

# IMPLICATIONS OF THE RESULTS OF COMMUNITY INTERVENTION TRIALS

*Glorian Sorensen,<sup>1,2</sup> Karen Emmons,<sup>1,2</sup> Mary Kay Hunt,<sup>1</sup>  
and Douglas Johnston<sup>1</sup>*

<sup>1</sup>Dana-Farber Cancer Institute, Center for Community-Based Research, Boston, Massachusetts 02115 and the <sup>2</sup>Harvard School of Public Health, Department of Health and Social Behavior, Boston, Massachusetts 02115;  
e-mail: Glorian\_Sorensen@dfci.harvard.edu; Karen\_Emmons@dfci.harvard.edu; Mary\_Kay\_Hunt@dfci.harvard.edu

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## ABSTRACT

This paper examines the results of population-level interventions conducted in three settings: entire communities, worksites, and schools. Four major conclusions are discussed: (a) Directions for the next generation of community-based interventions include targeting multiple levels of influence; addressing social inequalities in disease risk; involving communities in program planning and implementation; incorporating approaches for "tailoring" interventions; and utilizing rigorous process evaluation. (b) In addition to randomized controlled trials, it is time to use the full range of research phases available, from hypothesis generation and methods development to dissemination research. (c) The public health research agenda may have contributed to observed secular trends by placing behavioral risk factors on the social and media agendas. (d) The magnitude of the results of community intervention trials must be judged according to their potential public health or population-level effects. Small changes at the individual level may result in large benefits at the population level.

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## INTRODUCTION

Three decades ago, mounting evidence established the role of certain behaviors, such as smoking and consumption of high-fat diets, as risk factors for

chronic diseases, including cardiovascular disease and cancer. In response to this evidence, early studies, such as the Lipid Research Clinics Coronary Primary Prevention Trials (120, 121) and the Multiple Risk Factor Intervention Trials (140), were designed as traditional clinical trials to test strategies for reducing risk among medically high-risk individuals. There are, however, several limitations to translating this traditional clinical model into public health interventions. By targeting only high-risk individuals, the clinical model misses the potential for prevention of disease by ignoring underlying causes contributing to elevated risk. Identifying high-risk individuals—one at a time—makes it improbable that the entire population at risk will be reached (19, 173, 221). In addition, this high-risk strategy “decontextualizes” risk behaviors, overlooking the ways in which individual behaviors might be culturally and structurally maintained (133, 152).

Community intervention trials represented a radical departure from the traditional clinical model. Indeed, 15 years ago Blackburn (19) enthusiastically described community intervention trials as “something new under the sun in public health.” These population-based interventions sprang from the concept of *population-attributable risk*, which measures the amount of disease in the population that can be attributed to a given level of exposure (128). According to Rose, “A large number of people exposed to a small risk may generate more cases than a small number exposed to a high risk” (174). Thus, when risk is widely distributed in the population, small changes in behavior observed across an entire population are likely to yield greater improvements in the population-attributable risk than larger changes among a smaller number of high-risk individuals (128, 133, 174). Population approaches to disease prevention represent an upstream method for reducing behavioral risks, i.e. by addressing the conditions that contribute to and sustain the problems that eventually appear downstream, or at the individual level (221). Influencing individual behaviors on a large-scale basis within the population results in a shift of the distribution of risk, thus norms regarding socially acceptable behaviors and practices are changed (7, 9, 60, 128, 133, 174). A community-wide strategy directed at all ages targets both primary and secondary prevention, and thus has the added advantage of contributing to prevention of excess risk (19).

In the past 10 to 15 years, community intervention trials have been conducted in a variety of settings, including entire communities, workplaces, and schools. With results of many trials now in, concern has been expressed about the lack of significance in these trials and, when results were significant, with the magnitude of the results. It is time to examine these results and re-assess the role of community intervention studies. As in other scientific fields, community intervention research requires an iterative process to identify effective strategies for promoting behavioral change at the population level. The main purpose of this

paper is to contribute to the dialogue about the next generation of community intervention research, building on the lessons learned from community intervention trials completed to date. As a basis for this discussion, we provide a targeted review of the results of representative community intervention trials. While not intended to be an exhaustive review, this targeted review was conducted for the purpose of understanding the results of recently completed studies and providing directions for the next generation of population-level intervention research. This paper focuses specifically on the results of population-level interventions conducted in three settings: entire communities, worksites, and schools. From this review, we draw the following major conclusions, which will be discussed in detail:

1. *New directions for community interventions* Based on the evidence we reviewed, five key directions for the next generation of community interventions are: (a) targeting multiple levels of influence in the intervention; (b) addressing social inequalities in disease risk; (c) involving communities in program planning and implementation; (d) incorporating approaches for “tailoring” interventions; and (e) utilizing rigorous process tracking.
2. *Improving evaluation* Evaluation of interventions on the next horizon of research requires an expansion of research designs and methodologies. In addition to randomized, controlled trials, it is time to use the full range of research phases available, from hypothesis generation and methods development to dissemination research.
3. *Reciprocal and cumulative impact of community intervention research* In evaluating the effectiveness of community interventions, it may be necessary to reconsider the meaning of secular trends in health behaviors. Recommendations for health behavior change may spill over from intervention to control communities. In addition, ongoing public health research may have contributed to secular trends in improved health behaviors by placing behavioral risk factors on the social and media agendas, concurrently with the conduct of community intervention trials. Indeed, as a consequence of these secular trends, community intervention trials may be the “victims of successes in other forms of social interventions” (197).
4. *Interpreting the magnitude of the effects* The magnitude of the results of community intervention trials must be judged according to their potential public health or population-level effects. Small changes at the individual level may result in large benefits at the population level (173, 174), a maxim gaining increasing support from recent evidence that the magnitude of effects observed by these trials is likely to be both efficacious and cost-effective when implemented on a population level (39, 202). Using clinical

significance alone as the standard for interpretation of the results of community intervention trials is inappropriate for research at the population level.

## A SUMMARY OF THE RESULTS OF SELECTED COMMUNITY-, WORKSITE-, AND SCHOOL-BASED STUDIES

We examined studies targeting health behavior changes that are representative of community intervention trials, recognizing that an exhaustive review is beyond the scope of this paper. We have included studies that used the community, worksite, or school as the unit of intervention and assignment. Given the importance of shifting the population distribution of disease risk, the effectiveness of interventions must be measured among the entire population for whom the intervention is intended, not only among the program participants. In addition, we focused primarily on studies that included intervention and comparison or control conditions. [In order to narrow the scope of our review, we included only studies conducted in the United States, and examined trials targeting primary prevention of cancer or coronary heart disease.] We provide a brief overview of these studies as the basis for our discussion of their implications.

### *Community-Based Intervention Trials*

Two early studies targeting cardiovascular disease prevention set the stage for community-based intervention trials: the North Karelia Project (163) and the Stanford Three Community Study (63, 76). The North Karelia Project grew out of the community's concern about having the highest heart attack risk worldwide (19, 108, 219). Results of a community-wide intervention implemented in the area of North Karelia, Finland, were compared with a reference area in eastern Finland. After 10 years, the net effects among middle-aged males included significant reductions in smoking, mean serum cholesterol concentration, mean systolic blood pressure, and mean diastolic blood pressure; significant intervention effects were observed among women for mean systolic and diastolic blood pressure (163). Between 1972 and 1992, cardiovascular disease mortality declined in Finland by 55% among men and 68% among women, a decline accounted for primarily by dietary changes (159). This study set the stage for community-based intervention studies in the United States, the first of which was the Stanford Three Community Study. Initiated in 1972, this study demonstrated the feasibility and potential effectiveness of directing mass media-based educational campaigns at entire communities (63). Significant reductions in cholesterol and saturated fat were reported at the conclusion of the intervention, and were sustained during a one-year maintenance period (76).

In the late 1970s, three large community-based intervention trials were funded by the National Heart, Lung and Blood Institute: the Stanford Five-City Project (SFCP), the Minnesota Heart Health Project (MHHP), and the Pawtucket Heart Health Project (PHHP) (32, 62, 122). All three targeted change in risk factors for coronary heart disease (CHD), including high blood pressure, elevated blood cholesterol levels, cigarette smoking, and obesity. None of the studies was randomized; rather, in general the communities were matched to optimize comparability of the two study conditions (141). These multiple risk factor intervention trials varied in length from five to seven years, and additionally tracked changes in morbidity and mortality beyond the intervention period. The interventions were aimed at raising public awareness of risk factors for coronary heart disease and at changing risk-related behaviors through public education, education of health professionals, and environmental change programs such as grocery store and restaurant labeling. In the SFCP, significant intervention effects were observed in the cohort in blood cholesterol, smoking, and systolic and diastolic blood pressure; decreases in risk based on composite risk factor indices were significantly larger in the intervention than in comparison communities (61). At three years post-follow-up, although the magnitude of the long-term effects was small, this study suggested that it was possible to sustain at least some of the outcomes observed (229). Fewer significant results were observed in MHHP and PHHP. MHHP observed significant intervention effects for smoking prevalence among women and for physical activity (122). PHHP reported smaller increases in body mass index in the intervention communities compared to the control, with no other significant results (32).

In 1989, the National Cancer Institute (NCI) launched the Community Intervention Trial for Smoking Cessation (COMMIT) (41), using methods similar to those used in the community-based intervention trials for cardiovascular disease prevention. This randomized, controlled community-based intervention trial included 11 matched pairs of communities across North America, and was designed to test the effectiveness of a multifaceted, four-year community-based intervention to encourage smokers, particularly heavy smokers, to achieve and maintain cessation (41, 89). A significant intervention effect was observed among light-to-moderate smokers, and this effect appeared to be greater for the less educated subgroup (42). However, there was no intervention effect among heavy smokers (42, 43).

In a move toward ensuring greater community input, the Kaiser Family Foundation's Community Health Promotion Grant Program (CHPGP) offered communities substantial flexibility in developing program targets that responded to local needs and priorities. This program was designed to foster community health promotion efforts targeting cardiovascular disease, cancer, substance abuse, adolescent pregnancy, and injuries (198, 220). Comparisons between

11 intervention communities and 11 control communities, however, indicated little evidence of positive changes in the outcomes targeted by the intervention communities (220).

Although not a randomized controlled intervention trial, the American Stop Smoking Intervention Study (ASSIST) is a large-scale demonstration study building on these randomized community-based intervention trials. To assess the impact of the intervention, changes in smoking prevalence and cigarette consumption as well as policy changes, exposure to environmental tobacco smoke, and smoking initiation are being compared between ASSIST and non-ASSIST states. Comprehensive tobacco control programs, with an emphasis on policy interventions, are being implemented in 17 states; the five-year intervention will be completed in September 1998. Preliminary assessments suggest that the program is having an impact by decreasing cigarette consumption and increasing cigarette excise taxes (125).

Policy interventions represent an important trend in community-based intervention trials as upstream interventions. Tobacco Policy Options for Prevention (TPOP) was a randomized community trial designed to test the effects of changes in and enforcement of local policies to limit youth access to tobacco in 14 Minnesota cities (74). The intervention relied on community organizing efforts, and aimed to change ordinances, merchant policies and practices, and law enforcement practices to reduce youth access to tobacco. Compared to control communities, intervention communities adopted more and stronger comprehensive ordinances to ensure compliance with youth access laws, resulting in lower smoking prevalence among young adolescents.

### *Worksite Intervention Trials*

In the past 15 years, an increasing number of health promotion studies have been conducted in workplace settings, and worksites are now considered key channels for delivery of interventions designed to reduce chronic disease among adult populations (1, 2, 66, 95). Workplace-based interventions have targeted a number of risk factors related to cancer and cardiovascular disease, including smoking (103, 190), nutrition (31, 187, 189), cholesterol (31, 81, 82), and physical activity (109).

We reviewed the results of ten representative worksite trials that targeted smoking, nutrition, weight management, and/or cholesterol reduction, including eight conducted as discrete trials (31, 80, 82, 176, 185, 187, 189, 190); and two conducted within the context of larger community-based trials (81, 186). The primary outcomes for nine of these worksite studies were individual behaviors, and for the tenth, COMMIT, worksite-level changes in tobacco control programs and policies (81). Intervention methods included participatory strategies, and targeted individual behavior change among the entire workforce. Six of the ten studies incorporated a focus on the worksite environment in the

intervention. These interventions included the promotion of smoking policies and increasing the availability of healthy foods in cafeterias and vending machines; however, only two of these studies, COMMIT and the Working Well trial, provided data on environmental outcomes (17, 81). The interventions varied in length from one month to two years. A combination of cross-sectional and cohort samples was studied. The majority of these studies assessed change between baseline and post-intervention follow-up only, although three studies (31, 176, 186) included an extended post-intervention follow-up.

Of the six studies that targeted smoking, three achieved significant effects for smoking cessation (103, 176, 186). In a fourth study, Working Well, no trial-wide differences in smoking cessation were observed, although one of the four participating study centers observed significant intervention effects for six-month smoking abstinence rates (190). This study center was unique in that it integrated an occupational health focus into the health promotion intervention, thereby targeting a key concern of workers in the participating manufacturing worksites (184).

Of the six trials that targeted diet and nutrition, three had significant effects on the decrease in percentage of kilocalories as fat (80, 187, 190). Working Well and Treatwell 5-A-Day reported significant increases in consumption of fruits and vegetables (189, 190) and a significant reduction in blood cholesterol levels at 12-month follow-up (31). Healthy Worker, the only trial to target weight reduction, found no intervention effect on weight loss (103).

### *School Intervention Trials*

Over the past two decades, extensive attention has been paid to health promotion and disease prevention among youth, particularly through schools. Schools provide an established setting in the community for reaching children and their families (14, 143, 155, 193, 194). Two reviews summarized the school-based smoking prevention trials conducted in the 1980s (14, 71). These reviews have generally concluded that interventions that target adolescents' social influences have a significant impact on smoking onset, although it remains unclear with which students these programs are most effective (15). Two recent meta-analyses have evaluated the effect sizes produced by school-based smoking prevention programs (29, 172). The first meta-analysis (29) found that effect sizes were the largest for interventions that focus on social reinforcement for the target behavior, moderate for those with either a developmental orientation or a focus on increasing social norms and influence for the target behavior, and small for interventions with a health education focus. A second meta-analysis concluded that the impact of peer or social programs could be improved if they are delivered early during the transition from elementary to middle school (e.g. 6th grade), if same-age peer leaders are used, if they are part of a multicomponent health program, and if booster sessions are included in subsequent years (172).

We have focused on nine published school-based studies that have utilized the school as the unit of analysis. Six were conducted as free-standing school interventions (12, 22, 70, 94, 123, 157) and three were conducted in the context of a larger community-based intervention (107, 153–157). Three studies addressed dietary, physical activity, and/or smoking behaviors (12, 107, 123, 155–157), focusing on cardiovascular disease or cancer prevention, and a second group of five studies targeted substance use, including smoking (22, 70, 94, 153, 154, 158). The intervention period ranged in length from three months to seven years and targeted students in grades 3–5, 6–9, and 9–12. Three studies reported results of post-intervention follow-up (22, 94, 156). Three trials reported outcomes for interventions targeting the school environment (107, 123, 157); one study (Project Northland) also included an emphasis on community ordinances and resolutions, and focused a significant portion of the intervention on community activities outside of the school setting (158). With the exception of Project Northland, the substance abuse prevention studies focused primarily on the individual level, and did not include a focus on the environment. CATCH, HomeTeam, and Class of 1989 studies also targeted the environmental level. Two school projects were conducted as part of community-based studies, i.e. MHHP, which targeted the entire adult community (107, 157) and the Midwestern Prevention Project (MPP), which targeted adolescents in the community (153).

The three trials that targeted dietary behaviors consistently found significant differences between intervention and control schools (12, 123, 157). Of the two studies that targeted the school food service, one, CATCH, reported a significant impact in the intervention schools (123), and the other, Gimme 5, did not (12). The two studies that targeted physical activity both achieved significant intervention effects for the time per week spent engaging in physical activity (107, 123). The studies that focused on substance use employed a range of intervention targets, including prevention and cessation of tobacco, alcohol, and marijuana use. All five studies had a significant impact on smoking prevalence. Of particular note, the one study to conduct an extended follow-up found that the intervention still conferred a significant impact on both weekly and monthly smoking prevalence at the six-year follow-up (22). Of the five studies that targeted alcohol, two studies found significant differences in alcohol use favoring the intervention conditions (154, 158); an additional study found an intervention effect on the number of drunken episodes, marijuana use, and polydrug use (22).

### *Summary of the Results of Community-, Worksite-, and School-Based Intervention Trials*

In summary, although the early community-based trials held promise for the potential of community interventions to promote population-wide health behavior change, the level of change observed in the North Karelia and Stanford



Three Communities studies generally has not been replicated in subsequent community-based intervention trials. In contrast to these community-based interventions, there were more significant findings in the worksite- and school-based intervention studies. In the worksite-based studies, those which included extended follow-up periods found that intervention effects were maintained or increased beyond the post-intervention follow-up (31, 176, 186). Results from several recent community-, worksite-, and school-based studies suggest that policy interventions may be efficacious in promoting health behavior change.

Taken together, these trials have demonstrated the feasibility of activating entire communities, worksites, and schools in pursuit of healthier citizens and healthier institutions. They have also shown that the medical care sector need not take sole responsibility for community health (97); the mass media, business, education, and other sectors will also take on health as a priority. Through these trials, we have learned a great deal about the wide range of resources and skills needed to achieve individual and organizational change—from personnel and material resources to persuasive and educational skills to legislative access and authority. We have seen the synergism that results from community collaborations. These trials have also demonstrated that multi-channel, multi-strategy interventions can effect significant change among adults in behaviors that have developed over long periods of time and in organizations whose primary mission is not health.

There is still, however, much to learn. We need to define the elements that are most effective in these multiple component interventions; design and test interventions that target the underlying structures and social contexts influencing health behaviors; and study methods for interpretation of change in terms of population-level benefits to health. It is now time to build on the lessons learned from these community intervention trials, incorporating findings from recent research on intervention strategies and evaluation methods that have evolved since the early trials were designed.

## DIRECTIONS FOR THE NEXT GENERATION OF COMMUNITY INTERVENTIONS

As part of the iterative research process, we must seek new answers to the question: What strategies can be used to improve the effectiveness of interventions? The studies reviewed here generally tested comprehensive models, sometimes targeting change through multiple levels of influence. The study designs employed do not permit us to disentangle the influence of individual intervention methodologies. Rather, we draw from this review the indicators of effectiveness that point the direction for the next generation of community intervention research.

The studies conducted to date provide an important basis for next steps. Based on the evidence provided by this review, we recommend five key directions for the next generation of population-based interventions: (a) designing interventions that target multiple levels of influence; (b) addressing social inequalities in disease risk; (c) involving communities in program planning and implementation; (d) incorporating approaches for “tailoring” interventions at the population level; and (e) utilizing rigorous process evaluation.

### *Designing Interventions that Target Multiple Levels of Influence*

Different disciplinary lenses produce different answers and raise different questions regarding ways to reduce disease and improve health (5, 223). While none is more correct than another, each perspective brings certain issues to the fore, while others remain in the background (223). These alternative disciplinary lenses are illustrated in Figure 1. At the micro level, the biomedical lens focuses on biophysiological theories of disease causation and turns to biomedical interventions for solutions. The psychosocial lens maintains a primary focus on the individual, investigating questions about individual and social behaviors

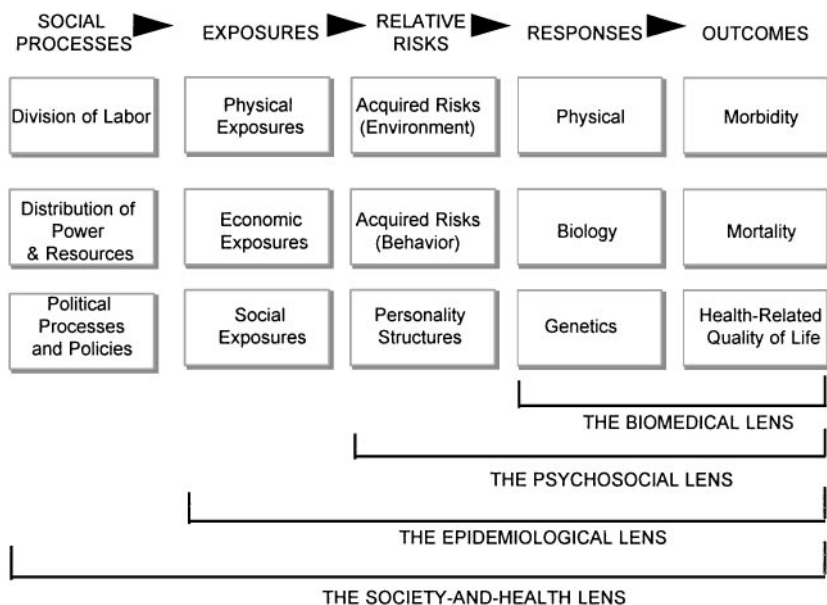


Figure 1 Alternative disciplinary lenses for factors influencing health outcomes. Adapted from Reference 223.

such as personality structures, a sense of control, and self-efficacy. It also makes recommendations for action at the individual and interpersonal levels—such as educational programs, skill building, and support groups. The epidemiological lens examines disease patterns within populations and aims to understand differential risk factors, including biological predispositions as well as behavioral and environmental exposures. By contrast, the society-and-health lens brings to the foreground cultural, social, economic, and political processes and aims to understand the ways in which these social structures influence differential risks (7–9, 106, 133, 168, 221, 225).

The social ecological model cuts across these disciplinary lenses and offers a theoretical framework that integrates multiple perspectives and theories (28, 135). This framework recognizes that behavior is affected by multiple levels of influence, including intrapersonal factors, interpersonal processes, institutional factors, community factors, and public policy. Recent reviews of the social ecological model underline the importance of several key principles. While many of the community-based studies reviewed here utilized intervention strategies that considered both individual and environmental influences, these concepts have been further defined since these earlier studies were designed. Drawing from the recent literature on the social ecological model, Table 1 identifies a set of core social ecological principles that may be used in defining operating guidelines for intervention design and implementation (11, 25, 30, 56, 77, 87, 88, 135, 152, 192, 199, 224).

Guided by the social ecological model, interventions planned at multiple levels of influence utilize various theories to inform and guide intervention and evaluation planning across each level. The workplace-based studies provide an instructive example of utilizing multiple levels of influence in the intervention. For example, the Working Well Trial drew upon several key theoretical models in targeting the *intrapersonal level*, where individual behavior change is the primary goal, including the social cognitive theory and transtheoretical model (38, 52, 53, 79, 90, 126, 127, 147, 160–162, 181, 217), while also targeting the *interpersonal level* via intervention activities focused on social support and social networks (13, 84, 85, 96, 102, 188). Working Well also included interventions targeting the worksite environment, drawing upon the literature on the diffusion of innovations (169, 191) and organizational change (83, 105).

Like most worksite-based interventions, however, Working Well did not address community and public policy factors. In contrast, Project Northland, a community- and school-based alcohol prevention study, did target community and policy levels. Of note, Project Northland achieved significant reductions of alcohol and tobacco use among the target population (158). Other strategies for addressing contextual issues, such as legislative mandates, pricing policies, restrictions on advertising, and availability of healthful products, deserve fuller

**Table 1** The implications of the social ecological model for community interventions<sup>a</sup>

Core social and ecological principles	Operating guidelines for intervention design and implementation
Physical, mental and social well-being are influenced by a variety of environmental factors.	Encompass multiple settings and life domains. Reinforce health-promoting social norms through existing social networks.
Personal characteristics and environmental conditions often have interactive as well as direct effects on well-being.	Target changes in the community or organizational environment, as well as in individual behaviors.
The degree of fit between people's biological, behavioral and sociocultural needs and the environmental resources available to them is a key determinant of well-being.	Tailor programs to fit the setting through participation of the community and target audience. Empower individuals to make changes.
Within the context of structured community settings, certain behaviors and roles exert pivotal influences on well-being.	Identify influential points in the community for promoting health. Utilize multiple delivery points and methods over an extended time period.
Examine links between physical and social conditions within particular settings, and the joint influences of multiple settings and life domains on persons' health over extended periods.	Address social conditions and recognize the social context of health behaviors in interventions. Implement coordinated interventions across multiple life domains.
Interdisciplinary research, linking the perspectives of public health, medicine, the behavioral/social sciences, and policy, is essential for developing comprehensive and effective health promotion programs.	Establish a collaborative, interdisciplinary research team. Link results of epidemiological research, intervention research, and policy analysis.

<sup>a</sup>Adapted from Reference 192.

testing and application in community intervention research. For example, preliminary reports suggest that ASSIST, which utilizes policy initiatives as part of its intervention approach to reduce smoking, is observing reductions in smoking prevalence (125). Similarly, the Tobacco Policy Options for Prevention study (TPOP) reported reduced smoking prevalence among adolescents in response to local policies enforcing limited youth access to tobacco in 14 Minnesota cities (74). Policy changes provide the basis for a health-promoting environment. As Breslow has described: "The aim must be to establish a health-promoting environment in the social space in which persons make health-significant decisions. The struggle is for the relevant space that various forces, some unconcerned with health and some actually detrimental to it, have thus far too largely preempted. Social ecology for health means deliberately occupying more of that social space and using it in the interest of health" (27). In essence, we

must “ignite and build a social movement”—at nongovernmental and policy levels (197)—in order to change broad-scale social norms and create a social environment supportive of health. Although many community-based studies have addressed multiple levels of influence on health behaviors, the results of the studies reviewed suggest that efforts to target the fuller range of levels within the social ecological model may be important in improving intervention effectiveness.

### *Addressing Social Inequalities in Disease Risk*

Inverse relationships between social class and disease have been found consistently across diseases (18, 21, 65, 93, 112, 129, 150, 182, 201). In addition, such differentials are increasingly prominent in the prevalence of health behaviors (124, 228). For example, education is the primary correlate of smoking status, with smoking prevalence at 38.2% among those with 11 years of education, compared to 12.3% among college graduates (33). Similarly, healthy dietary habits are more prevalent among those with greater education or higher income (98, 151). Other studies have similarly reported that persons with low incomes or low educational levels are especially likely to have multiple risk-related behaviors (57, 58). Data from the Stanford Five-City project confirmed that social class, as indicated by education, was associated with cigarette smoking, hypertension, serum cholesterol, and body mass index, with higher risk for those with lower education (227). To better understand these relationships, more comprehensive and consistently utilized measures of social class are needed (116).

Socioeconomic class influences the availability of an array of social and material resources that ultimately have profound effects on health (4, 86, 106). For example, the Alameda County Study identified multiple risk factors associated with low income, including smoking, obesity, unmet needs for food and medical care, living in an unsafe neighborhood, and lack of social supports (106). Graham (86) demonstrated the relevance of these socioeconomic factors for one risk-related behavior, smoking. She concluded that different dynamics drive the smoking habits of low-income women, compared to those in middle and upper classes: low-income women used smoking as a means of coping with their economic pressures and the resulting demands placed on them to care for others. Similarly, Romano et al (171) found that African-American individuals who reported experiencing high levels of stress associated with their socioeconomic circumstances, such as being out of work or not having enough money for basic needs, were more likely to smoke than those reporting less of this type of stress.

Even beyond the stressors associated with low income, social structure clearly shapes people's day-to-day experiences (7, 106, 221). To illustrate this link further, consider the ways in which the effects of income extend beyond purchasing

power, to influence daily life in diverse ways. Studies have shown that middle-class neighborhoods have proportionally more pharmacies, restaurants, banks, and specialty stores, whereas low-income areas have more fast food restaurants, check-cashing stores, liquor stores, and laundromats. Typical food purchases cost approximately 15% more in poor neighborhoods, and fresh produce may cost as much as 22% more than in higher-income areas. In addition, the quality of the food on average is poorer in low-income areas (203). Relatively higher food costs in low-income neighborhoods may in part be associated with limited access to supermarkets and reliance on small and medium-sized stores (46) in which the quality, quantity, and variety of both fresh fruits and vegetables and meats are limited (139). As a result, people living in low-income areas are much less able to meet their needs for healthful foods in their own neighborhoods. In order to improve the day-to-day realities of low-income populations, the public health response to social class differences in health behaviors must extend to structural changes, factors that clearly shape health behaviors. Broad-based policy initiatives designed to reduce social inequalities are likely to contribute to improved health at both the community and individual levels (7, 8, 106, 136).

The society-and-health lens offers an important means for understanding the social factors influencing health and a basis for crafting policy and environmental changes. Generations of researchers have documented the impact on health of social conditions, including class, race, education, and gender (7, 20, 60, 221). Social pathways such as social integration, social structure, residential characteristics, and the division of labor chart the impact of these social factors on health outcomes (6, 8, 106, 133, 152, 168, 221). There is, however, a clear schism between the findings of this epidemiological research and the typical targets of community intervention research. Increasingly, calls have been made for applying such an upstream perspective to community intervention efforts (8, 9, 106, 133, 221).

### *Involving Communities in Program Planning and Implementation*

Many community intervention trials have relied on community organizing principles as a means of involving communities in program planning and implementation. For example, SFCP, MHHP, and PHHP used the community organization typology of Rothman (175) to provide a fundamental intervention framework (62, 118, 122). Rothman identified three distinct models of practice within the framework of community organization: locality development, social planning, and social action. Locality development includes the processes of consensus and cooperation in building group identity, whereas the social planning model is task-oriented, stressing problem-solving and often utilizing

outside experts. The social action model incorporates both a task and process orientation, aiming to increase a community's problem-solving abilities and address imbalances in power and privilege between disadvantaged groups and the larger society (137, 175). The community-based cardiovascular disease prevention trials mixed social planning with elements of locality development (137). They focused on implementing key concepts of community organization related to relevance or "starting where the people are," and participation of community representatives in the change process. Comparable approaches were used in later studies, such as Treatwell, COMMIT, and the Working Well Trial (42, 183, 190).

The application of community organization principles in randomized controlled intervention trials creates an inherent tension between the need for standardization given the design, and allowance for flexibility in the intervention in response to community priorities. This flexibility enhances the possibility that the intervention will be suited to the needs and perceptions of specific audiences, thus increasing participation and intervention effectiveness. Following a clinical trials model, standardization of a clearly specified intervention makes it possible to interpret study outcomes. Unlike a clinical trial, however, in a community trial rigid specification of the intervention may actually inhibit its effectiveness because it is imposed by an external source rather than designed in response to the perceptions and characteristics of the community itself.

Several alternatives to address this tension between standardization and responsiveness to the community might be considered. In response to COMMIT's specification of mandated activities to participating community advisory boards, Fisher (68) described an alternative process in which investigators might define with the community the process by which the intervention could be developed or the range of choices communities could make. Thus, a trial might standardize the level of authority given to local groups to rank program objectives, choose among intervention characteristics, identify the range of groups that might be invited to program planning, or choose among channels of influence.

In addition, research conducted since the early community-based trials have expanded Rothman's model to incorporate other key concepts of community organizing, including community empowerment (137, 164, 222) and community competence (99). The next generation of community intervention trials can benefit from the latest research on empowerment, self-efficacy, social support and social networks, and community psychology to identify ways to improve community health through community organization and community building (137, 222). New methods are needed that provide for rigorous assessment of study outcomes while also enhancing intervention effectiveness through community participation and input. Increased community involvement

is likely to increase the amount of time needed for intervention planning and implementation, and may ultimately have implications for the cost of such studies. In the long term, however, application of these methods is likely to contribute to improved intervention effectiveness.

### *Incorporating Approaches for “Tailoring” Interventions*

The majority of community intervention trials have employed a one-size-fits all approach to intervention. The results of the studies reviewed above as well as others in the literature (23, 24) suggest that more intensive programs and those focused on populations with the greatest prevalence of the target risk factors are needed. “Tailoring” is one strategy that has been used at the individual level to target at-risk populations and improve intervention effectiveness. Tailored interventions typically use print communication (110, 167, 218) or telephone counseling (48) to enhance the relevance of interventions to the daily lives of the target population, thereby increasing the likelihood of achieving short-term and sustained intervention effects (3, 166). Individually tailored interventions are typically algorithm-based and utilize expert systems or computer-based programs to match a large library of messages to target individuals’ information needs and level of motivation, combining specific statements and graphics into a personalized intervention for a specific individual (48, 110, 166).

Most work to date using tailored interventions has occurred at the individual or micro level; a growing body of evidence supports the efficacy of these types of interventions (45, 167, 180, 195). In comparison to more intensive clinical interventions, individually tailored interventions offer the advantage of accomplishing the same kind of individual-matching of intervention strategies, but can be delivered at the population level. However, the appropriateness of individually tailored interventions has yet to be demonstrated with low socioeconomic groups, among whom behavioral risk factors are high. These interventions typically rely upon completion of extensive questionnaire batteries, conducted either by telephone or in person (218). Low-income populations may be less likely to complete extensive questionnaires that form the basis of tailored interventions, given that they may be less likely than higher-income groups to be accessible by telephone (165) or are more likely to have low literacy skills (111). Alternative strategies for delivering tailored interventions at the population level, such as using peer health advisors to deliver interventions in workplace (49) and in home-based settings, may expand the potential benefits to be derived from this approach.

Individually tailored interventions have rarely considered social contextual factors that may be critical for health behavior change to occur among socioeconomically and politically disadvantaged groups. Given the focus of tailored interventions on individual behavior change, to many community intervention



researchers tailored interventions may seem like a contradiction to the principle of targeting population-level change as a means of shifting the entire distribution of risk within the population (128, 173, 174). However, what appears to be an even distribution of risk may actually be an artifact of averaging (68). Shifting the distribution of risk in the population may require a departure from the one-size-fits-all intervention strategy in order to enhance the effectiveness of community interventions. It may be necessary instead to match, or tailor, the intervention with the distribution of risk factors in the population, which are concentrated in defined “pockets of prevalence” (3, 27, 68). Tailoring at the macro-level is consistent with social marketing approaches, which recommend that a target audience be “segmented” into subgroups with similar geographic, demographic, psychological, and problem-relevant characteristics (8, 26, 117). It is also consistent with “stepped care” strategies, which provide a method for intervening with entire populations, using a large number of strategies that, as a group, are responsive to individual needs, rather than treating all persons alike (3). Interventions may also be tailored to the unique needs and cultures of communities, including factors such as social class, literacy level, culture, or neighborhood of residence.

### *Utilizing Rigorous Process Evaluation*

In large community-based trials, especially where there is a reliance on participatory strategies and community involvement, it is important to assess the degree to which the intervention has been implemented as planned. Recent trials have included rigorous assessments of the implementation of interventions through process tracking systems measuring such indicators as dose, or the amount of intervention delivered; fidelity, or the extent to which the intervention was delivered as planned; and program coverage, including participation (44, 130, 131, 177). These data provide important information that enhances the ability to interpret outcome assessments, identify competing explanations for observed effects, and measure exposure to the intervention. (101, 132, 178). By building on this initial work in process evaluation, future community intervention trials will contribute to explicating the impact of intervention implementation on health-related outcomes.

An important outcome of process evaluation is the assessment of intervention “dose,” or the amount of intervention delivered and received by community members. Intervention dose varies markedly between the community intervention studies reviewed here, and the impact of dose on levels of outcomes observed remains unclear. In response to the small effect sizes resulting from some community trials, investigators have postulated that the intervention dose or intensity may have been insufficient, or that participation rates were too low (32, 82, 122, 123). Alternatively, the dose of intervention may have been

inadequate relative to other forces in the environment, such as an information environment already saturated with sophisticated advertisements and product promotions, promoting products from tobacco to fast foods (104). For example, in the Stanford Five-City Project, on average adults in the intervention community were exposed to 100 educational messages per year, estimated to be about five hours per year combined across radio, TV, and print media. In comparison, the average adult in the United States is exposed to 35,000 television advertisements alone per year, equivalent to approximately 292 hours (75).

Others have suggested that intervention effectiveness has been limited by the length of the intervention. For community-based interventions, Mittlemark and colleagues (138) recommended that the intervention period be at least five years, given the time it typically takes for the community to be mobilized into action. It may not be realistic to expect that large individual changes in lifetime habits will occur with complex behaviors, such as eating patterns, within the time frame of most community studies. At the organizational or community level, additional time must be built in for "institutionalization"; that is, the continuing process of building local, regional, and national capacity to mount permanent health promotion programs.

Evaluations conducted to date have not provided sufficient information to identify the most effective intervention dose. There has been little systematic research investigating the impact of intervention timing or length on behavior change outcomes. Decisions about dose and intervention length are typically driven by funding constraints, rather than by science. Further, the interaction between intervention dose and population characteristics has not been studied. For example, in workplace-based interventions it would be important to know more about the level of intervention dose that companies will accept and support. Information is needed on whether it is more effective to spread a given dose out over an extended period of time, rather than to compress it into a shorter time frame to maximize the population's focus on the intervention messages. Detailed and careful evaluation of issues related to intervention dose is an important part of the next generation of community intervention research.

## RECONSIDERING METHODS FOR EVALUATING COMMUNITY INTERVENTION TRIALS

In the early 1980s, both the National Heart, Lung and Blood Institute and the National Cancer Institute suggested a sequence of research phases for the development of programs effective in modifying behaviors (91,146). These phases of research range from hypothesis development (Phase I) and methods development (Phase II) to controlled intervention trials (Phase III) to studies

in defined populations (Phase IV) and demonstration research (Phase V). This range of research phases reflects the importance of methods development in providing the basis for large-scale trials, as well as the need for studies of the dissemination and diffusion process as a means of identifying effective application strategies. In the past two decades, however, studies have generally been funded with a focus on Phase III and IV trials; the trials reviewed here generally reflect that trend. The few exceptions have included Phase V studies, such as ASSIST.

The design and evaluation of controlled community intervention trials have been discussed at length in the literature (75, 89, 113, 115, 141, 179). In general, the randomized controlled design is the widely accepted paradigm for assessing the effects of community interventions (115, 197). This review highlights the importance of several design and evaluation issues in applying randomized controlled designs to community intervention research.

**UNIT OF INTERVENTION AND EVALUATION** The community or organization is the appropriate unit of allocation in these trials, since interventions are aimed at entire populations. Randomization by cluster or group is necessary to avoid contamination between individuals assigned to different intervention groups. Also, in many studies, the interventions are, by definition, conducted at the group level, given the social influences on health behaviors (89, 114).

Using the cluster as the unit of allocation limits the number of units that can be included in community intervention trials, given cost and feasibility concerns. The small number of units may restrict statistical power and may also contribute to selection bias, particularly in cases where the allocation of communities or organizations is nonrandom (89, 115, 138, 141).

Since the cluster is the unit of randomization and intervention, it is important to assess the effectiveness of the intervention in the cluster as a whole. Following the principle of "intention to treat," all members of the community or organization must be included in the evaluation, regardless of their exposure to the intervention. Thus, the intervention is generally assessed in a sample of eligible members of the community or organization—not only among those sufficiently motivated to participate in the intervention. For this reason, community trials tracking change in the entire community are likely to observe smaller effect sizes than other studies tracking change in intervention participants alone.

Although the unit of assignment is the cluster or group, primary outcomes are generally measured at the individual level. Drawing inferences at both levels—the individual and the cluster—is important. It is possible to use the community or organization as the unit of analysis, which is especially appropriate for environmental outcomes. Where the intention is to draw inferences at the individual level, it is necessary to control for cluster in analyses (54, 55, 113). Cluster

members cannot be assumed to be independent, since individual community residents or worksite employees are likely to share a variety of characteristics.

**SELECTION OF PRIMARY OUTCOMES AT THE INDIVIDUAL LEVEL** The overall aim of these community intervention trials is morbidity and mortality reduction. Results from the North Karelia study documented the importance of health behavior change in cardiovascular disease reduction. The three cardiovascular disease prevention studies—MHHP, SFCP, and PHHP—similarly tracked change in cardiovascular disease morbidity and mortality. For most intervention studies, however, it is not possible to follow participants long enough or in sufficient numbers to determine the long-term costs and consequences of the interventions in terms of survival, quality of life, and disease incidence. Instead, this research rests on epidemiologic evidence to link behavioral outcomes to health benefits, such as reductions in morbidity and mortality.

To determine the cost-effectiveness of these trials, however, estimates of the health benefits are needed; such analyses are crucial in order to identify the magnitude of health behavior change needed to produce meaningful disease reductions. Tracking long-term change in health outcomes may be difficult in worksite-based intervention studies, where employees may leave the worksite long before disease events occur; or in school-based studies, where long-term tracking may not be feasible. Simulation models offer an important alternative method for projecting the implications of changes in behavioral risk factors at the population level (202). Such forecasts can help set priorities for research and development of preventive strategies by identifying areas of effective prevention.

**COMMUNITY-LEVEL ASSESSMENTS** Evaluation of the community or organizational environment is important for several reasons. Community-level outcomes provide necessary indicators of the effectiveness of environmental interventions, which may target such changes as local legislation restricting youth access to tobacco (74) or worksite cafeteria offerings of healthy foods (17). In addition, environmental assessments may provide indicators of change preceding individual outcomes, provide alternative measures of change in addition to self-reports, and may identify competing explanations for observed individual outcomes (36, 37, 114, 133, 134). Community-level indicators offer the added advantages of being substantially less costly than large-scale data collection from individuals, and of being less susceptible to bias resulting from the inability to blind subjects to condition (113).

**ASSESSMENT OF MEDIATING AND MODIFYING MECHANISMS** Clear specification of the theoretical or causal model guiding the intervention is needed in order to clarify the ways in which the “black box” of the intervention is expected to

work (51, 113, 115). This black box may include mediating mechanisms, meaning the pathways by which the intervention will influence the outcomes, such as motivation to change or social support for health behavior change. In addition, this black box may also include modifying conditions, or the factors that are not influenced by the intervention but can independently influence outcomes, such as social class, race and ethnicity, and neighborhood characteristics. To elucidate the specific mechanisms by which change occurs, the development of theoretical models that integrate individual-level factors with those at the levels of the community and social context are needed. Although the level of specificity of theoretical models has increased since the initial community-based intervention trials were conducted, not all studies have fully specified theoretical models to guide the interpretation of results. In addition, few studies have clearly articulated the key hypothesized mediating variables, and fewer still have measured and evaluated the impact of mediating and modifying mechanisms. Although some heuristic frameworks and models suggest strategies for targeting multiple levels of change (47, 89, 92, 135, 192), many current theoretical models are limited by their focus on the individual level. Baranowski and colleagues (12) call for a priority to be placed on research that increases understanding of the relationships between outcomes and variables defined by theory, and the impact of community interventions on these mediating variables. The assessment of mediating mechanisms also needs to take into account the dose and type of intervention delivered, as described above in the discussion of process evaluation.

**TIMING OF THE ASSESSMENTS** Most of the studies reviewed here included only post-intervention follow-ups, and therefore have not evaluated long-term or delayed intervention effects, although there are a few interesting exceptions. The Stanford Five-City Project's three-year follow-up suggested that maintenance of observed changes was clearly feasible (229). In the two worksite studies that included extended follow-ups, one found a delayed treatment effect for serum cholesterol level at 6- and 12-months (31), and the other reported that a substantial intervention effect was maintained through the two-year post-intervention assessment (176). Assessing behavioral outcomes only at the completion of the intervention may reflect a mismatch between the research timeline and the timeline of change as it occurs in settings such as workplaces and communities, and therefore may underestimate intervention impact.

**SAMPLING ISSUES** Formative research is needed to identify strategies to increase the representativeness of samples, both at the level of the community and the individual. Communities or organizations selected for inclusion in the study must be representative of a larger population of communities or organizations,

and individuals surveyed as part of the outcome assessment must represent the community or organization from which they were sampled.

Although school- and community-based studies have seldom provided information about the representativeness of the community or school, worksite participation rates have often been reported and provide instructive information on the importance of estimates of the representativeness of the organizations or communities. At issue is that the self-selection of worksites into the studies may contribute to a response bias at the worksite level. In these studies, between 25% and 62% of eligible worksites invited to participate actually joined the study. When compared to other worksites, participating worksites have been found to have more health promotion programs (95). In comparison to companies declining participation, recruited worksites have been reported to have more favorable financial outlooks and to employ fewer workers (16). The potential for response bias may contribute to the observed secular trends in comparison worksites, perhaps reflecting a "healthy worksite" effect in which already "healthy" worksites are most likely to participate in studies. Assessment of the potential representativeness of communities or organizations included in intervention trials may contribute to the interpretation of study results, particularly when results observed in control communities do not reflect national or regional trends (122, 190).

Response rates of individuals to surveys have also varied across studies. Differential response rates are of particular concern; in the worksite trial that found no significant effects—Take Heart I (82)—the response rate was 20% higher in the control group than in the intervention group, a factor potentially capitalizing on secular trends, and thus masking intervention effects. Similarly, inferences drawn from community-based intervention studies utilizing a cohort are highly dependent on response rates, which have also varied considerably across studies. Formative research may provide guidance on strategies for improving response rates, especially among populations less likely to respond to surveys, such as those with low levels of education or literacy.

### *Research Methods for the Next Generation of Community Intervention Research*

Developing and testing community interventions that are effective in reducing risk-related behaviors require many levels and types of research (69, 89, 91). Unfortunately, by comparison to the randomized controlled trial, nonexperimental approaches have been classified as being less scientifically rigorous. Recently, however, questions have been raised about the appropriateness of the randomized controlled trial for addressing the research questions posed in community intervention trials (132, 152, 197). The randomization of communities to condition raises challenges for intervention research in terms of both expense and statistical power (114, 141). The restricted hypotheses that the

randomized controlled trial is able to test may fail to consider the complexities of communities (197). In addition, as noted by Fisher (68), the randomized controlled trial may actually alter the interaction between the intervention and the community, resulting in an attenuation of the intervention's effectiveness. McKinlay (133) has further argued that the randomized controlled trial is not appropriate for community intervention research targeting upstream interventions, but may rather be more appropriate for downstream interventions in which individual behavior change is the target. At the level of sociopolitical intervention, experimental control may not be possible, especially when change is unplanned.

An expanded range of research methodologies is required to address the diverse needs for scientific rigor, appropriateness to research questions, and feasibility in terms of cost and setting. By inclusion of the full range of phases—from hypothesis generation to demonstration research—it may be possible to develop a more balanced and diversified approach. Indeed, the research phases described above need not progress in a linear pattern, but rather function as a cyclical process, with feedback to hypothesis generation and methods development as needed. Although the reliance on the randomized controlled trial has perhaps limited our insights into the effectiveness of community interventions, abandoning it is not the answer. Rather, the randomized controlled trial must be supplemented with other research methods. It is time to diversify our methodologies, to triangulate our data collection strategies, and expand our armamentarium of study designs. Consider, for example, several possible options that have been underutilized in much community intervention research to date:

**OBSERVATIONAL STUDIES** Susser (197) has argued that observational studies provide a no less valid and necessary method than do randomized controlled designs, and offer both practicability and generalizability. Such studies may also provide information about the process of community change and the ways that interventions may be developed to fit with this process (75).

**QUALITATIVE RESEARCH** These methods may provide further insight into our interpretation of the results of quantitative studies (75, 133). In addition, qualitative methods are an important tool in formative research, and they play a role in program development. Qualitative research methods can be used to define the program's goals and objectives, select the most promising target audience, identify appropriate delivery channels, design educational materials, track audience exposure and reaction, and, finally, refine the program (78).

**ACTION RESEARCH** Israel and colleagues (100) and others (59, 70, 168) have advocated for the use of action research methods as a means of incorporating participants into the research process, thereby also potentially enhancing intervention effectiveness. By giving communities a voice, public health researchers

and funders may need to be ready to expand the scope of trials in response to the outcomes communities define as priorities.

**METHODS DEVELOPMENT RESEARCH** Targeted studies may also provide the basis for refining the large-scale intervention designs and enhance our understanding of methods to influence group behavior and social change (68, 197, 226). Such research also needs to borrow from “stepped care” approaches for tailoring interventions at the community level (3, 149).

**DURABILITY AND DISSEMINATION RESEARCH** Two important questions have received little attention in community intervention research: (a) What intervention characteristics contribute to sustainable programs that can be “institutionalized” within the community or organization? and (b) What are effective methods for diffusing or disseminating effective intervention models? “Institutionalization” of interventions refers to the extent to which the program becomes embedded within the host organization (83, 191). Research is also needed to identify effective methods for disseminating tested intervention models (148, 170).

As a fuller range of research methodologies is applied, we must critically examine the conditions under which it is most appropriate to utilize randomized controlled trials within community settings. Given their expense, launching large-scale disease prevention intervention trials may be most appropriate when:

1. Evidence from earlier phases of research supports the potential efficacy or effectiveness of the intervention;
2. A study is able to answer questions that cannot be addressed in smaller scale studies;
3. The research design is consonant with the phase of research and the research questions being asked.

In addition, standards of excellence must guide the intervention and research methods utilized in community intervention research. To maximize their effectiveness, interventions must be theory-driven, address multiple levels of influence, and pay particular attention to structural factors and the influence of the social context on health behaviors. Interventions will be most effective when they are adapted to the community setting, giving voice to community priorities. Comprehensive evaluations must include: (a) outcome assessments based on validated measures appropriate for use at a population level; (b) assessment of mediating and modifying mechanisms; (c) methods for assessment of intervention implementation; (d) methods for tracking secular trends;



(e) assessment of community-level changes; and (f) extended follow-up assessments beyond the conclusion of the intervention.

## THE RECIPROCAL AND CUMULATIVE INFLUENCE OF COMMUNITY INTERVENTION RESEARCH

The results of the community intervention trials reviewed here must be understood within the historical context in which they occurred. These large-scale public health trials were both a *response* to mounting evidence on the important role of health behaviors in disease prevention, evidence that was increasingly available to the lay public; and an additional *voice* in the growing public discussion promoting health behavior change. This public discussion contributed both to health behavior change among individuals and to policy and environmental change initiatives in support of individual health behavior changes.

Indeed, the impact of population-wide efforts to modify risk-related behaviors are beginning to be observed, both in terms of behavior change and declines in morbidity and mortality. Deaths from cardiovascular diseases have declined dramatically, from 512.1 deaths per 100,000 in 1968 (209) to 362.1 deaths per 100,00 in 1995 (213). In the United States, cancer mortality has declined for the first time since such records were kept, with a total reduction of 5.4 cancer deaths per 100,000 (40). These changes in chronic disease morbidity and mortality reflect considerable alterations in the health behaviors of the US population. For example, according to Cole & Rodu (40), the decline in smoking contributed to reduced cancer deaths by about 2 deaths per 100,000, over one third of the total decline. Bailar & Gornik (10) have argued that further progress in reducing cancer mortality depends on an increased emphasis on prevention. Since 1965, the proportion of Americans who smoke has decreased from 42.4% to 25.5% (34, 35). Recent data from the Department of Agriculture indicate that, on average, Americans are now consuming about four and one half servings of fruits and vegetables per day, up from approximately 3.9 servings in 1989–91 (142). Similarly, Americans' consumption of high-fat foods such as red meat and lard has decreased substantially (205).

Although dramatic changes have not been uniformly observed for all behavioral risk factors, these trends indicate a strong movement toward improved health behaviors. Many of the trials reviewed here have observed remarkable changes in the comparison groups. In some cases, the secular trend outpaced the level of hypothesized changes in the outcomes. For example, although MHHP observed few significant net changes, there were beneficial and strong secular trends for both sexes across risk factors, except for weight and for smoking in women. Among these changes, total blood cholesterol dropped by 11 mg/dL,

which represents about a 5% change (122). Similarly, in Working Well, although the six-month abstinence rate in the intervention sites was 13.8%, the rate in the control group was 12.3% (190). The forces promoting change in the intervention communities have extended to the general public, and comparison groups have not been exempt from this trend (67, 104).

These secular trends toward improved health behaviors are not surprising in light of numerous social and environmental changes that coincided with the implementation of these community intervention trials. Using tobacco control and nutrition-related milestones as examples, Figure 2 and Figure 3 illustrate some of the remarkable social, political, and public health events that clearly shaped social norms, altered available products, and changed patterns of tobacco and fat consumption in the United States over the past three decades.

Figure 2 traces the decline in percent of calories as fat from 40.1% in 1977 (204) to 34.4% in 1990 (205) to 32.9% in 1994 (206), and the increase in the public's concern about fat in the diet from a low of 8% (72) in 1984 to a high of 65% in 1995 (73). Not shown in the figure, the consumption of fruits and vegetables increased from 308 pounds per capita in 1970 to 382 pounds per capita in 1994 (207). As a backdrop to these changes, the figure also plots nutrition-related milestones that occurred between 1972 and 1996, the period preceding, during, and immediately following the implementation

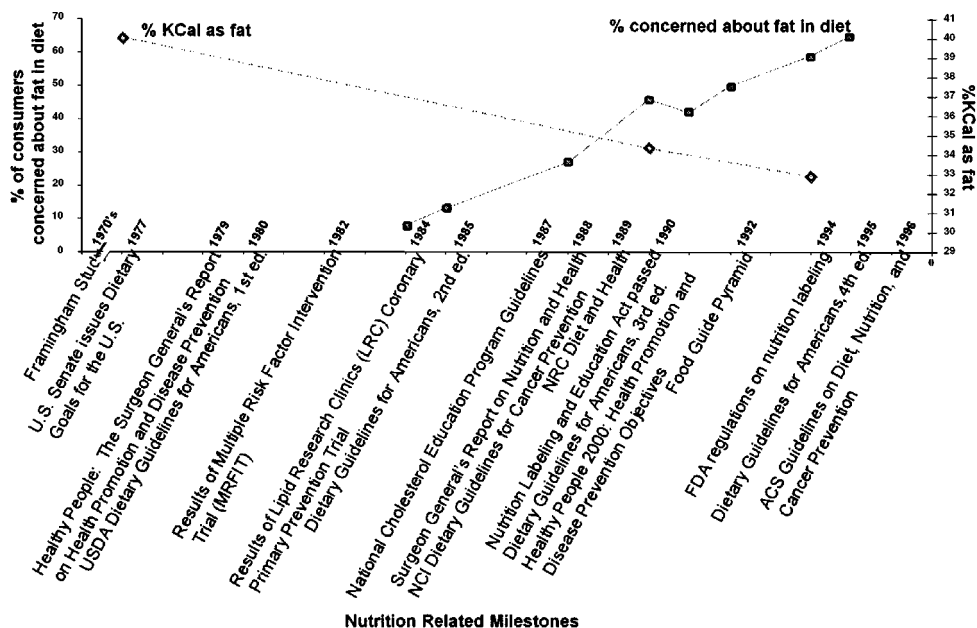


Figure 2 Fat consumption and nutrition-related milestones (1970–1996).

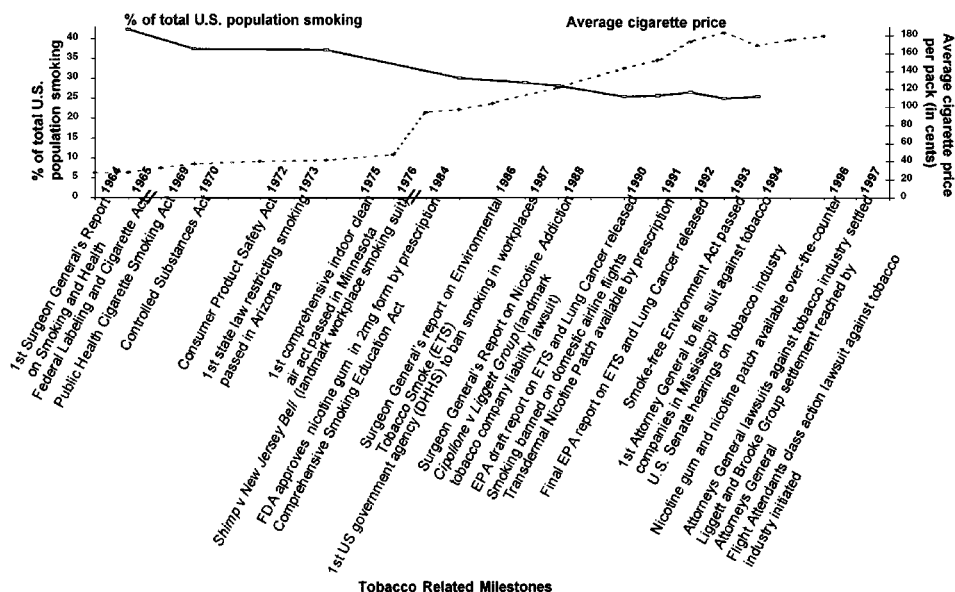


Figure 3 Smoking prevalence, cigarette price, and tobacco-related milestones (1964–1997).

and evaluation of major community-, worksite-, and school-based trials. During this period, there was constant growth both in scientific knowledge of the relationships between diet and health, including results from the Framingham epidemiological study (50) establishing definitive relationships between dietary fat, dietary cholesterol, blood cholesterol, and coronary heart disease; and from the Lipid Research Clinics Coronary Primary Prevention Trial on the efficacy of cholesterol lowering in reducing risk of coronary heart disease (120, 121). Based on these findings, several government agencies and health organizations published guidelines and introduced public education campaigns to aid health care providers and public health practitioners in translating research findings for the general public (119, 145, 208, 211, 212, 215). By 1997, 51% of shoppers interviewed in the annual Food Marketing Institute survey reported always reading the nutrition label when buying a product for the first time (73). Not shown on Figure 2, the marketplace also responded to consumer concerns about dietary fat by markedly increasing the availability of nutritionally improved foods. Indeed, in 1996 alone, 1200 new reduced-fat and reduced-cholesterol products were introduced into the market (196).

Figure 3 plots tobacco control milestones occurring between 1964 and 1997, reflecting important societal changes contributing to the decreased social acceptability of smoking. Smoking prevalence decreased from 42.4% in 1965 to 25.5% in 1994 (34, 35), whereas the average price of a pack of cigarettes

rose from 27.9 cents to 169.3 cents (200). In the past three decades, there have been remarkable changes influencing public attitudes about smoking, beginning with the first Surgeon General's Report on Smoking and Health in 1964, which concluded that smoking is a cause of lung cancer (216). Legislative actions included the 1984 action requiring rotating warning labels on cigarette packages, and later legislation to reduce smoking in public settings, including on domestic airline flights. Significant credit for the shift in social norms may also be traced to the reports about the impact of second-hand smoke on non-smokers' risk of lung cancer and other diseases, offered by the Environmental Protection Agency (EPA) (214), the Surgeon General (210), and the National Institute of Occupational Safety and Health (NIOSH) (144). This evidence laid the foundation for increasing restrictions on smoking in public places. Increasing availability of nicotine replacement products provided new supports for cessation. The tobacco industry has come under increasing pressure, with law suits filed by numerous state attorneys general to recapture tobacco-related health care expenditures. As a result of these varied actions, the social context for smoking in the United States has been irrevocably altered.

In summary, a major factor in the net effects observed in the community intervention trials reviewed here is the impact of secular trends. The profound impact of the favorable secular trends leads us to ask: How can we replicate and indeed accelerate these trends? Although examination of secular trends relies on ecological inferences, the potential benefits of system-level changes are apparent. Few community-based intervention trials have utilized policy interventions to promote change, although the exceptions are promising [see ASSIST (125), TPOP (74)].

The field of public health walks a fine, often undefined line between research and advocacy. In observing the secular trends found in comparison communities, public health researchers need to take responsibility—and credit—for cultivating a social environment that promotes policy initiatives and social norms supportive of health (64, 138). These secular trends present a challenge for public health research, but also represent an accomplishment. Researchers involved in the conduct of these intervention trials have been part of the social movement that has generated a change in consciousness about health risks and behaviors (67, 197, 226).

## CONCLUSION: USING PUBLIC HEALTH STANDARDS TO INTERPRET THE RESULTS OF COMMUNITY INTERVENTION TRIALS

Evidence has begun to demonstrate the population-level significance of the results of community intervention trials. A recent study estimated the cost-

effectiveness of population-wide strategies to reduce serum cholesterol, using the changes achieved in the North Karelia and Stanford Five-City Projects as standards for comparison. The authors concluded that community-based interventions to reduce serum cholesterol are cost-effective if serum cholesterol is reduced by only 2% or more (202). Similarly, recent estimates by Colditz & Frazier (39) suggest that if the entire population increased their level of physical activity by 30 minutes of brisk walking each day, colon cancer incidence alone would be reduced by 15%. Additional studies are needed to inform interpretations of population-level interventions by translating intervention effects into population-level benefits in disease rates.

As Rose observed (173, 174), small changes in behavior observed across entire populations are likely to have large effects on disease risk. However, interpretations of the results of community intervention trials continue to apply the standard of clinical significance in assessing the value of the magnitude of the results of these trials. The standards used for interpretation of the results of community intervention trials must be based on the public health significance of these effects, in line with the underlying foundation of these trials. Indeed, critiques of the magnitude of these effects have too often ignored the difference between clinical relevance and public health significance. The *impact* of an intervention is a function of its *efficacy* in producing individual behavior change, and its *reach*, defined as the penetration of the intervention within the population (3). The magnitude of the individual changes observed in community intervention studies is likely to have substantial public health implications when assessed in terms of overall impact, not just efficacy. Use of new research strategies and paradigms will maximize what can be learned from the next generation of community intervention research.

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