

Community-based Health Intervention Trials: An Overview of Methodological Issues

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INTRODUCTION

Health interventions applied on a community-wide basis have come into increasing use in public health and epidemiologic research over the past several decades. With the promise of community-based interventions as a means of increasing the generalizability of health program benefits, providing information to health policy-makers beyond that obtained by individual-based clinical trials, and improving health in a cost-effective manner (1), researchers have forged ahead to expose numerous communities to large-scale health interventions. The emergence of community health intervention trials represents a shift in health research from investigations that focus primarily on the individual to those that focus on larger community groups. This emphasis on interventions focusing on communities has created distinct methodological challenges for researchers.

In this paper, we provide an overview of major methodological issues pertaining to community-based intervention trials as compared with the more traditional, individual-based clinical intervention trials. Although the boundaries distinguishing community-based research from individual-based research are not always easily discernable (2), the well-established literature on individual-based clinical trials can stand as a useful point of comparison against the relatively recent development of community-based health trials. The methodological issues we focus on here include randomization, statistical power, cohort versus cross-sectional assessments, secular trends, outcome measurement, and the role of conceptualization in methodological design. Furthermore, the balance between scientific methodology and other practical issues (e.g., economic and sociopolitical issues) is discussed.

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Abbreviations: COMMIT, Community Intervention Trial for Smoking Cessation; HIV, human immunodeficiency virus; INCAP, Institute of Nutrition of Central America and Panama.

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DEFINITION OF COMMUNITY AND SUMMARY OF PREVIOUS COMMUNITY-BASED INTERVENTION TRIALS

Prior to addressing methodological issues, the definition of “community” requires clarification, as it has only briefly been discussed in previous reviews that have focused on the methodology of community-based prevention studies in areas such as cardiovascular disease research (3–7). Prior community-based intervention studies have typically conceptualized a “community” along geographic boundaries (e.g., cities, counties, villages). Some empirical reviews of community-based intervention trials have included studies that examined small social units (e.g., workplaces and schools) other than geographically defined groups (3, 8, 9), and alternative conceptualizations of community have been advanced (10, 11); yet geographic units represent the most common way in which researchers have defined communities for study.

Pioneering longitudinal studies in community water fluoridation (see reviews by Horowitz (12), McDonagh et al. (13), and Milgrom and Reisine (14)), community nutrition interventions (15–18), and initial community-based cardiovascular disease prevention studies (i.e., the North Karelia Project (19) and the Stanford Three-Community Study (20)) each evaluated the effectiveness of health interventions that were administered to individuals living within distinct geographic regions. The health interventions in the community water fluoridation and nutrition studies involved providing health resources directly to a large number of individuals, whereas the interventions in the cardiovascular disease prevention studies consisted primarily of community-wide education intended to modify behavior and risk factors. Each of these initial studies provided preliminary evidence that community-level health interventions could benefit large groups of individuals.

Second-generation community-based intervention studies in the United States, particularly in the field of multifactorial cardiovascular disease prevention, also defined communities primarily along geographic boundaries. Such cardiovascular disease prevention studies included the Stanford Five-City Project (21, 22), the Pawtucket Heart Health Program (23), and the Minnesota Heart Health Program (24–26). The results of these prevention trials have been the topic of much discussion and debate (see the symposium in volume 142 of the *American Journal of Epidemiology* (September 15, 1995) and the reviews by Altman and Goodman (2), Labarthe (8), Mittelmark et al. (27), Shea and Basch (6), and Susser (28)).

In general, declines in cardiovascular disease risk factors were documented in these community-based interventions (i.e., in the Stanford Five-City Project, the Pawtucket Heart Health Program, and the Minnesota Heart Health Program), but favorable secular trends (of comparable magnitude in many cases) were also noted in control communities. Beneficial health effects favoring intervention communities were generally of modest magnitude, were short-term, and were noted in longitudinal cohort analyses but not in repeated, cross-sectional, independent-sample analyses.

In some recent studies and discussions, researchers have used smaller social and demographic characteristics (e.g., socioeconomic status, population size, degree of urbanization) in conjunction with geographic boundaries to further define communities. For example, one study of an intervention designed to prevent human immunodeficiency virus (HIV) infection used socioeconomic factors (i.e., low-income housing developments) within geographic boundaries (i.e., cities) to define community groups (29) and found that community education can reduce HIV risk at the community level. In a community-based longitudinal intervention that focused on reducing smoking rates at the community level (the Community Intervention Trial for Smoking Cessation (COMMIT) (30–33)), community was defined using both geographic units and sociodemographic characteristics (e.g., population size, socioeconomic status, age and sex composition). Similar to results in the cardiovascular disease prevention trials, smoking rates in COMMIT declined in the intervention communities but resembled strong secular trends displayed in control communities. Still another large-scale intervention initiative aimed at reducing the risk of various chronic diseases through community activation (the Henry J. Kaiser Family Foundation Community Health Promotion Grant Program (34–39)) defined communities according to both geographic and sociodemographic (e.g., population size, urban/rural residence) parameters. Results from this large-scale community intervention were generally disappointing, with few differences being noted between the intervention and control communities (38).

In other recent community-based interventions conducted in the United States, geographic boundaries have remained the principal unit delineating community inclusion. These studies have included community interventions targeting alcohol-related injuries (40–42), cancer prevention and/or screening (43–45), prevention of HIV infection and acquired immunodeficiency syndrome (46–50), use of child safety seats (51), tobacco control (52), pneumococcal immunizations (53), health care utilization (54, 55), and cardiovascular disease risk factors (56). Numerous other community-based interventions have been conducted in countries other than the United States (see descriptions of selected interventions by Grabowsky et al. (57)). Because we focus here on methodological issues, a detailed review of all community-based interventions is beyond the scope of this paper.

The poorer-than-expected outcomes of several community-based health intervention trials, particularly in the area of cardiovascular disease prevention (e.g., the Stanford Five-City Project, the Pawtucket Heart Health Program, the

Minnesota Heart Health Program, and COMMIT), have suggested that the exploration of additional parameters along which “communities” of individuals can be meaningfully divided should continue. In particular, characteristics of communities that may enhance the delivery and sustainability of interventions deserve further study. In addition, the mixed results of a number of community-wide efforts have prompted discussions of methodological issues that may help to explain findings and/or improve future community-based health intervention studies.

METHODOLOGICAL ISSUES IN COMMUNITY-BASED INTERVENTIONS

Randomization

In contrast to the potentially large numbers of participants available for randomization in individual-based intervention trials, the limited number of communities typically examined in community-based interventions has created challenges to researchers with respect to randomization. Randomization refers to the assignment of sample units (e.g., individuals, communities) to study conditions on a chance basis. The use of randomization removes the possibility that the study conditions will systematically differ from each other according to idiosyncratic factors, thereby reducing the potential for sample bias and increasing the likelihood that causal inferences can be drawn when study conditions are compared (5, 58, 59).

Some researchers have argued that randomization may not always be feasible in large community-based intervention trials because of pragmatic and political factors specific to community-based intervention research, including 1) the possibility that the intervention may be diffused across adjacent communities, 2) the likelihood that randomization with a small number of communities will still not produce balanced treatment groups, and 3) the uncertainty of whether communities will be receptive to the randomization process (24, 60–62). Thus, earlier community-based health intervention studies, including the North Karelia Project, the Stanford Three-Community Study, the Stanford Five-City Project, the Pawtucket Heart Health Program, and the Minnesota Heart Health Program, were designed as quasi-experimental studies; that is, intervention communities were compared with nonintervention communities, but randomization was not employed.

Several community-based interventions carried out after these earlier studies were conducted attempted to address the issue of randomization. In these interventions, researchers studied more communities and conducted “restricted randomization” after matching or stratifying communities according to selected factors. For example, in COMMIT (30–33), investigators examined 11 pairs of communities that were matched on sociodemographic factors and then randomly assigned to receive either the intervention or no intervention. The Kaiser Foundation’s Community Health Promotion Grant Program (34–37, 39) stratified 14 communities according to selected sociodemographic factors (e.g., population size, ethnicity proportions, extent of urbanization) and randomly assigned communities

within each stratum to the intervention. Since researchers generally agree that randomization should be employed in future community studies (63), the use of restricted randomization with a larger number of matched or stratified communities offers an approach that may increase analytical precision (i.e., reduce the standard error of the intervention effect) and remove bias (i.e., ensure comparability between study conditions on selected factors) (59). However, matching small numbers of communities on variables that are *not* strongly related to the outcome of interest can reduce rather than increase statistical power, because precision does not increase and the degrees of freedom are reduced in a matched-pair design (3, 59, 64, 65). For detailed discussions of the advantages and limitations of matched-pair and stratified designs, see Klar and Donner (66) and Murray (59).

Statistical power

It has been commonly noted in the community-based cardiovascular disease prevention literature that statistical power to detect true treatment differences is often reduced because the primary study unit is the community, rather than the individual (3–5, 30, 60, 62, 67). It is well known that sample size weights heavily in determining statistical power (68). Typically, only a handful of communities are available or feasible for assignment to treatment conditions in community-based research, in comparison with the multitude of individuals available for assignment to treatment conditions in individual-based research. The nesting of individuals within communities, in which estimates of both individual-level and community-level variation must be considered, further complicates issues of statistical power in community-based intervention research (5, 67). Failure to consider positive intraclass correlations (i.e., similarities among individuals within communities), if they are present, will create overestimates of community-level treatment effects due to biased estimates of individual-level error, whereas more accurate analyses that account for positive intraclass correlations will have reduced statistical power (59, 61).

Because sample size strongly influences statistical power, researchers have increased the robustness of community-based trials by including larger numbers of *communities* within a study. For example, COMMIT more than doubled the number of communities ($n = 22$ communities) studied in comparison with prior community-based trials (e.g., the Stanford Five-City Project, the Pawtucket Heart Health Program, and the Minnesota Heart Health Program; $n = 6$ communities or fewer). However, the potential methodological benefits of including more communities in interventions must be balanced with feasibility and economic costs (discussed below). Increasing the number of individual observations within communities can increase statistical power by reducing within-community variance in the measures of interest (62), although the benefit to statistical power with increased sample size at the individual level for multilevel analyses plateaus as numbers become very large (61). As we noted above, matching or stratifying communities according to factors that influence the out-

comes of interest may also increase statistical power by increasing precision.

Another strategy that has been used to increase statistical power in community interventions involves conducting joint analyses by pooling data across multiple studies with similar measures. This strategy has been employed to jointly examine results from cardiovascular disease prevention trials in medium-sized cities in the United States (69), as well as cardiovascular disease prevention trials in smaller communities in the United States and Sweden (70, 71). While pooling data in joint analyses may increase power by increasing the sample size (i.e., the number of communities), common or comparable measures must exist among the various studies, and study-specific sources of variance must be taken into consideration. Moreover, the longitudinal designs typically seen in community-based interventions create further complications for joint analyses using pooled data, since discrepant assessment periods among different intervention trials must be considered.

Cohort samples versus cross-sectional samples

In many studies, community-based health interventions are implemented at the larger group level, while assessments and/or observations typically occur at the individual level over time. Repeatedly assessing all individuals of interest in the community is preferred, and this may be feasible in small communities (e.g., the Institute of Nutrition of Central America and Panama (INCAP) study (17)); yet it is typically not possible to assess all individuals of interest in the selected communities. Two main sampling approaches to obtaining these longitudinal individual-level data are 1) to follow panels of individuals (i.e., cohorts) over time and 2) to assess different groups of individuals (i.e., cross-sections) in each time period. Several researchers have extensively discussed and debated the merits of these two approaches (5, 21, 62, 63, 72, 73). Briefly, longitudinal cohort analyses will typically have greater statistical power than repeated cross-sectional analyses, since sampling error can be reduced by controlling for individual baseline levels (assuming fixed sample sizes and positive associations between baseline and follow-up levels) (5, 21, 72, 73). However, repetitive assessments may increase participants' knowledge of healthy behavior and artificially influence behavior, which can confound results. In addition, the representativeness of cohorts may be compromised by attrition (e.g., out-migration, dropping out) or maturation (5, 72, 73). Because the primary aim of community-based interventions is to detect change in health at the broader community level (67), some researchers have argued that repeated cross-sectional analyses are more appropriate than cohort analyses for measuring the effectiveness of interventions in the community (5, 62, 63). Disadvantages of repeated cross-sectional analyses include the possible inclusion of individuals who received limited exposure to the intervention (because of in-migration), the possibility of intervention diffusion across adjacent communities (because of out-migration), less statistical efficiency, and an inability to examine processes of change within individuals that may help to explain results (5, 21, 72, 73).

Several large-scale community-based intervention trials (e.g., the Stanford Five-City Project, the Pawtucket Heart Health Program, the Minnesota Heart Health Program, and COMMIT) have utilized both longitudinal cohort analyses and repeated cross-sectional analyses, with the recognition that results from these analytical strategies may not be parallel (21). Alternative analytical strategies recommended for future research include repeated cross-sectional analyses with individuals whose residence has remained stable throughout the intervention (72) and treating length of residence in follow-up cross-sectional evaluations as a covariate (5). Still, less statistical efficiency and difficulty in analyzing mediating factors that change within individuals across time remain limitations of these alternative strategies.

Methods of analysis

Because communities (rather than individuals) are the primary units of interest in community-based interventions, some researchers have argued that general or generalized linear models (typically used in individual-level clinical trials) are not appropriate for community-based studies (59). Instead, general or generalized linear mixed models (also termed hierarchical linear models, random-effects models, covariance component models, and multilevel analysis) have been suggested as more appropriate for community-level interventions, given that both individual-level and community-level influences on health can be examined simultaneously (59, 74). However, some researchers have cautioned against the rash utilization of these complicated statistical techniques, recommending that investigators wait until the techniques are better understood and the conceptual models that specify how both individual and community factors influence health are better developed (74). For detailed discussions of statistical models for community interventions, see Diez-Roux (74), Donner and Klar (75), and Murray (59).

Assessment of secular trends

Prior community-based cardiovascular disease prevention trials (e.g., the Stanford Five-City Project, the Pawtucket Heart Health Program, the Minnesota Heart Health Program, and COMMIT) documented greater-than-expected health improvements in the control conditions due to favorable secular trends or historical effects (33, 60, 61, 76). A common interpretation of the failure to detect treatment differences in prior cardiovascular disease prevention trials is that secular trends hindered the investigators' ability to make causal inferences concerning the effectiveness of various interventions. Similar to the case with individual-based interventions, secular trends represent a serious "threat" to the internal validity of community-based interventions, yet monitoring secular trends at the community level may be more costly and time-consuming than making individual-level assessments. Furthermore, the mechanisms that influence secular trends (and community change in general) are not well understood (60). Some researchers have even suggested that the development and implementation of

community-based cardiovascular disease prevention trials may itself have shaped secular trends by making behavioral risk factors a public priority (9), though evaluation of such a relation would be difficult to establish empirically.

The issue of secular trends is not specific to community-based cardiovascular disease prevention studies; it has also been a salient topic in the community-based water fluoridation literature (12, 77, 78). Specifically, detection of the health benefits of water fluoridation has diminished over time, and researchers have speculated that the development, availability, and widespread use of other fluoridated products may account for the narrowing of differences between fluoridated and nonfluoridated communities. Thus, inclusion of control communities in the design of future community-based health interventions remains essential to the identification of strong secular trends. Assessing levels of exposure to the health intervention, from both researchers' and participants' perspectives, may help investigators determine whether a given community-based intervention was potent enough to have beneficial effects beyond those of positive secular trends (J. Farquhar, Stanford University, personal communication, 2001). In addition, the inclusion of an extended baseline period with repeated preintervention assessments prior to randomization may also help investigators determine the influence of secular trends on community-based health interventions and address other methodological issues, such as statistical power (S. Fortmann, Stanford University, personal communication, 2001).

Outcome measurement

In evaluating the effectiveness of community-based interventions, several outcomes can be assessed by either asking participants about their health (i.e., self-report measures) or obtaining data on health measures that do not require participants' responses (i.e., "objective" measures). Nonverbal ("objective") measures include physiologic assessments, surveillance of relevant clinical endpoints, and observational techniques. Some researchers have warned against sole reliance on self-report measures because of the problems of recall bias and/or reactivity to the assessment (5, 27). However, the capability of self-report measures to collect health information from a large number of individuals can make them useful tools for evaluating large-scale community-based interventions. In comparison, the demands and costs of gathering nonverbal information can limit the number of individuals in the community that can be assessed. To offset concerns about the use of self-report measures, it can be beneficial to empirically demonstrate the reliability and validity of such measures.

Some researchers have asserted that community-based interventions are expensive (79), particularly the individual-level surveys needed to evaluate effectiveness (63). Assessing environmental indicators (also termed community-level indicators) to evaluate the effectiveness of community-based health intervention may reduce the cost of community-based trials (5, 10, 27, 63, 80). Environmental indicators represent macro-level evaluations (e.g., the Kaiser Family Foundation Community Health Promotion Grant Program

evaluated the availability of healthy food choices in stores (34, 35, 37)), as compared with the micro- or individual-level assessments (e.g., individual dietary behavior) that are typically conducted in community-based intervention trials. However, additional research on the reliability and validity of environmental indicator assessment is needed.

Conceptualizing change in community-based intervention studies

In discussions of prior community-based cardiovascular disease prevention trials, several researchers have suggested that examining the process of *how* community-based interventions improve health may be just as critical as (if not more important than) evaluating the outcomes of community interventions (2, 5, 9, 60, 81, 82). Evaluation of mechanisms or processes in community-based interventions requires the specification of conceptual or theoretical models. As Koepsell et al. noted, “evaluations based on treatment theory should advance the state of the art by identifying the details of good ideas for replication or enhancement and bad ideas for a return trip to the drawing board” (5, p. 36). Past community-based cardiovascular disease prevention studies have combined diverse conceptual/theoretical models in the development of interventions (see reviews by Altman and Goodman (2) and Shea and Basch (7)), but evaluation and specification of particular mechanisms responsible for community change has been scant (9). Researchers in the fields of cardiovascular disease prevention (2, 9, 10, 27) and prevention of HIV infection and acquired immunodeficiency syndrome (83) have argued that specification of the manner in which various factors at different intervention levels (e.g., individual behavior, social environment, physical environment) intersect to influence health is essential to the development of more effective and enduring programs, and thus requires further attention.

In addition to heightened interest in how complex conceptual models for community intervention influence methodological issues, reexamination of appropriate models for interaction between researchers and community groups has garnered increased attention. In 1995, Fortmann et al. stated, “Much more thought and time must be devoted to establishing a relationship with a community than was the case a decade ago. Concepts such as trust, mutual benefit, feedback, and relationships must enter the vocabularies of public health interventionists” (60, p. 584). Several other researchers have echoed this sentiment regarding the need to build stronger, more collaborative relationships between researchers and communities (2, 9, 11, 82, 84). However, much work needs to be done in this arena to overcome historical and current rifts between researchers and communities (2).

Balancing scientific methodology and feasibility

As we have noted intermittently above, researchers testing community-based interventions not only must consider how to maximize methodological rigor that can clarify causal relations but also need to ensure that the large-scale interventions being developed are feasible. The cost of

implementing an intervention and political issues related to implementation (e.g., the receptivity of community leaders) represent two main feasibility factors that can compromise methodological rigor and external validity. While the delivery of health interventions to entire communities can be conducted in a cost-effective manner (e.g., through the mass media) (76), the research costs of evaluating the effectiveness of community-wide health interventions can be relatively high, especially if individual assessments or large surveys are used (63). As we noted above, increasing the numbers of communities included in future large-scale interventions (e.g., multisite community-based interventions) may help to remedy methodological problems of past trials (e.g., randomization, statistical power) but can add significantly to the evaluation costs and complexity of community-based research (60). Subsequently, future research must balance the methodological gains accrued by changing statistical parameters (such as sample size) against the economic costs of making those changes.

Political issues can influence the design of community-based interventions, as well as the inclusion of communities in a research study. A political issue of critical importance is the receptivity to research shown by key members (and ideally all members) of the communities of interest. As we noted above, concern about community receptivity to randomization is partly what has led some investigators to use quasi-experimental designs (24), subsequently reducing methodological rigor. This issue further underscores the importance of collaborative relationships between researchers and communities. Developing mutual trust and common goals may decrease the public’s concern about research interventions and the tools used to evaluate programs, as well as assist in the development of sustainable health programs. Issues and potential problems that should be addressed in building collaborative relationships include possible conflicts over control of programs, decisions concerning allocation of funds, alignment of priorities, development of a common vocabulary, and conflicts concerning how communities will be defined (see discussions by Cheadle et al. (84) and Israel et al. 1998 (11)). Working through these issues will take much time and effort (84), but it may increase the effectiveness of community interventions. In support of this notion, promising results have been reported from interventions in which rural communities actively collaborated in the focusing and implementation of cardiovascular disease prevention programs (85). Thus, prior strategies of providing community-wide education (termed the “top-down” approach) may be less effective in changing health than interventions that *also* target collaborative community involvement and infrastructure development (termed the “bottom-up” approach) (85).

Still, discussions of the collaborative relationships between researchers and communities have raised other questions about community interventions and informed consent. As Brody has noted (86), difficult questions remain concerning 1) whether the consent of a community is required prior to randomization to and/or implementation of a community intervention, 2) how to specify the person(s) who will give consent if it is required, and 3) whether to

inform participants who provide survey data about the community intervention study. Resolution of these important ethical questions may require much debate and discussion.

CONCLUSIONS AND FUTURE DIRECTIONS

Improving the methodological design of community-based health interventions requires that researchers closely examine the methodological pitfalls, challenges, and achievements of previous community-wide trials. In addition, the economic and sociopolitical contexts within which these community-based interventions occur require further deliberation, given the potential limitations placed on methodological designs by economic and sociopolitical factors. In this paper, we have reviewed several methodological issues in community-based health interventions and other factors that can influence the methodological rigor of community-based trials.

While communities are typically defined by geographic units, it is important to recognize that much economic, social, political, cultural, and demographic heterogeneity exists between and within communities (83, 87). Given this heterogeneity, several researchers have argued against a "one-size-fits-all" approach to community-based interventions (9, 79, 85, 88). Others have further suggested that health researchers should target subpopulations within communities (e.g., high-risk groups) to improve the effectiveness of large-scale interventions (9, 60, 87).

The equivocal findings from prior community-based intervention trials, particularly in the area of cardiovascular disease prevention, have prompted many more suggestions concerning ways to improve future studies. These suggestions have included focusing on the process of how communities and individuals change rather than on the outcome (60), changing the measures that we use to assess community health (e.g., assessing environmental indicators) (5, 10, 27, 63, 80), and modifying how researchers relate to the community (2, 9, 11, 60, 82, 84, 85). Previous community-based trials have been instructive in delineating the issues to be addressed in future research. In the words of Fortmann et al., "Perhaps the most important lesson we have learned about communities is that there is much we do not know" (60, p. 583). In this light, evaluation of previous community-based intervention methods in combination with the application of new conceptual models and approaches represents an important step towards improving our understanding of communities and how they change.

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