

CONTRIBUTIONS OF PUBLIC HEALTH TO PATIENT COMPLIANCE

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ABSTRACT: This paper discusses the contributions of public health to compliance in five areas: clinical trials, smoking cessation, dietary compliance, breast cancer screening and hypertension control. Public health programs have been based on a number of theoretical foundations, most notably, social learning theory and the health belief model. Social marketing, community organization, and, more recently, consumer information processing models also are important. The strongest public health programs embody an ecological approach, with interventions directed not only at individuals, but also at groups, communities and changing institutional norms. Among the most important contributions of public health interventions are: multiple levels of intervention and evaluation, tailoring to target audiences, use of social support and community organization for behavior change. Together, community health and clinical compliance-enhancing strategies can exert a synergistic impact on health behavior change.

INTRODUCTION

There is substantial overlap between public health, health promotion and disease prevention in clinical settings. Public health interventions have been influenced by behavioral theory and practice; likewise clinical professionals have benefited from many of the lessons learned in the public health sector. A primary contribution of public health has been the promotion of compliance to primary, secondary and tertiary prevention programs. Compliance has been defined as the de-

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gree to which a person's behavior is in accord with recommended health practices.¹

The success of public health initiatives has directed our attention to the need to incorporate compliance-enhancing strategies into the constellation of behavioral, social and community forces that affect individuals. The strongest public health initiatives have taken an ecological approach, using multiple methods and integrating attention to intrapersonal factors, interpersonal processes, institutional factors, community factors and public policy.² Within a broad community health framework, more effective compliance-enhancing strategies can be chosen and disseminated.

This paper reviews public health research in several important areas, including: clinical trials, smoking cessation, dietary restrictions, breast cancer screening and detection and hypertension control. For each area, we discuss how compliance has been or could be enhanced by educational and behavioral interventions. We begin with a brief overview of cognitive and behavioral models which have been employed in public health research programs for disease prevention and health promotion.

THEORETICAL MODELS OF PREVENTIVE HEALTH BEHAVIOR

The behaviors and cognitions which underlie compliance with preventive health practices have been studied extensively. The conceptual framework used in many of these studies is the health belief model.³ The health belief model predicts that persons who adhere to preventive practices are those who believe that they are susceptible to the disease, that the disease is serious, that the recommended actions (e.g., dietary changes, smoking) are effective, and that the benefits outweigh any costs involved. Most recently, the notion of self-efficacy has also been added to the model. The elements of the health belief model have been associated with a wide range of behavior changes including smoking cessation,^{4,5} dietary management,^{6,7} breast cancer screening,^{8,9} and heart disease prevention.¹⁰ In addition, recent research has indicated that perceived self-efficacy has a moderating influence on behaviors related to smoking, dietary practices and physical exercise.^{11,12} Other health behavior models emphasizing perceived ability to cope with disease-related fears have shown much promise.^{13,14} These concepts have

been employed in several of the public health initiatives discussed in this paper.

Social learning theory provides a rich source of behavioral techniques which can be applied to public health efforts to promote compliance. This model suggests that behavior is influenced by the reciprocal interplay of three primary influences: environmental events; reinforcement; and cognitive mediation.¹⁵ Education information, advice, modeling, and reminders are all examples of environmental events which have been used to alter smoking and other behaviors of populations¹⁶ and to promote compliance with anti-hypertensive medications.¹⁷ Incentives and modeling have also been applied to smoking cessation and dietary compliance with promising results.^{18,19} Interventions that heighten feelings of personal efficacy and expectations for success are likely to be most effective in promoting health behavior change.¹¹

Social learning theory has also been employed to promote physicians' involvement in public health efforts. For example, educating physicians and cueing them with chart reminders have been shown to increase their performance of smoking counseling in clinical practice.²⁰ Computer-generated reminders and chart reviews also can enhance physician efforts to refer patients for preventive screening.^{20,21}

PUBLIC HEALTH IMPLICATIONS OF COMPLIANCE WITH CLINICAL TRIALS

Non-compliance threatens the validity of clinical trials, and thus, advances in medical science.^{22,23} Sample size requirements are influenced by drop-out rates and non-compliance; and incomplete compliance can be a source of distortion regarding the efficacy of a treatment regimen.^{22,24} Even when clinical trials have included efforts to maximize the adherence of subjects, the generalizability of findings depends on the ability of clinicians to motivate free-living patients to comply with therapeutic regimens.²³

The research methodology of public health measurement sciences, epidemiology and biostatistics has long been central to the design and analysis of clinical trials.²⁴ However, with increasing attention to prevention and management of chronic diseases, public health approaches take on increasing importance. Both our understanding of preventive and treatment modalities, and our ability to promote their widespread adoption, depend on understanding the behaviors of popu-

lations, implementation of strategies to educate and persuade at-risk patients, and interdisciplinary cooperation to communicate and use this knowledge.

Randomized controlled trials, including major multi-center studies, demonstrate how variable adherence can confound study findings. Large studies of drugs to reduce risk of coronary heart disease (CHD) exemplify the issues surrounding adherence in clinical trials and their implications for risk reduction. They also have resulted in controversies regarding the appropriate interpretation of findings. In the Coronary Drug Project, for example, three study groups had to be discontinued prematurely due to severe drug side effects. In addition, there was a significant inverse relationship between mortality and adherence to the *placebo*, which investigators attributed to self-selection.²⁵

The Lipid Research Clinics Coronary Primary Prevention Trial (LRC-CPPT) was a multi-center, randomized, double-blind study of 3,806 middle-aged men with elevated blood cholesterol levels for an average of 7.4 years. It tested the efficacy of cholesterol lowering medication in reducing the risk of CHD, and both the experimental and placebo groups were advised to follow a moderate cholesterol-lowering diet. Findings, based on packet counts of medication, indicated that the better adherers in the experimental group showed greater decreases in cholesterol levels than the poor compliers. Nevertheless, the major study findings and coronary endpoints were reported for treatment groups by assigned group, irrespective of compliance.²⁶

The analyses of the LRC-CPPT were biased by non-compliance, but the policy implications have considered the potential of cholesterol-lowering for preventing CHD. The 1984 publication of the LRC-CPPT findings marked a turning point in U.S. health policy and the launching of a major national educational campaign to control elevated blood cholesterol levels. Yet, both the rationale for, and the success of this major public health initiative, hinge on the adherence of large segments of the population to dietary and/or drug treatment to reduce CHD risk.²⁷

The contribution of public health in the area of clinical trials is most important for highly prevalent chronic diseases. The ultimate effectiveness of cancer prevention and detection technologies, blood pressure control measures, smoking control, and dietary adherence depends on *both* the careful conduct and interpretation of clinical trials, and the ability and efforts of health professionals to translate research into practice.²³ Lessons of adherence research in natural field settings should be applied in controlled clinical trials to detect noncompliance and/or maximize compliance. And lessons from clinical trials should be carried into

health care practice settings to enhance disease prevention efforts, reduce unnecessary health care utilization, and increase the cost-effectiveness of medical care and health education.

CONTRIBUTIONS OF PUBLIC HEALTH TO SMOKING CESSATION

Early smoking cessation research often focused on case studies²⁸ and therapist-intensive behavioral interventions.^{5,29} While effective in helping many smokers to remain abstinent, these clinical approaches had limited population reach. As public health professionals became engaged in smoking cessation research, they began to devise methods that could reach more smokers, often in their communities, with less intensive and potentially more cost-effective interventions. Often, as in the case of the federally-sponsored community heart health programs, smoking cessation programs are delivered in the context of multi-focus cardiovascular risk reduction programs.³⁰⁻³³

The heart health programs apply community health intervention methods to increase smoking cessation, along with other health-enhancing behaviors to reduce cardiovascular risk. These programs share a number of public health strategies, including citizen participation based on principles of community organization, use of the mass media and social marketing techniques, delivery of self-help materials in clinic settings as well as by mail, and use of survey and other data for evaluation. In addition, these approaches aim to involve health professional gatekeepers and to identify smokers at high-risk, such as women, minorities and blue collar workers.

While in most cases the data are not complete, the heart health programs appear to have achieved modest reductions in smoking, as well as improvements in other health behaviors in the targeted communities. They also have contributed substantially to our understanding of behavior change and patient compliance and have expanded the arsenal of tools available for enhancing compliance. In addition, these studies have brought home the importance of community.³⁴ Intervening with patients in clinical settings, away from the pressures of family and friends is, of course, important. But, ultimately, patients return to their communities. It is there that they are left to comply with their regimens, perhaps with the support of family and friends, but often without such support. Thus, public health interventions that assist patients in their

communities may have the strongest potential for sustained behavior change.

Public health professionals traditionally have focused a significant part of their efforts on harder-to-reach populations. In the case of smokers, survey data show that as United States smoking rates decline, remaining smokers are more likely to be blue collar, minority and lower socioeconomic status people who live in networks dominated by other smokers. Smokers trying to quit may face a lack of support or outright derision. Public health efforts, such as the *A Su Salud* project in Texas, have shown how important it is to alter community norms about smoking. In that project, social learning theory was applied by using community people to model the recommended behaviors and the processes of change.³⁵ While social learning theory evolved from controlled laboratory settings, it was in the community setting that it achieved full power. Interventions developed through such public health efforts now are being used in community settings to strengthen support for patient compliance.

Similarly, psychologists developed the stages of change model (ranging from precontemplation to maintenance) to explain the process of smoking cessation.³⁶ Public health researchers and the developers of the model have extended the model, making its impact accessible to many more smokers. An example is the use of the stages of change model in guiding the development of the American Lung Association's *Freedom from Smoking® For You and Your Family*.³⁷ The guide is being used in a variety of settings, including those with patients as well as schools, worksites and community organizations.

In the National Cancer Institute's self-help smoking cessation trials, most participants were recruited from communities. In all, 5,389 smokers were recruited over three years to participate; 12 month point prevalence quit rates averaged 14% across the seven participating sites.³⁸ In the *Quitting Times* program, a public health smoking cessation program directed at mothers with young children, sixth-month point prevalence quit rates of 11.5% were achieved using brief smoking cessation counseling (average = less than 5 minutes) in combination with a self-help guide tailored to women with reading abilities of about sixth grade.³⁹ Smoking history data were gathered on nearly 20,000 women, and about half the smokers were counseled by public health workers. In these and similar trials directed at physicians, the public health implications of brief counseling have been profound. Glynn and Manley⁴⁰ estimate that as many as 4.5 million smokers in the United States might be motivated to quit each year through brief physician counseling if

150,000 office-based physicians participated. Such minimal contact public health interventions make it possible to reach smokers who would be unlikely to participate in more intensive interventions.

An important contribution of public health smoking cessation interventions has been the refinement of mass media approaches to enhance individual behavior change. For example, interpersonal features of the media can be used to support individual behavior change.⁴¹ Among the most important projects using mass media, in combination with intrapersonal and interpersonal compliance-enhancing strategies, are the Stanford Three and Five Community Studies,⁴² the Minnesota and Pawtucket Heart Health Programs,^{31,32} and the A Su Salud program.³⁵ All have used the mass-media to enhance individual change by creating environments supportive of change and by providing people with access to information. For example, in the A Su Salud program, simple forms of verbal cueing and reinforcement were communicated widely through brief, direct contacts of community members by volunteers.⁴³

CONTRIBUTIONS OF PUBLIC HEALTH TO DIETARY COMPLIANCE AND NUTRITION EDUCATION

Our understanding of compliance with lifestyle modification regimens has been enriched greatly through public health efforts to promote healthy eating patterns for disease prevention and management. The most notable contributions have emerged from efforts to reduce cardiovascular disease risk through prevention or management of elevated blood cholesterol, and attempts to develop more effective techniques to achieve and maintain weight control. Both conditions are highly prevalent, and it is difficult to distinguish clinical populations from self-treating individuals trying to adhere to public health recommendations for healthy eating.

Traditionally, nutrition education and counseling have focused on changing the knowledge, attitudes, skills and eating practices of individuals and small groups identified as at risk. Now, the need to reach large populations has promoted population-based and environmental intervention strategies.⁴⁴ The growing consensus that moderation of dietary fat and calorie intake are prudent and safe eating practices for all adults^{45,46} further underscores the need for efficient strategies to promote dietary adherence among large populations.

The increased efforts with population-based and environmental

interventions have been influenced explicitly by social science theories. The most prominent models have been related to social learning theory⁴⁷ and marketing and consumer behavior approaches.^{44,48} In addition, principles of community organization, diffusion theory and mass communication recently have been applied to programs to improve nutritional status.

Educational efforts which apply social learning theory emphasize attention to cognitive, interpersonal, and environmental factors that influence eating behavior. The Family Heart Study includes behavioral self-regulation techniques, group sessions, cooking demonstrations, family involvement and group decision methods to overcome barriers to adherence, teach skills, involve learners, and mobilize group support by modifying group norms for dietary change.⁴⁸ A multi-strategy community cholesterol campaign in Pawtucket, Rhode Island is based on social learning theory principles,³¹ and community education efforts of the Minnesota Heart Health Program (MHHP) use social learning theory as a guiding theoretical framework for nutrition behavior change.^{32,44} The Multiple Risk Factor Intervention Trial (MRFIT), a large scale long-term clinical trial of strategies to reduce risk of coronary heart disease, also has contributed to our understanding of methodologies for assessing and enhancing adherence. The experimental group in this trial achieved average cholesterol reductions of 7.5% and maintained those levels for six years.⁴⁹

When social learning theory principles are applied at the organizational, community and societal levels, they set the stage for healthy eating patterns through cues, reinforcement, and policies. For example, worksite nutrition programs often include making low-calorie and low-fat food choices available in the cafeteria.⁵⁰ Worksite weight-loss competitions based on social learning theory principles use both incentives and group cohesiveness to promote short term weight reduction.⁵¹ They have proven to be a popular and cost-effective approach to increasing the availability of weight control programs.

Consumer information processing (CIP) models also hold promise for improving dietary adherence in populations. This framework suggests that consumers vary in the amount of time and attention they give to information, and that they employ heuristics, or rules-of-thumb, to help them make satisfactory choices with minimum effort.^{52,53} Thus, behavior change may be promoted through presentation, placement, and activation of nutrition information.⁵² The application of consumer information processing theoretical frameworks to improve widespread dietary adherence provides a parallel to the behavioral medicine-public

health reciprocal relationships mentioned earlier. It involves using what was conceived as primarily an *individualistic* approach to address community and population-wide needs.

CONTRIBUTIONS OF PUBLIC HEALTH TO BREAST CANCER SCREENING

Important contributions to our understanding of patient compliance and to the intervention arsenal have come from public health interventions to increase acceptance of cancer screening. A major impetus for activity has come from promulgation of the National Cancer Institute's (NCI) Year 2000 objectives for reducing avoidable mortality from cancer.⁵⁴ Here, we discuss breast cancer screening initiatives as an example.

Ideally, breast cancer screening should include three modalities for women aged 40 and over: breast self-examination (BSE), clinical breast examination and mammography. Survey data show that there are a number of barriers to mammography utilization. These include both access and psychosocial barriers. Women report that they have not thought about mammograms, that they are not necessary in the absence of symptoms, that their physicians have not recommended that they get mammograms, or they are afraid of finding something.^{9,55} Access barriers also are important.⁵⁶ Most women say they would get mammograms if their physicians recommended, if they had symptoms or if mammography was convenient.^{56,57}

Across the U.S., a number of public health programs are aimed at increasing utilization of mammography among women, with a special focus on poor and older women whose rates remain the most resistant to change.^{58,59} These public health efforts are characterized by multi-intervention efforts to reach women at special risk, especially older women, poor women and minorities. A variety of intervention strategies have been used to enhance compliance. They include use of printed and audiovisual materials, reduction of cost, outreach and advocacy for special clients, such as Latina women, community organization, telephone counseling to discuss a woman's personal mammography barriers and education of community physicians and modification of delivery system factors.^{8,55,59}

Public health interventions directed at increasing women's BSE practices also have been varied. They include the use of memory aids to cue and reinforce women⁶⁰ as well as guided practice⁶¹ and feedback strat-

egies.^{62,63} Among the most important factors in continued practice is the initial teaching of BSE and reinforcement by health professionals.^{64,65} Promising strategies also include efforts to increase normative support and community organization techniques such as attempts to reach women through the organizations to which they belong.^{66,67} A number of evaluations have shown multi-modality programs to be the strongest.⁶⁸ But few studies have shown one motivational or learning technique to be superior.⁶⁹ As with smoking cessation programs, most of the strategies described here reflect the theoretical foundations of the health belief model and social learning theory. For example, modeling and guided practice (social learning theory) are designed to heighten perceived susceptibility, overcome barriers and provide cues to action (health belief model).

CONTRIBUTIONS OF PUBLIC HEALTH TO HYPERTENSION CONTROL

Hypertension, or high blood pressure, is a leading public health problem. It is a major risk factor contributing to premature death and disability from cardiovascular and cerebrovascular diseases. Adherence to antihypertension regimens depends on a series of steps, some of which frequently occur outside clinical settings: participation in screening or detection; entering treatment; continuing treatment (appointment-keeping); and adhering to a prescribed regimen.⁷⁰ Adherence is central to the control of hypertension and prevention of complications, and the single most significant clinical problem in the management of hypertensives.

Efforts to improve compliance with steps to control hypertension have taken place over the past two decades through a combination of major public health campaigns and small scale, controlled research. In 1972, the National High Blood Pressure Education Program (NHBPEP) was established by the National Heart, Lung, and Blood Institute (NHLBI) to reduce high blood pressure through professional, patient and public education. The program is based on a commitment to concepts of community organization, principles of the two-step flow of mass communication, and, importantly, the use of social marketing principles.⁷¹ Findings from the 1985 National Health Interview Survey indicate that awareness, knowledge, continuation of treatment, and adherence to prescribed regimens have improved markedly since the inception of the NHBPEP.⁷² While the NHBPEP is only one contributor to these

encouraging results, its emphasis on mobilizing resources throughout the country mark a successful public health approach to improving adherence to hypertension control strategies.

Both theory and research regarding psychosocial correlates to compliance with blood pressure treatment regimens have emerged from public health settings. Patient surveys have been used both to study the problems of noncompliance and design better interventions, and to assess the effectiveness of strategies. The conceptual bases which have been used include the health belief model, social support and social networks, operant conditioning, and coping skills and behavioral rehearsal.^{17,73-75}

A number of educational interventions have been tested in controlled studies and found effective for improving hypertensives' adherence. They include not only attempts to inform, motivate and persuade patients, but also to change the structure of the treatment system.⁷⁰ Referral to medical care has been increased by mail reminders.⁷⁶ Appointment keeping has been improved with mail and phone reminders and through restructured clinic appointment systems.⁷⁷ Adherence to regimens for patients in treatment has been improved through self-monitoring, contingency contracting, nurse phone follow-up, exit interviews to clarify and reinforce the regimen, support groups, and problem-solving training in coping skills.^{17,73} Changes in the regimen or the structure of treatment also have proven effective: they include special medication packaging, clinic surveillance systems, and physician tutorials.⁷⁰ No one intervention has emerged as the most effective, through most studies indicate that long-term continuation of interventions is necessary to achieve the benefits of long-term compliance.

Perhaps the most exemplary public health efforts to improve hypertension compliance are the integrated systems of screening, referral, and professional and public education. The worksite has proven an effective setting for such interventions: not only can operational components of the program be feasibly implemented, but organizational systems and norms can be fostered to promote long-term compliance.⁷⁸ Programs which remove financial and access barriers to hypertension control have the potential to improve compliance further.⁷⁹

The promise of public health contributions to high blood pressure compliance lies in the potential cumulative effect on reducing hypertension-related morbidity and mortality. A five-year follow-up of a controlled trial of three educational interventions resulted in improved appointment-keeping and significant reductions in mortality in a low-income black clinic population.⁸⁰ The educational interventions involved exit interviews, family support at a home visit, and small group sessions

emphasizing coping skills and confidence among patients. This single study is unique in its long follow-up period, and suggests that long-term effects are achievable through educational interventions. Its strengths include intervention development based on baseline surveys and tailoring of educational content for the population. However, it leaves many questions unanswered and further studies will be needed.⁸¹

CONCLUSION

Public health approaches reflect a recognition that multiple levels of intervention are needed to affect individual compliance.⁸² They also show the importance of tailoring print, audiovisual and interpersonal interventions to the sociocultural needs of target populations. Many of the materials produced for community health research are being used in conjunction with health professional counseling protocols to encourage patient compliance. Public health programs also use outreach advocacy methods to underserved populations and to make programs more accessible. Likewise, changes in clinic structures and reminders have enhanced compliance. Finally, public health researchers have refined epidemiologic and statistical methods for conducting and analyzing community-based trials.

The strongest public health initiatives embody an ecological approach with interventions directed not only at individuals, but also toward the groups to which they belong, workplaces and governments. Community level prevention efforts need to involve a wide variety of experts in developing and implementing health promotion programs.⁸³ Thus, in the ideal scenario, individual behavior change is supported in medical care, in the family, at work and in the community. Point-of-purchase information and health professional support can enhance individual behavior change. In the future, both public health and clinical efforts must motivate people to enroll and remain in chemoprevention trials for cancer and other diseases. Together, the combination of clinical and public health initiatives can produce a synergistic effect greater than either could achieve alone.

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