watsonville, we were able to use random assignments to create a true experimental high risk control group of participants receiving media education only.

To assess the effects of these interventions, we gathered baseline and yearly follow-up data from surveys comprised of interviews and medical examinations of a random sample of thirty five 59-year-old men and women in each of the three communities following the sequence presented in Table II.

TABLE IIStudy Design and Timetable

	1972 Sep Dec.	1973 Jan Apr. May - Aug	g. Sep Dec.	1974 Jan Apr. May - Aug	g. Sep Dec.
Watsonville (W)	Initial survey (S-1)	Media campaign (C-1) Intensive instruction for high-risk subjects	Second survey (S-2)	Media campaign (C-2) Intensive instruction for high-risk subjects	Third survey (S-3)
Gilroy (G)	Initial survey (S-1)	Media campaign (C-1)	Second survey (S-2)	Media campaign (C-2)	Third survey (S-3)
Tracy (T)	Initial survey (S-1)		Second survey (S-2)		Third survey (S-3)

We went into the field and took our baseline measures in the fall of 1972 in the three communities, then put our media campaigns into effect in the two communities from January to December. We took a second survey exactly a year later, then presented a modified media campaign the second year. We also worked again with the high risk people, and took a fourth survey at the end of the third year. I do not have the results of this yet. I can, however, report the results from the first two years.

We have data on response rates and that is a serious problem, although we did exceptionally well. Our annual interviews in three communities were designed to measure both knowledge of coronary disease and individual behavior related to cardiovascular risk. The assessment covered the following variables: knowledge of risk factors (a test of knowledge about dietary and other risk factors associated with coronary heart diseases based on 25 multiple choice items), eating habits (a survey of eating habits which allowed us to estimate daily intake of cholesterol, saturated fats, sugar, and alcohol), smoking behavior (a self-reported smoking rate), and physiologic data, (gathered at the baseline and one or two intervals at which the interviews were conducted). Each examination yielded values of plasma cholesterol and triglyceride concentration, systolic and diastolic blood pressure, weight, and other physiologic variables.

Data were gathered in a survey center in each of the three communities, and results were sent to participants and their named physicians. Overall risk of coronary heart disease in each of the participants was estimated from a multiple logistic function of risk factors predicting the probability of developing coronary heart disease within twelve years according to the person's age, sex, plasma cholesterol concentration, systolic blood pressure, relative weight, smoking rate and electrocardiographic findings. This calculation, which was a modified Cornfield risk score as used in the Framingham study, allowed us to identify the high risk study groups described above and to monitor the estimated risk of coronary heart disease in participants in all study groups over the three years of research reported here.

The design also involved development and application of the mass media and face-to-face instruction campaigns. These communication efforts were designed to overcome deficiencies in previous unsuccessful campaigns to change behavior. Each campaign was intended to produce awareness of the probable causes of coronary heart disease and the specific behaviors which may reduce risk. The campaigns also aimed at providing the knowledge and skills necessary to accomplish the recommended behavior changes. Lastly, they attempted to have individuals become self-sufficient in the maintenance of these newly acquired health habits and skills. Dietary habits recommended for all participants were those, which if followed, would lead to a reduction in saturated fats, cholesterol, salt, sugar, and alcohol intake. We also encouraged reduction in body weight through caloric reduction and increased physical activity. Cigarette smokers were asked to stop smoking or at least to reduce their daily rate of cigarette consumption.

In the mass media campaign a coordinated set of messages was prepared to be appropriate to the lay audiences of Gilroy and Watsonville. Over time, these basic messages were transformed into a variety of media — TV spots, bus cards, radio materials, print materials, posters, school kits, monographs, books, pamphlets—released to the target audiences through a variety of the most generally available media channels. A broad range of materials was produced. During the first year we produced about 50 television spots, three hours of television programming, over a hundred radio spots, several hours of radio programming, weekly newspaper columns, newspaper advertising and stories. Billboards were also used. Printed materials were sent by direct mail to sample members. Posters and other assorted materials were also used. The media campaign began two months after the initial survey and continued for nine months in 1973, stopped during the second survey, then continued for nine more months in 1974. Given a sizable Spanishspeaking population (roughly 20 percent in each community), the

campaign was presented in both Spanish and English. Incidentally, the Spanish campaign was not a direct or literal translation of the English campaign. It was specifically designed in terms of what we knew about the cultural aspects of the Spanish speaking community. For example, we used a 5 - 7 minute radio soap opera in Spanish, but not in English.

The dominant characteristic of the mass media campaign structure was its organization as a totally integrated information system such that its primary function was to create a transformation of the medical risk reduction message into media events. The formative evaluation of those events, their distribution in coordinated packages over time, and their cumulative effectiveness in promoting change could all interact to improve and refine decisions in how best to allocate remaining available resources. The management of the system input was by a process of continuous monitoring of the target audience's existing knowledge, beliefs, attitudes, and risk-related behavior and their media use. Decisions concerning the onset of the campaign were based primarily on data gathered at the initial survey. When the campaign was underway, further guidance was obtained from the second annual survey, and a series of systematic but informal information gathering efforts were designed to provide media planners with a medium of feedback on the public's awareness and acceptance of some particular set of media events, as well as to gauge progress to date. We called these media snoops. Thus the total campaign can be seen as a set of phased media events where the information obtained from monitoring was used to refocus priorities, reset directions, and modulate the course of the campaign in the desired direction.

The intensive face-to-face instruction program was directed at two-thirds of the Watsonville participants whom we identified as being in the top quartile of risk of coronary heart disease according to the multiple logistic formula. Their spouses were also invited to participate. This educational effort was launched six months after the first baseline survey and was conducted intensively over a ten week period. In other words, there had already been much use of mass media prior to this effort. A less intense effort was conducted during the second year. A hundred and seven of the 113 participants originally assigned to receive intensive instruction were successfully recruited for treatment and 77 high risk individuals and 34 spouses completed all three interviews and examinations.

The intensive instruction program was composed of education and persuasion in the context of behavior modification and selfcontrol training procedures designed to enhance the same kinds of changes in cholesterol and saturated fat consumption, body weight, cigarette smoking, and physical exercise as were advocated in the media campaign. The protocols were pre-tested in a controlled setting before being applied in the field. The basic sequential strategy was to present information about behavior which influenced risk of coronary heart disease, to stimulate personal analysis of existing behavior, to demonstrate desired skills, for example food selection and preparation, to guide the individual through tentative practice of these skills and gradually withdraw instructor participation. The expectation was that through this process eventually the behavior would be maintained in the group setting without the instructor.

During the initial stage, intensive instruction was conducted in group classes and home counseling sessions. In the second year, the frequency and amount of contact were successively reduced. A less intensive educational campaign was conducted in the summer months of the second year. These consisted primarily of individual counseling in difficult problem areas, e.g., smoking and weight loss, and social activities such as parties, picnics and hikes which were intended primarily to encourage participants to maintain changes that had been produced during the first stage of instruction.

RESULTS

Data presented here are based on our analysis of the baseline surveys in three communities and surveys made one or two years following. Sample characteristics closely matched the census characteristics in each of the three communities. The response rates were satisfactory. Analyses of characteristics of refusals and dropouts reveal these groups to be slightly younger and to have less income and education. The magnitude of possible bias in projecting sample effects to the total community propulation are readily estimated, if one assumes no effect from our campaigns on these individuals, which is the most conservative assumption to be made. Only a few differences in the baseline were found. For example, the mean plasma triglyceride concentration and the systolic blood pressure in Watsonville and Gilroy were significantly greater than in Tracy. In Watsonville, participants exhibited significantly lower relative weights than those in either Gilroy or Tracy. Substantial improvement in cholesterol levels were recorded for the high risk subiects in Watsonville who included the intensively treated groups. Finally, from our multiple logistic formula of risk, participants in Watsonville were at greater overall risk than those in Gilrov and Tracy, probably because of their greater age.

Examination of the pattern of significant differences and percent change values indicates that both the media and media plus face-to-face instruction treatments did have positive effects on almost all relevant variables after both one and two years of campaigning (Table III).

TABLE III

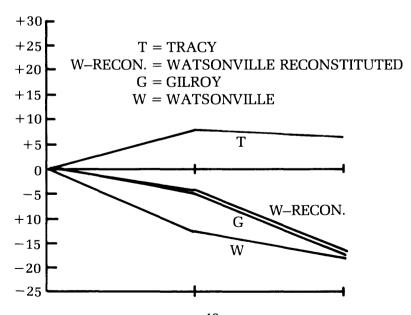
Percent Net Change in Mean Risk Factors
After Two Years of Health Education
(Relative to Control=No Change)

	Systolic		Smoking			
	Plasma Cholesterol	Blood Pressure	Cigs/ Day	# Smoking	Relative Weight	
Gilroy (mass media)	-3.8	-8.6	-4.8	-5.8	-0.6	
Watsonville (mass media)	-2.3	-5.9	-11.2	-2.6	+0.2	
Watsonville (mass media and individual instruction)	-3.6	-5.8	-25.1	-31.6	-0.5	

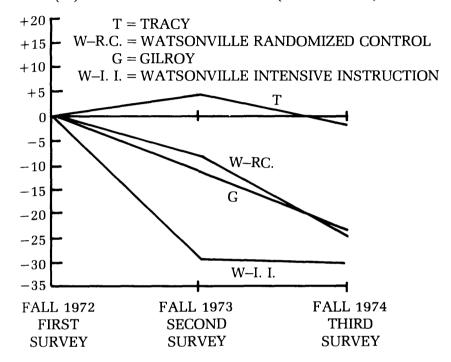
Figure II shows that in Watsonville, the maximum intervention community, we had, in every case, a gain at the end of the first year and in Gilroy, a very much smaller gain.

FIGURE IIPercent Change in Risk from Baseline

(A.) TOTAL PARTICIPANTS (S₃ COHORTS)



(B.) HIGH RISK PARTICIPANTS (S3 COHORTS)

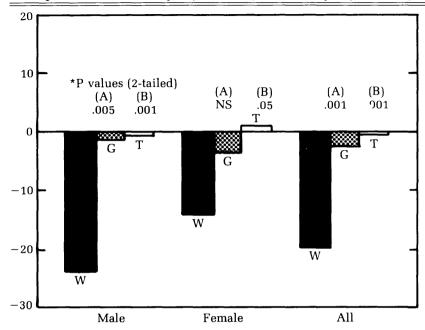


In knowledge about triglycerides, almost nobody knew anything, and we succeeded in teaching people about triglycerides.

In cholesterol intake there are differences in the two test communities compared with the control community. In saturated fat intake the same phenomenon occurred. In the percent change in cigarettes smoked at the end of the second year Tracy was off 2.5 cigarettes instead of 1.1. Gilroy was off 7.3 instead of 2.3, and Watsonville was off 13.7 instead of 6.9 (Figure III).

FIGURE III

Percent change in cigarettes smoked per day among total community samples between Survey 1 (late 1972) and Survey 2 (late 1973)



^{*}Significance of difference between:

- (A) Wastonsville and Gilroy, and
- (B) Watsonville and Tracy

We reconstituted the sample in Watsonville by leaving out the intensive instructees and thus we have a second mass media-only sample. In this reconstituted sample in Watsonville, we have more change in smoking than in Gilroy but by far the largest change is noted when we include the intensive instructees.

In Figure II we show you the overall results. This is the multiple logistic analysis of risk—at base, at the end of year one and at the end of year two.

The data presented in this report are interesting in many ways, but we must acknowledge some uncertainties and possible artifacts in interpretation of our results. Changes that we observed must be considered in the context of the samples in which they were obtained. The fact that participants were randomly sampled from open populations and thus may be more readily generalizable distinguishes our efforts from other studies in smoking cessation and weight reduction. But since we were able to recruit only about two-thirds of the total sample of eligible participants selected in the three

surveys, the generalizability of our results may be limited. Further analysis of the characteristics of refusals and dropouts will help pinpont biases introduced by our response rate. Some of the observed changes in blood pressure may be due to measurement bias. especially in Gilroy where diastolic blood pressure may have been originally underestimated, despite our best efforts to standardize the measurement procedure. Realizing the high variability of blood pressure determinations, we must be cautious in interpreting these data. The reduction in smoking achieved among participants receiving intensive instruction is impressive, in view of past failure to influence smoking, even in self-selected samples undergoing intensive clinical efforts. But we are awaiting the results of thiocvanate assay before fully accepting the conventional self-report measures. Finally, we must acknowledge that we were unable to measure accurately any increase in physical activity, although it might have occurred in treatment communities. We were able to produce sustained weight loss.

Despite these reservations and shortcomings, we are very encouraged by the results that we have observed. Our view of past efforts to inform and influence open populations through mass media led us to be initially pessimistic about the possibility of achieving meaningful change. Finding that media and face-to-face health education can affect knowledge and behavior, if these methods are used to teach specific behavioral skills and not merely to exhort, has confirmed our most hopeful expectations. We tentatively attribute much of our success to the synergistic interaction of our multiple educational inputs and to the interpersonal communication among participants, which was stimulated by application of these inputs in a community setting. It must be remembered that in towns of this size-10,000-12,000 (not bedroom communities but stable towns where we had a good chance of being able to find the same people if we went back one, two and three years later) there may be much more diffusion than would be the case in large cities and towns.

We are especially gratified to find, in general, that the changes in knowledge, behavior, and physiologic end points that were observed in the first year of treatment were maintained and even improved in the second year of study, despite a reduction in the magnitude of some of our educational efforts. In fact, we applied the principle of increasing intervals between reinforcements as a way of building and maintaining stability and behavior change. We are currently awaiting results of our fourth survey to find out if these changes have been sustained through a third year, during which a further reduction in scope of campaigning occurred.

The results presented here provide evidence that behavior change for better health can indeed be accomplished through sustained community based education. We have only begun to define the optimal strategy of conducting that education. Intensive face-to-face instruction and counseling seem important for changing behavior. We must learn how to use these methods to correct obesity as well, and to employ them effectively with limited resources, e.g., by training volunteer instructors. The mass media are clearly a powerful source of influence on knowledge and dietary behavior, but we believe that the power of the potentially more cost-effective mass media can be enhanced if we can find ways to use them to stimulate and coordinate programs of interpersonal instruction in natural community groups, and to deliver some forms of specialized training and counseling, e.g., training in improved eating habits to achieve weight loss or skills to avoid smoking.

In our future work we will explore the potential of mass media and intensive face-to-face instruction for reducing risk of coronary heart disease in larger, more heterogeneous populations, by conducting large scale health education efforts in open populations in towns of 80-100,000 to validate both intervention methods and the underlying hypothesis that coronary heart disease can be prevented through education. This will require monitoring the rates of morbidity and mortality in these communities, which due to the inadequate sizes of the populations was not done in this study. In addition to the measurement of changes in knowledge, behavior, and physiological risk factors as reported here, such community studies of prevention should be well worth the research investment considering the huge annual cost of coronary heart disease.