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Editorials

The Future of Community-Based Cardiovascular Disease Intervention Studies

In 1959, health professionals in the United States initiated the first major response to the cardiovascular disease epidemic by calling attention to the primary cardiovascular disease risk factors: cigarette smoking, high blood pressure, and elevated plasma cholesterol.[1] Interventions aimed at modifying these risk factors began in the 1960s, using a medical model approach that focused on the identification and treatment of high-risk individuals.[2–5] Even though this approach was effective at the individual level and raised the awareness of risk factors among health practitioners and the general public, it had little impact on the social factors that influence cardiovascular disease risk. It was logical, therefore, to consider a primary prevention, public health model that attempted to change the distribution of risk factors at the community level.

This public health model is being tested in the United States by three investigator-initiated, community-based field trials funded by the National Heart, Lung, and Blood Institute. These trials assume that personal health behaviors are dominant forces in the development of cardiovascular disease. In addition, these trials approach cardiovascular disease risk reduction by facilitating adoption of health practices in entire communities.[6] The goal of these trials is to document significant declines in cardiovascular disease risk factors that will lead to declines in cardiovascular disease morbidity and mortality beyond the declines in risk factors that are attributable to secular trends.[6] These studies follow the earliest US community-based cardiovascular disease control effort, the Stanford Three-Community Study in California. This study, which was initiated in 1972, showed significant net improvements in the reduction of smoking rates, cholesterol levels, and blood pressure levels in intervention cities over control cities.[7]

The three current US studies are among the most comprehensive cardiovascular disease risk reduction studies undertaken. The Stanford Five-City Project, funded in 1978, includes two intervention cities and two control cities; a third control city contributes only morbidity and mortality data.[8] The Minnesota Heart Health Program, funded in 1980, includes three intervention cities and three control cities in Minnesota and the Dakotas.[9–10] The Pawtucket Heart Health Program, which was funded 1 month after the Minnesota program, includes one intervention city in Rhode Island and one control city in Massachusetts.[11] All three studies address the prevention, treatment, and control aspects of smoking, hypertension, high dietary fat, obesity, and physical inactivity. They include multifactor risk reduction education programs lasting from 5 to 8 years and use media and direct, interpersonal education programs both for the general public and health professionals. In addition, community organization strategies for these studies were designed to create institutional and environmental support for educational goals.

Although morbidity and mortality have not been reported yet for any of the studies, risk factor changes are available for the Five-City Project and the Minnesota program and will be available soon for the Pawtucket program. The Five-City Project documents strong favorable secular declines in a broad set of cardiovascu-

Editor's Note. See related article by Luepker et al. (p 1383) in this issue.

lar disease risk factors in treatment cities as well as in control cities. For the population-based cohort sample (individuals followed over time), improvements in health knowledge, blood pressure, and smoking, but not in plasma cholesterol or obesity, are significantly greater in the treatment cities than in the control cities.[12–14]

In this issue of the Journal, Luepker et al.[15] report the main risk factor findings from the Minnesota Heart Health Program. Similar to the Five-City Project, the Minnesota program documents strong, secular trends in health promotion activities and risk factors in all study communities. However, net improvement of risk factors in treatment cities over control cities is modest, generally limited in duration, and usually within chance levels. The authors of the study conclude that the Minnesota program was unable to generate enough additional exposure in a sufficient proportion of the population to exceed the "remarkably favorable secular trends that were ongoing in the study communities."

It is tempting to criticize the modest or negative results of the current cardiovascular disease intervention studies. The results, however, should be evaluated within a broader context that assesses limitations as well as strengths of community-based designs. As noted by Mittelmark et al., community-based outcome research includes "a plethora of problems," such as too few analysis units, too many sampling difficulties, and most important, strong secular trends in control cities—all of which compromise the ability of even the best-endowed studies to detect statistically significant treatment effects.[16]

Indeed, the secular trends in the Minnesota program are even greater than previously observed in the National Health and Nutrition Examination Survey.[17] Contributing to the secular trends during the 1970s and 1980s was the acceleration of health promotion via the popular press; increased health promotion activities by such voluntary health agencies as the American Heart Association and American Cancer Society; and the advent of such broad-based federal programs as the National High Blood Pressure Education Program,[18] the National Cholesterol Education Program,[19] and the American Cancer Society's Great American Smokeout.[20]

Contributions of the three National Heart, Lung, and Blood Institute community-based studies, however, are significant on several fronts. These studies provide valuable models, methods, and strategies for planning and conducting community-based interventions. They have advanced community organization and activation principles, social marketing theories, and evaluation theory and practice.[21] In addition, these studies have developed a wide array of risk reduction-health promotion methods and materials that are the foundation of countless cardiovascular disease control programs, both in the United States and abroad. These studies' methods, created and tested in "real" environments, penetrate further and are more generalizable than methods from clinic-based trials. When evaluated individually, numerous intervention components (e.g., smoking cessation methods, self-help kits, restaurant menu labeling programs, school-based dietary interventions) have been shown to be successful risk reduction strategies.[22–29] Finally, the methods and materials have gained high acceptance at the community level. They have been adopted and maintained by local groups and have been extended to other prevalent chronic diseases (e.g., cancer, diabetes, osteoporosis) that share common life-style correlates.

Another major scientific contribution of these studies is the documentation of secular declines in cardiovascular risk factors among population-based samples of women and men during the 1980s. Surprisingly, few cross-sectional data reflect trends in risk factor levels within geographic regions, and few data use standardized blood pressure and cholesterol measures and biochemically confirmed smoking status. Both the Five-City Project and the Minnesota program document strong declines in multiple risk factors in intervention cities and control cities, with favorable changes occurring in both women and men and across all age and educational levels.[30–31] It is likely that the impact of these risk factor changes on coronary heart disease mortality will be considerable. In his 1981 review of coronary heart disease primary prevention strategies, Jeremiah Stamler concluded that "it is a reasonable inference, given all the facts, that the positive changes in lifestyles and risk factors among Americans relate causally to the decline in coronary mortality rates."[32] Certainly, there is little doubt that the behaviors at issue owe their decline to the social movement that generated a change in consciousness about health risks and life-style behaviors. The question, perhaps, is how community-based interventions can outpace the changes already induced by the forceful, ongoing, contemporary health promotion movement.

How, then, should the next generation of studies proceed to advance the public health approach to cardiovascular disease risk reduction? Should we conduct larger multicenter trials to enhance the possibility of demonstrating stronger treatment effects at the community level? "Bigger and better" probably is not the solution; multicenter trials are more appropriate for single risk factor studies, are limited in size, and are extremely costly. Nor is ending community-based studies the solution. Few would disagree with the community approach to cardiovascular disease control, which includes a high degree of generalizability, cost effectiveness due to the use of mass communication methods, diffusion of information through increased discussion about health, and the ability to influence environmental, regulatory, and institutional policies that enhance health. Still fewer would argue against strategies that encourage people to stop smoking, undergo blood pressure screening and treatment, lower dietary fat consumption, and exercise regularly.

The future of community-based cardiovascular disease studies may lie in a combination of approaches. Luepker et al. suggest that community programs built around public policy initiatives, combined with the more traditional health education strategies of the 1980s, may be an effective combination that was not possible when broad-based community support was lacking.[15] The three National Heart, Lung, and Blood Institute community trials provide the basis for this evolving model. In addition to these broad-based studies, there is a need for smaller, more focused studies within communities, especially studies that target population subgroups that have not been reached successfully (e.g., ethnic minority groups, adults with low literacy levels, older women).

We have learned that communities are heterogeneous and have differential responses to interventions.[33–34] Perhaps communities in most need of appropriate targeting are those that include individuals from lower socioeconomic groups, who have disproportionate levels of smoking, hypertension, high cholesterol, and obesity.[31,35] Despite the multiple cardiovascular disease activities during the 1980s, the disparity in risk factors and mortality between the upper and lower socioeconomic status groups increased.[36,37] This continuing disparity was documented by

the Five-City Project, the Minnesota program,[30-31] and the Pawtucket Heart Health Program.[38] Although low socioeconomic status often is considered synonymous with ethnic minority status, it is important to recognize that most socioeconomically disadvantaged individuals from the Five-City Project and the Minnesota program were White. These individuals are part of the largest subgroup of America's poor—23.0 million Whites, 9.5 million African-Americans, and 4.8 million Latinos live below the poverty level.[39] We must remember that ethnicity is not a proxy for social class; the influence of both on cardiovascular disease risk must be considered and evaluated by community-based studies.

Evaluation of cardiovascular disease risk reduction studies remains challenging. The difficulties of risk factor and disease surveillance illustrate the need for community-based programs to demonstrate links between intervention strategies and audience exposure and behavior change.[40] Evaluations must be broadened from biomedical outcomes to proximal effects and social factors that influence the distribution of risk factors.[40-41] Qualitative parameters are important aspects of evaluation, which, like quantitative parameters, need to be measured at the individual, organizational, and environmental level.[16,42]

Our charge as health professionals is to use the wealth of knowledge produced by community-based cardiovascular disease intervention studies wisely. We should modify and improve the community studies carried out in the 1980s by coupling public policy initiatives with health education strategies, developing more focused studies that target high-risk groups, and broadening our evaluation concepts. These methods and approaches will form the basis of cardiovascular disease prevention programs in the 1990s. With success, they will become imbedded in a social movement that will ensure that all Americans, regardless of socioeconomic status, are actively engaged in cardiovascular disease prevention activities that lead to improved lifestyles and control of major risk factors. □

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The Impressionable Fetus? Fetal Life and Adult Health

Fetal life, once a subject of interest to only a minority of medical practitioners and public health officials, now commands the attention of anyone concerned with the prevention of heart disease, cancer, hypertension, diabetes, or schizophrenia. This development, which oddly parallels the rise of interest in fetal life in the political arena, is attributable to the recent publication of several studies that purport to have traced the origins of common diseases in adults to disturbances of fetal development. These studies seem to hark back to the age in which the experiences of the mother during pregnancy were seen as "impressing" themselves upon the fetus, determining risk of congenital anomalies and later temperament, among other things.[1]

The best-known modern fetal impression studies are those of Barker and colleagues, which relate measures of birth size—birthweight, head circumference, length, placental weight, and their interrelationships—to impaired glucose tolerance,[2] hypertension,[3] and ischemic heart disease[4] in middle-aged to elderly British men and women. Impaired fetal growth, interpreted as reflecting restricted fetal nutrition in pregnancy, appears to increase the risk of chronic diseases whose clinical onset is often detected as many as 5 or 6 decades later. Another line of investigation links birth anthropometry to hormone-dependent cancers in women. Here, the hypothesized relationship is reversed, with higher rates of fetal growth (thought to reflect larger amounts of circulating estrogens in utero) tending to be associated with higher risk of breast cancer.[5]

In this issue of the Journal, three articles connect fetal life experiences to later health states. Two articles find no relationship between exposure and outcome. Sampson et al.[6] find that carefully ascertained alcohol intake during pregnancy is not associated with height, weight, and head circumference of the offspring at age 14, even though in other analyses of the same data set, prenatal alcohol intake was associated with these measures at birth and with neurodevelopment and behavior in adolescence.

According to Wilcox and his colleagues, nutritional and other forms of deprivation associated with the German occupation of Norway during World War II, while capable of affecting growth, sexual maturation, and childhood mortality, failed to alter perinatal mortality.[7] Nor did women born during this stressful time experience any apparent adverse effect on their own reproduction a generation later, though data on the early phase of their childbearing (to about their mid-twenties) were not available. On the other hand, Kandel et al.[8] find, in two separate data sets, a striking relationship between maternal smoking in pregnancy and the risk that the exposed daughter, but not the exposed son, will take up smoking in adolescence.

In studies of the later effects of fetal exposures, two difficulties commonly arise—lack of singularity of the exposure and uncertainty about timing of the exposure. The timing issue itself has two components:

1. Does the exposure exclusively reflect events during pregnancy and not events before and after pregnancy?
2. What epoch of pregnancy was affected by the exposure?

Anthropometric measures at birth are the end result of a complex mixture of exposures and susceptibilities. Even as a measure of fetal growth, birthweight is meaningful only when pregnancy duration is taken into account. In turn, fetal growth can be taken as a measure of maternal nutritional intake in pregnancy only when the great variety of preconceptional influences on fetal growth rates is considered. These include the mother's birthweight,[9] maternal age, parity, maternal and possibly even paternal size,[10] and sibling birthweight.[11] Table 3 in the article by Sampson et al., for example, lists eight preconceptional variables that in their data have a correlation coefficient of 0.1 or greater with birthweight.

Most important, social stratification is reflected in rates of fetal growth, and in developed countries, this effect is unlikely to be entirely nutritional. Thus, not only does birthweight carry with it information on events preceding the pregnancy, but it also serves as a marker for events occurring after birth, because the social and environmental conditions that produce low birthweight are likely to continue to operate on the infant and child postnatally. A population with lower than average birthweight is a population whose subsequent education, housing, and employment will likely differ from that of other populations.

In addition, we must not forget that fetal growth appears to be affected by

Editor's Note. See related articles by Sampson et al. (p 1421), Wilcox et al. (p 1463), and Kandel et al. (p 1407) in this issue.