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Design and Analysis of Community Trials: Lessons from the Minnesota Heart Health Program

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Community trials remain the only design appropriate for the evaluation of lifestyle interventions that cannot be allocated to individuals. The Minnesota Heart Health Program, conducted in Minnesota and the Dakotas between 1980 and 1993, is one of the largest community trials ever conducted in the United States. That study suggests several lessons that should guide future community trials. Planners should 1) carefully assess the secular trends for their outcomes and be confident that they can demonstrate an intervention effect against those trends; 2) be confident that they have effective programs that can be delivered to a sufficiently large fraction of their target population; 3) avoid differences between study conditions in levels and trends for their outcomes through random allocation of a sufficient number of communities to each condition; 4) develop good estimates of community-level standard errors prior to launching future trials; and 5) take steps to ensure that power will be sufficient to test the hypotheses of interest. *Am J Epidemiol* 1995;142:569–75.

epidemiologic methods; research design; space-time clustering; statistics

The papers from the first symposium on the design and analysis issues for community trials in epidemiology were published in the *American Journal of Epidemiology* in 1978. Since that time, many more papers have appeared, and many community trials have been undertaken. As a result, there is now much greater experience with the issues that are common to this design. The logic behind community trials remains strong in many instances, but disappointing results from some trials raised questions about the utility of a community-based approach to disease prevention and health promotion. It is therefore a good time to look to the major community trials conducted over the last decade for lessons that can aid in planning future studies.

The purpose of this paper is to offer lessons learned from the Minnesota Heart Health Program (MHHP), the largest study ever funded by the National Heart, Lung, and Blood Institute to assess the efficacy of a communitywide approach to primary prevention of coronary heart disease (1). The MHHP was designed in the late 1970s and involved approximately 500,000 persons in six communities in the upper Midwest (2). It was hypothesized that an intensive 5- to 6-year intervention program would improve health behaviors and lower population levels of coronary heart disease risk factors, and that these changes would result in reductions in cardiovascular disease morbidity and mortality. The MHHP produced many papers on evaluation and intervention methods and demonstrated the efficacy of many of the individual components of the intervention program; the major risk factor results were recently published (3). Following an overview of the MHHP, this paper will suggest lessons that may be applicable to the design and analysis of future community trials.

THE MINNESOTA HEART HEALTH PROGRAM

Design

The design of the MHHP is described in detail elsewhere (2) and is only summarized here. Three pairs of communities were selected for the study, each pair with one education and one comparison site. Communities were matched on size, community type (small agricultural, independent urban, or metropolitan), and distance from the Minneapolis-St. Paul metropolitan area. Assignment of communities to conditions from within the matched pairs was nonrandom, completed before collection of any data, and structured to optimize the baseline comparability of the two study conditions. Following a 16-month baseline period used for study planning, community analysis, and baseline data collection, a 5- to 6-year intervention program was introduced in November 1981 in Man-

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Abbreviation: MHHP, Minnesota Heart Health Program.

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kato, a small rural community in southern Minnesota. Twenty-two and 28 months later, respectively, the program was introduced in Fargo-Moorhead, an urban area along the North Dakota-Minnesota border, and in Bloomington, a large Twin Cities suburb. This staggered entry allowed for gradual development of the intervention program and strengthened the design through replication; it also provided two, three, and four baseline surveys in the first, second, and third pairs, respectively, to improve the precision of the preintervention time trends estimated from the data. The three pairs and their assignment to intervention and comparison conditions are shown in figure 1.

Risk factor and health behavior surveys

Risk factor surveys measured community and individual changes in risk factors and health behaviors in each community. Periodic cross-sectional surveys of 300–500 randomly selected 25- to 74-year-old adults were conducted in each community based on a two-staged cluster sampling design (4). Discrete sequential surveys were implemented throughout the study, and each community was assigned to a 2-month survey window; paired communities were assigned to adjacent windows to maximize seasonal comparability. Cohort surveys consisted of periodic remeasurements in participants from the baseline cross-sectional surveys. To minimize the effect of repeated testing, the follow-up surveys were structured so that roughly half the cohort was contacted after 2 years of intervention, while the other half was contacted after 4 years of intervention; all cohort participants were contacted after 7 years of intervention. This plan resulted in the staggered series of cross-sectional and cohort surveys in each community shown in figure 1.

Mortality and morbidity surveillance

The vital statistics units in Minnesota and North and South Dakota provided death certificate information for the counties of each MHHP area as well as for those entire states. Specially trained nurses assigned codes from the *International Classification of Diseases,* Ninth Revision, to all listed causes of death for all deaths occurring in MHHP areas. For residents in MHHP areas, detailed information on out-of-hospital deaths was obtained from a telephone interview conducted with next-of-kin; cases were selected for interviews using criteria of eligibility based on age, residence, out-of-hospital site of death, and a code from the *International Classification of Diseases,* Ninth Revision, suggestive of a cardiovascular or nonneoplastic, nontraumatic death. The informant interview

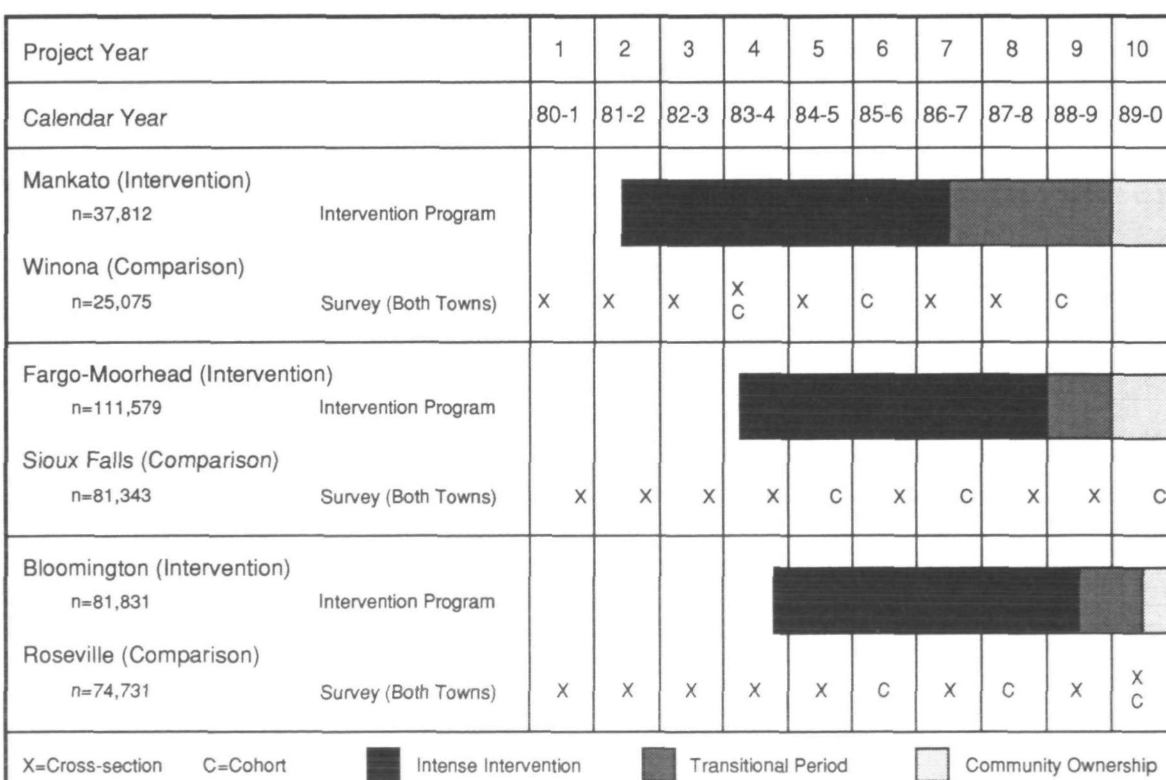

FIGURE 1. Minnesota Heart Health Program study design: Minnesota and the Dakotas, 1980–1990.

was developed to validate the timing, the circumstances surrounding the fatal event, and the final classification of the type of death.

Annually, all hospitals serving the MHHP communities provided a list of target discharge codes from which morbidity cases were identified and abstracted. Eligibility was determined by age and residence status. Most of this selection was done using computer-generated hospital discharge records to ensure uniform and complete case selection. Cases were abstracted in detail by a trained nurse-abstractor at each hospital. A computer algorithm was used to classify all abstracted cases of potential myocardial infarction and stroke into event categories.

Intervention methods

The MHHP intervention program advocated hypertension prevention and control, healthy eating patterns for lower blood cholesterol and blood pressure, nonsmoking, and regular physical activity. It operated at the individual, group, and community levels and embraced a wide range of strategies and theories, including social learning theory (5), persuasive communications theory (6, 7), and models for involvement of community leaders and institutions (8). Community analysis and organization methods were utilized to engage community leaders and organizations as active participants in the intervention programs; this resulted in active involvement of leaders and their organizations, gradual environmental change to support risk reduction, and community planning for program continuation (9–11). The mass media were utilized to increase individual contact with the MHHP risk factor messages; such exposure helped to establish awareness of the program and increased the salience of the program messages (12–16). Health professionals were involved through their local organizations and preventive practice advisory committees and served as role models and opinion leaders (17, 18). Systematic risk factor screening and education were conducted during the first 3 years of the intervention program; over 60 percent of all adult residents received on-site measurement, education, and counseling (19). The adult education component made available personal, intensive, and multiple contact programs to reduce cardiovascular risk; this strategy focused on self-management and included changes in existing behaviors, in the meaning of those behaviors, and in the environmental cues that supported those behaviors (20–28). Direct education programs for school-aged youth discouraged health-compromising behaviors and promoted health-enhancing behaviors in youth and their parents (29–31).

Analysis methods

The analysis methods used for the main risk factor outcomes are described in detail elsewhere (32) and are only summarized here. As in other community trials, the community was the unit of assignment in the MHHP, while the individual was the unit of observation. Observations on persons within clusters such as communities tend to be correlated (4), and this intraclass correlation adds an additional component to the variability of the treatment group means over that attributable to either the individual participants or the treatments (33). Unless this extra variation is accounted for in analysis, the evaluation of treatment effects will be positively and often substantially biased (34). The extra variation was accounted for through a two-stage analysis that approximated a stratified hierarchical analysis of covariance; the nested community was treated as a random effect while condition, time, and the stratification factors were treated as fixed effects.

In a first stage, least-squares adjusted means were generated for each city in each survey year after stratifying by sex, educational attainment, and age; adjustments were made for confounding variables by standardizing all subjects to the population average within strata for each covariate. A second stage used these adjusted strata-specific city-year means as the unit of analysis in a series of regressions to evaluate the main and strata-specific effects of the intervention program. Recognizing that planned contrasts can provide tests that are more interpretable and potentially more powerful, researchers tested two specific patterns of program effect. For both patterns, a quadratic secular trend was modeled using the baseline intervention city-year means together with all of the comparison city-year means. The intervention program effect was modeled first as a series of year-specific departures from that secular trend and second as a linear departure from that trend.

The analysis of the cohort data followed the same plan. Modifications were made to accommodate time-varying covariates and the fact that different members of the cohort participated in each of the four cohort surveys.

RESULTS

The results for the main risk factor outcomes are described in detail elsewhere (3) and are only summarized here. It was apparent that there were strong and favorable secular trends of both increasing health promotion activities and declining coronary heart disease risk factors in all study communities, both education and comparison. It was also apparent that the net improvements in health promotion activities and individual risk factors that could be attributed to the MHHP intervention program were modest, generally of limited duration, and usually within chance levels. In light of the results from previous studies that have supported the efficacy of many of the MHHP intervention program components in targeted populations, it was inappropriate to conclude that those components were ineffective. Instead, the MHHP investigators concluded that the MHHP intervention program was unable to generate enough additional exposure to those risk-reduction activities in a large enough fraction of the population to accelerate the favorable secular trends in health promotion activities and in most coronary heart disease risk factors that were present in the participating communities over the course of the study.

DISCUSSION OF LESSONS LEARNED

Estimation of the secular trend for the outcome

For any community trial that extends over more than just a few years, the secular trend for the outcome(s) of interest in the comparison communities stands as the criterion against which the intervention effect must be measured. The challenge for the investigator is to modify the secular trend in the intervention communities so as to create an intervention effect. The magnitude of that challenge will depend on the slope of the secular trend, since it may be very difficult to accelerate a steep favorable trend or to reverse a trend moving in the wrong direction. As a result, it is important that the investigators have good data on both the direction and the magnitude of that secular trend. Such information will not protect against a significant change in the trend over the course of the study, but will offer some protection against launching an expensive trial at a time when it is unlikely to succeed.

MHHP did not fully anticipate the magnitude of the decline in coronary heart disease risk factors that occurred in the comparison communities during the 1980s. It was clear at the outset that the risk factors were declining, but it was assumed that the intervention program would accelerate the trend, whatever its magnitude. As it turned out, the trend for most risk factors was much steeper than expected. It is unlikely that the members of the intervention team would have accepted the challenge to accelerate those trends if they had realized how steep they would be. In the future, planners should more carefully assess the secular trends and be confident that they will be able to demonstrate an intervention effect against those trends.

Estimation of the secular trends for exposure

Similarly, the secular trend in the exposure(s) of interest in the comparison communities stands as the criterion against which the true magnitude of the intervention program must be measured. The challenge for the investigator is to increase the level of exposure to intervention-like activities in the intervention communities above and beyond that observed in the comparison communities. In most community trials, the ideas and activities that make up the intervention program are likely to appear in the comparison communities over time, with the likelihood increasing as the length of the trial and the publicity attached to it increase. To the extent that the level of exposure attributable to the intervention program is no greater than the level observed in the comparison communities, the effective magnitude of the intervention program must be considered small, no matter how large the intervention program appears to be when measured against other criteria (e.g., cost, number of direct contacts, minutes of television or radio time, etc.).

During the first several years of the MHHP, it became clear that it was going to be difficult to engage a large fraction of the population in MHHP programs aimed at changing complex and deeply ingrained behaviors such as eating patterns and smoking, even given resources of the scale available to the MHHP. The study was never able to recruit a significant fraction of the population to participate in its most intensive behavior change programs, and attention gradually shifted toward development of programs that could attract more people. Unfortunately, those mass appeal programs often were not as effective. In addition, the process evaluation data collected as part of the annual surveys suggested that exposure to intervention-like activities in the comparison communities increased steadily over the course of the study, and that there was little net difference in exposure at the end of the MHHP. Planners of future community trials should be confident that they have effective programs that can be delivered to a sufficiently large fraction of their target population to allow them to accelerate the secular trends for the exposures of interest.

Estimation of the treatment effect

The analysis of data from a community trial can take many forms, but all compare an estimate of the treatment effect with an estimate of the standard error for that treatment effect. The first requirement for this analysis is an unbiased estimate of the treatment effect.

By their design, community trials are more susceptible to bias related to selection than are trials based on randomization of individuals to conditions. Community trials usually involve only a limited number of intact social groups allocated to each condition, and the allocation may not be random. As a result, it is much more likely that the study conditions in a community trial will show important differences at baseline in both levels and trends for the major outcomes or exposures of interest. Such differences can pose serious threats to the interpretation of the data from the trial.

In the MHHP, three pairs of communities were selected for the study, pairs that were roughly matched on size, community type, and distance from the Minneapolis-St. Paul metropolitan area. Randomization of communities to conditions from within pairs was rejected for logistical and political reasons, and preference for assignment to the education condition was given to communities that were located in Minnesota (Fargo-Moorhead vs. Sioux Falls), involved only one municipal government (Bloomington vs. Roseville), or were judged to be more receptive to the intervention program than was the other community (Mankato vs. Winona). Contrary to expectations, and in spite of the matching, substantial differences were observed at baseline in both levels and trends for many of the outcomes of interest.

The best defense against such sources of bias in any comparative trial is the assignment of a large number of units at random to each of the study conditions. Matching on levels and/or trends of the outcome variable(s) may reduce these threats, but will be much more difficult and expensive than matching on variables such as size, community type, etc. Even if a large number of matched units is involved, nonrandom assignment can leave a trial open to these threats, and random assignment is clearly preferred. Nonrandom assignment of only a few poorly or unmatched units to each condition is a weak strategy and should be avoided in future trials.

An alternative defense is to conduct more surveys during both the baseline and the follow-up periods so that the differences in levels and trends can be estimated and taken into account during the analysis. Fortunately for the MHHP, the multiple baseline and follow-up surveys in each community provided some help in this regard (32), but even in the MHHP, the number of observations was limited. The MHHP could have conducted more surveys in each community, each involving fewer individuals, and been in a position to more precisely estimate the levels and trends and more fully take them into account during the analysis. It is important to note, however, that such adjustments will never be complete, and it would be better to avoid differences through random allocation of a sufficient number of units to each condition.

Estimation of the standard error

As noted above, all analyses of community trials compare an estimate of the treatment effect with an estimate of the standard error for that treatment effect. The second requirement for this analysis is an unbiased estimate for the standard error.

Community trials stand apart from other comparative trials because of the allocation of intact social groups rather than individuals to conditions. As Cornfield said so eloquently in his paper for the first symposium, "Randomization by cluster accompanied by an analysis appropriate to randomization by individual is an exercise in self-deception, however, and should be discouraged" (35, pp. 101–2). The rationale for this statement is as clear today as it was in 1978; i.e., positive intraclass correlation causes the standard errors computed at the individual level to be positively biased when randomization occurs at a group level, often substantially. To avoid this bias, community trials must be evaluated using standard errors computed at the level of the unit of assignment. Unfortunately, this requirement will often have adverse implications for power, as noted below.

In the MHHP, the within-community correlations over time were much larger than anticipated, greatly inflating the community-level standard errors (36). Data of this kind from other studies are sorely needed to help planners estimate the magnitude of the intraclass correlation to be expected in future trials. The MHHP correlations stand as a warning that it is essential to develop good estimates of community-level standard errors prior to future trials.

Power

Power to detect the effect of interest is an issue during the planning stage for any study and must be for community trials. Several recent papers have discussed the factors that affect power in community trials (33, 37–39), and there is no need to repeat their entire discussions here. The main point is that the power for an analysis based on community-level standard errors will almost certainly be much less than for an analysis based on individual-level standard errors, because of positive intraclass correlation and the limited degrees of freedom available to estimate that correlation. In addition to recognizing that point, planners must also recognize that the usual steps suggested to bring power to an acceptable level in an individually randomized trial may not be adequate in community trials. In particular, adding more individual participants to each condition has a rapidly diminishing payoff in community trials once the number of participants per community survey reaches a few hundred. Instead, the most important factors affecting power in a community trial are the number of communities allocated to each condition and the magnitude of the intraclass correlation among participants within a community that remains after adjustment for confounding factors.

As noted earlier, the MHHP investigators discovered that the intraclass correlations were much larger than anticipated; they also discovered that the number of communities allocated to each condition was substantially less than optimal for adequate power. This pushed the MHHP analysis team to unusual lengths to squeeze as much power from the design as possible (32), and even with that effort, power to detect treatment effects was limited.

Planners of future studies should consider the power of their design and analysis plan very carefully before launching an expensive community trial. Alternatives to increase power are available, but none are painless and all require careful planning. An obvious strategy is to increase the number of communities per condition. This is tremendously helpful, but may present logistic challenges depending on the nature of the intervention; it can also greatly increase the cost of the study.

A second strategy is to increase the number of times a community is observed. This does not increase the cost of the intervention, but will increase the cost of the evaluation, all other things being constant. The increase in cost can be offset in part by a reduction in the size of each community survey, recognizing that the relation between power and the number of respondents per survey is one of diminishing returns.

It may be possible to anticipate the shape of the secular trend and the shape of the intervention effect so as to design a survey schedule well positioned to capture the effects of the program. Koepsell et al. (39) suggest methods to estimate power given information about the shape of the secular trends for the outcomes and exposures of interest.

Careful measurement of important covariates at the individual and community levels may allow regression adjustment so as to reduce the variance at both levels. As part of the effort to reduce the magnitude of the intraclass correlations observed in the MHHP, considerable time was spent evaluating covariates that might explain some of the correlation. For many outcomes, this effort was at least partly successful and increased the power of the analysis.

Caution in interpretation

Certainly when the resources put into a single study are as large as they were for the MHHP, and when a study takes as much time and energy as the MHHP took, it is tempting to try to make more out of it than is justified. In spite of its size and cost, the MHHP remains a single study, and judgments on the utility of its design, its intervention components, and its approach must be based on the wealth of information developed on these issues over the last 15 years and not on any single study, no matter how large or how visible it may be. The MHHP risk factor results suggested that any favorable acceleration of the secular trends was short lived and often within chance levels (3). That may be disappointing, but it would be dangerous to conclude that the community trial design is so inherently bad that it should not be used. It would also be inappropriate to conclude that the individual components of the MHHP intervention program are ineffective and should not be used. A more prudent interpretation is that it is far easier to change the risk profiles of the people who participate in community-based programs than to engage a large enough fraction of the community in those activities so as to change the risk profile of the entire community.

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