Community Intervention Trial for Smoking Cessation: Description and Evaluation Plan

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INTRODUCTION The Community Intervention Trial for Smoking Cessation (COMMIT) was a large-scale undertaking that incorporated virtually all key features of past community trials. It was the largest National Cancer Institute (NCI) effort to test methods to help people stop smoking. COMMIT used many methods and strategies developed in smaller NCI-funded trials conducted in the early 1980's (U.S. Department of Health and Human Services, 1990) and incorporated many of these methods into a community-based approach, which involved community groups, institutions, and organizations in confronting the smoking problem in their community.

COMMIT focused on heavy smokers (those smoking more than 25 cigarettes per day). At the time of trial development, heavy smokers represented about one-third of all adult smokers. Heavy smokers account for nearly half the lung and other smoking-related cancers, and the risk of disease and death from heart and lung diseases dramatically increases as the number of cigarettes smoked per day increases (U.S. Department of Health and Human Services, 1982 and 1989).

Heavy smokers appear to face special problems in quitting. Several large prospective studies have indicated that spontaneous quit rates are lower among heavy smokers than among light-to-moderate smokers. Data from the Multiple Risk Factor Intervention Trial (MRFIT) special intervention group indicate that even when fairly intensive smoking cessation interventions are offered on a continuous basis for up to 6 years, heavy smokers have more difficulty quitting and maintaining abstinence (Hughes et al., 1981). Similarly, some community-based studies (Gutzwiller et al., 1985; Steenkamp et al., 1991) suggest that light and moderate smokers have less difficulty quitting than heavy smokers. Thus, it was appropriate to target this group of hard-to-reach smokers who account for much of the excess morbidity and mortality related to smoking.

TRIAL COMMUNITIES In response to a request for proposals from NCI, several investigators competed for participation in a community-based trial aimed at reducing smoking rates in heavy smokers. Major criteria for being selected for participation were the ability to recruit two similar communities that agreed to be randomized to receive either active intervention or control surveillance and having experience in smoking control and community studies. For purposes of the study, a community was broadly defined and could include a well-defined portion of a major metropolitan area or two small cities in the same geographic region. Communities within matched pairs were required to have some boundary separation to maintain

independence of intervention activities and to prevent contamination. Within each pair, communities were matched for general sociodemographic factors, including population size, age distribution, demographic profile (ethnicity, proportion female, age distribution, educational distribution, and mean family income level), mobility and migration patterns, extent of urbanization, estimated smoking prevalence rates, and access to a variety of intervention channels.

Criteria for selecting the pair of communities varied by research institution; however, they were required to fall within certain size parameters. The communities were later examined for characteristics thought to be related either to cigarette smoking behavior or access to channels that had been defined for intervention. Some of the latter characteristics included whether community residents received their health care within the community, whether they worked within the community, the availability of media resources, and baseline smoking prevalence. The research institutions and their associated community pairs are identified in Table 1.

Table 1
List of the 22 COMMIT communities

Contracting Organization	Community Sites
Waterloo Research Institute Waterloo, Ontario, Canada	Brantford[a] Peterborough
Kaiser Foundation Research Institute Oakland, CA	Vallejo[a] Hayward
Roswell Park Memorial Institute Buffalo, NY	Utica[a] Binghamton/Johnson City
Research Triangle Institute Research Triangle, NC	Raleigh[a] Greensboro
Fred Hutchinson Cancer Research Center Seattle, WA	Bellingham[a] Longview/Kelso
University of Medicine and Dentistry of New Jersey Newark, NJ	Paterson[a] Trenton
Oregon Research Institute Eugene, OR	Medford/Ashland[a] Albany/Corvallis
University of Massachusetts Medical School Worcester, MA	Fitchburg/Leominster[a] Lowell
The Lovelace Institutes Albuquerque, NM	Santa Fe[a] Las Cruces
University of Iowa Iowa City, IA	Cedar Rapids/Marion[a] Davenport
American Health Foundation New York, NY	Yonkers[a] New Rochelle

[a] *Community randomized to receive intervention.*

The community populations ranged from 49,421 to 251,208 with comparable statistical means for the pooled intervention and comparison communities. Overall, the intervention and comparison communities were well matched with regard to general sociodemographic variables (see Table 2). A cluster analysis was performed using census data for eight demographic variables on which the pairs could demonstrate agreement: racial distribution, Hispanic ethnicity, gender by age, gender by marital status, general occupational category, educational attainment, family income, and years resident in the current household. This analysis verified the comparability of the households in the community pairs.

Table 2
Sociodemographic characteristics of community pairs

Community/Area	Population	White (%)	Female (%)	Ages 25-64 (%)	High School Graduate (%)	Low Income (%)
Vallejo, CA	120,060	52.1	50.2	51.1	80.7	17.1
Hayward, CA	141,893	63.5	50.8	53.9	75.3	16.3
Cedar Rapids/Marion, IA	144,243	96.3	51.7	52.1	85.0	20.6
Davenport, IA	125,593	91.0	52.1	50.5	81.5	24.9
Fitchburg/Leominster, MA	79,339	91.3	51.8	49.8	72.0	24.2
Lowell, MA	103,439	81.2	51.4	47.5	65.8	27.9
Paterson, NJ	141,431	41.3	52.1	49.3	54.9	28.2
Trenton, NJ	91,688	42.0	51.3	49.9	58.2	29.7
Santa Fe, NM	68,092	81.3	52.3	55.7	83.4	22.0
Las Cruces, NM	69,015	88.8	51.0	48.2	78.4	34.3
Yonkers, NY	61,698	68.3	53.6	53.0	72.9	22.5
New Rochelle, NY	49,421	70.9	53.5	52.7	72.5	21.3
Utica, NY	76,967	87.8	53.1	46.8	68.8	37.1
Binghamton/Johnson City, NY	73,632	93.2	53.1	47.8	74.2	35.8
Raleigh, NC	232,652	70.8	51.5	54.8	86.5	18.9
Greensboro, NC	251,208	71.1	52.7	53.4	79.0	21.0
Medford/Ashland, OR	66,832	94.7	52.4	49.1	83.4	29.8
Albany/Corvallis, OR	77,323	92.2	50.4	45.6	87.5	31.4
Bellingham, WA	76,908	92.9	51.3	48.4	85.4	24.9
Longview/Kelso, WA	62,433	95.0	50.9	50.3	77.5	28.2
Brantford, Ontario, Canada	88,525	[a]	51.5	50.7	56.3	14.9
Peterborough, Ontario, Canada	91,075	[a]	52.2	49.7	63.4	15.0
Mean for Intervention Sites	105,159	74.6	51.8	51.4	76.2	22.7
Mean for Comparison Sites	103,338	76.6	51.8	50.6	74.5	24.6

[a] *Data not available.*

TRIAL TIMELINE The COMMIT trial was initiated in September 1986 and was implemented in three phases. Phase I (October 1986 through October 1988) focused on the development of a standard intervention protocol, an evaluation plan, and the baseline assessment, randomization, and mobilization of communities. During Phase II (October 1988 through December 1992) the intervention was implemented in the 11 intervention communities. During Phase III (January 1993 through March 1995) final surveys were conducted, and data from the trial continue to be analyzed.

OVERALL EVALUATION PLAN The study's evaluation plan measures changes in community smoking patterns and allows for testing the assumptions that have guided the development of the intervention strategies. Evaluation strategies are organized into four components: (1) outcome evaluation, which measures changes in smoking behavior; (2) impact evaluation, which measures changes in factors thought to be important in facilitating communitywide smoking behavior changes (including social norms about smoking, tobacco intervention activities by health care providers, and media coverage of tobacco issues); (3) process evaluation, which documents the extent of intervention implementation; and (4) economic evaluation, which estimates the costs of the COMMIT interventions.

OUTCOME EVALUATION The primary hypothesis to be tested in the trial was that the implementation of a defined intervention protocol, delivered through multiple community groups and organizations and using limited external resources, would result in a quit rate in heavy smokers that was at least 10 percentage points greater (e.g., 25 versus 15 percent) than that observed in the comparison communities. Outcome evaluation was designed to measure the effect of the COMMIT intervention on (1) smoking cessation rates among cohorts of heavy smokers, (2) smoking cessation rates among cohorts of light-to-moderate smokers, (3) the prevalence of overall smoking among adults, and (4) smoking onset among adolescents. The primary outcome measure was the smoking cessation rate of a representative cohort of heavy smokers; a secondary outcome measure was the smoking cessation rate of a representative cohort of light-to-moderate smokers.

Endpoint and Evaluation Cohorts To identify residents to be tracked as cohort members and to provide baseline prevalence estimates, a telephone survey was performed at baseline (January 1988) prior to randomization of communities. The baseline telephone survey provided information on smoking prevalence and recent quit rates for adults between ages 25 and 64 in the paired communities. The overall estimated prevalence of cigarette smoking was about 28 percent, which was comparable with national estimates of 30 percent, as reported in the 1984 National Health Interview Survey (Kovar and Poe, 1985). The specific estimates for the 22 communities (shown in Table 3) demonstrate that the community pairs were well matched not only on demographic characteristics but also on smoking prevalence and recent cessation behavior.

Table 3
Estimated smoking prevalence (by percent) and quit rates (by percent) in the COMMIT communities

Community/Area	Smoking Prevalence 1988	Quit Rate		
		Rate for 2.5 Years, 1983-85	Rate for 2.5 Years, 1986-88	Rate for 5 Years, 1983-88
Vallejo, CA	26.06	11.8	18.4	28.0
Hayward, CA	24.90	10.6	18.9	27.5
Cedar Rapids/Marion, IA	22.35	14.0	18.8	30.1
Davenport, IA	26.22	14.2	16.3	28.2
Fitchburg/Leominster, MA	26.27	12.2	17.5	27.6
Lowell, MA	29.08	11.1	16.9	26.1
Paterson, NJ	26.49	7.0	14.5	20.5
Trenton, NJ	28.76	9.9	13.3	21.9
Santa Fe, NM	21.96	16.0	22.5	34.9
Las Cruces, NM	19.54	13.6	21.0	31.7
Yonkers, NY	24.76	11.8	18.4	28.0
New Rochelle, NY	24.87	14.0	16.9	28.5
Utica, NY	26.49	11.9	16.9	26.8
Binghamton/Johnson City, NY	25.54	11.4	17.0	26.5
Raleigh, NC	22.84	12.4	19.7	29.6
Greensboro, NC	25.67	11.8	16.9	26.6
Medford/Ashland, OR	21.05	13.5	20.1	30.9
Albany/Corvallis, OR	18.29	13.2	19.2	29.8
Bellingham, WA	20.10	13.1	22.6	32.8
Longview/Kelso, WA	25.53	12.7	18.3	28.7
Brantford, Ontario, Canada	32.02	11.2	13.2	22.9
Peterborough, Ontario, Canada	28.06	10.3	17.0	25.6
Mean for Intervention Sites	24.45	12.3	18.4	28.4
Mean for Comparison Sites	25.44	12.1	17.4	27.4

Source: COMMIT Research Group, 1991.

The baseline telephone survey was conducted centrally using a modified random-digit-dialing technique with community-specific geographic screening to identify households within the target areas. Questions about gender, age, name, and smoking status of each adult household member (age 18 or older) were asked of an eligible proxy. This roster was used to identify potential members of the cohorts and to provide the basis for community smoking prevalence and quit-rate estimates. The response rate for this survey was 88.1 percent, with an average of 6,000 households listed in each of the 22 communities.

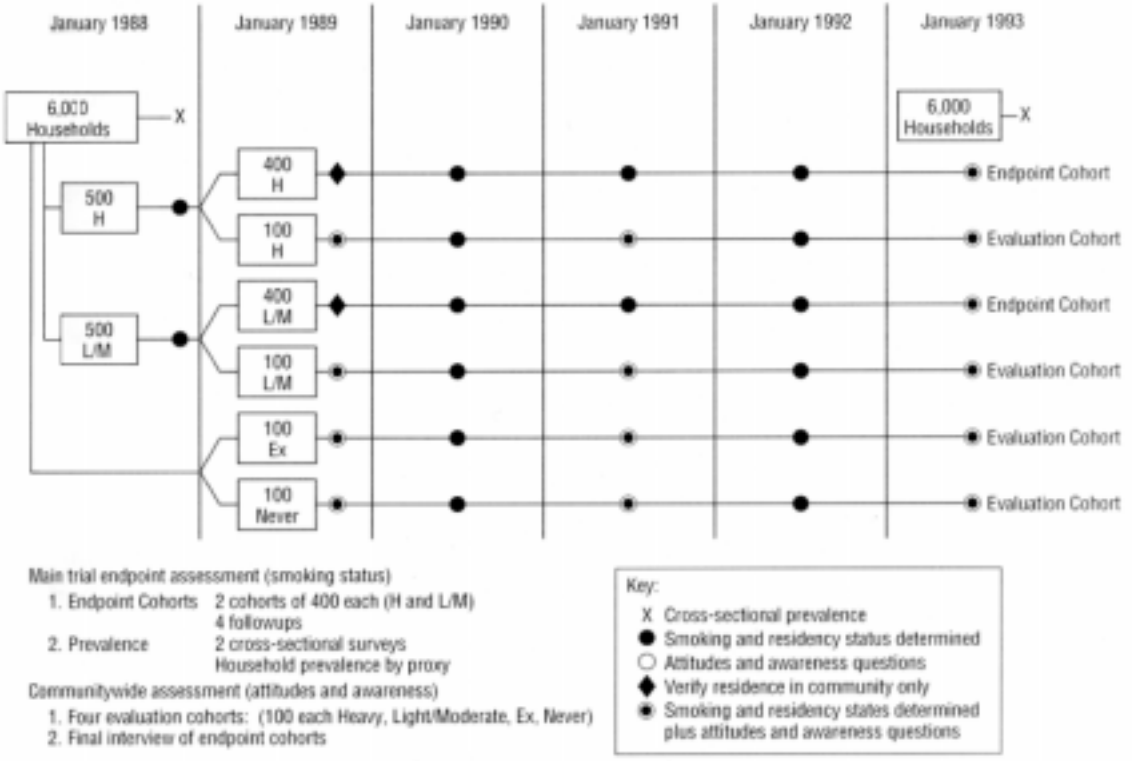
From this roster, current smokers and recent quitters were interviewed to determine the quantity and duration of cigarette smoking, quit attempts, desire to quit, and demographic and socioeconomic characteristics and to obtain tracking information. Groups of about 500 heavy smokers and 500 light-to-moderate smokers between ages 25 and 64 were identified in each community. (A smoker was defined as one who has smoked at least 100 cigarettes and who smokes currently; a heavy smoker was defined as one who smokes 25 or more cigarettes per day.) The response rate for this extended interview was 86.4 percent. The group of approximately 500 heavy and 500 light-to-moderate smokers was then subdivided into an endpoint cohort and evaluation cohort.

A randomly chosen 80-percent sample was drawn from each heavy and light-to-moderate smoker group to form the endpoint cohorts. Cohort members were not explicitly notified of their status; however, respondents were informed that annual contacts would occur. The endpoint cohorts were contacted briefly by telephone each year to determine smoking status and to update tracking information. To minimize reactivity, these cohorts were resurveyed indepth only at the end of the study. Figure 1 gives information on cohort size and smoking habits and shows the timing of cohort surveys. Attrition within cohorts was anticipated; the initial cohort sample sizes were selected so that sufficient statistical power would exist for the cohorts at the end of the trial.

The remaining 20 percent (approximately 100 individuals) of each heavy and light-to-moderate smoker group, along with approximately 100 recent quitters (who had quit within the previous 5 years) were identified to be part of the evaluation cohort. In 1989, an additional 100 nonsmokers (who never smoked or had quit more than 5 years earlier) per community were added to this cohort. At the beginning of the intervention (1989), members of this cohort were asked questions to assess three elements related to intermediate trial goals: the population impact of COMMIT on intervention program awareness, receptivity, and participation; recognition that smoking is a public health problem; and change in the social acceptability of smoking (see Figure 1). Questions also were asked at the midpoint (1991) and the end (1993) of the intervention. Members of the evaluation cohort also were contacted in 1990 and 1992 to update smoking status and tracking information.

The primary analysis compared quit rates among cohorts of heavy smokers in the pooled intervention and comparison communities. Other analyses compared quit rates among cohorts of light-to-moderate smokers, changes in prevalence of smoking, and changes in norms and attitudes about smoking. To ensure that the cohorts remained as representative as possible of their communities, no intervention activities were directed at individual cohort members; trial investigators and local program staff members had no knowledge of which smokers had been selected for the COMMIT cohorts. Population-based surveys were conducted centrally by

Figure 1
Surveys to assess smoking status (endpoint) and surveys to assess communitywide changes (evaluation)



Key: H = heavy; L/M = light-to-moderate; Ex = ex-smoker; Never = never-smoker.

Source: COMMIT Research Group, 1991.

independent contractors. All surveys were identified as being sponsored by the U.S. Public Health Service and were not linked to local COMMIT activities.

Definition of Trial Endpoints At the end of the trial, smoking status among individuals in the heavy smoker cohort was determined and compared for the intervention and comparison communities. A "quitter" was defined as a smoker who did not smoke for at least 6 months prior to the final followup survey in 1993. The quit rates were selected as the primary endpoint and—because an estimated 6,000 households in each community would have to be contacted to identify the heavy smokers—community members' change in smoking prevalence served as a secondary endpoint. The two endpoints provided different but complementary information. The cohorts gave information on individuals followed over time, but the data might have been complicated by loss to followup and reactivity. The community was the unit of analysis, and the community quit rates and prevalence of smoking were also valid indicators of community change.

Because the community was the unit of analysis, the power calculations for the cohort endpoint depend mainly on the number of communities and the estimates of variance in quit rates between communities. The power was less sensitive to the number of individuals in the cohort in each community. Using an estimate of the intercommunity variance based on data from the MRFIT and assuming that matching was completely ineffective, a cohort of 250 heavy smokers in each community yields a power of about 90 percent for detecting a 10-percent difference in the quit rate among heavy smokers, using a one-sided test, with the probability of a Type I error set at .05. The power to detect a difference of 10 percent among all smokers is also about 90 percent (Gail et al., 1992).

Matching Communities COMMIT was a randomized study employing a matched-pairs design. Matching was not necessary for evaluation plan efficiency; however, because the study consisted of matched pairs of communities, efficiency was increased (Freedman et al., 1990). Pairs of communities were selected on the basis of their geographical proximity and were later matched on variables strongly expected to relate to the outcome variable—the smoking quit rate. The matching variables ideally would be related to the smoking quit rates, but quantitative data on the gain in efficiency from the matching were not available. Therefore, before randomization, the baseline survey of each community was conducted to determine the prevalence of smoking and, of great relevance, the smoking quit rate over the previous 5 years. When this sequence (initial matching, acquisition of baseline information, randomization) was utilized, it was possible, even before the study began, to estimate the gains in efficiency from the matching. With the use of the baseline quit rates as surrogates for the quit rates to be observed over the 5 years of the study, an efficiency gain resulting from matching is predicted. The power for the cohort analyses may be as high as 98 percent, if the matching is as effective as findings indicate (Freedman et al., 1990).

IMPACT EVALUATION Impact evaluation was conducted by special population surveys to monitor whether changes in the channels of intervention that were hypothesized to reach the smokers were occurring. These included surveys of physicians and dentists, physicians' and dentists' office staffs, worksites, schools, cessation resources and services providers, and religious organizations. Hypotheses also were suggested that youth would be affected by a community trial; thus, youth also were surveyed. Each population is briefly described below; for more detail, see Mattson and colleagues (1990-91).

Physicians and Dentists Surveys of physicians and dentists within the communities were conducted to assess the impact of interventions on patients' counseling. Questionnaire items corresponded to the practice behaviors that were included in the intervention protocol. Information also was collected on office environments (smoke-free or not) and opportunities for training in smoking cessation counseling.

Physicians' and Dentists' Office Staffs Surveys of physicians' and dentists' office staff were conducted to determine office environments, availability of smoking cessation assistance for patients, signage regarding nonsmoking, and presence of chart reminder systems for smoking patients.

Worksites Worksite surveys focused on the presence of restrictive smoking policies, the presence or absence of employer motivational or incentive programs, and the availability of worksite smoking cessation programs.

Schools Surveys in schools focused on restrictive smoking policies, including identification of groups to whom restrictions applied (e.g., students, staff).

Cessation Resources and Services Providers This survey assessed the number of cessation resources and services available in the communities and the extent to which such services were used.

Religious Organizations This group was surveyed for the presence of restrictive smoking policies as well as the availability of smoking cessation resources.

Youth The COMMIT intervention targeted adult heavy smokers, but it was likely that a communitywide campaign against smoking would also affect the smoking behavior of adolescents. For this reason, the COMMIT evaluation included assessments of the smoking habits and attitudes of representative samples of ninth-grade students in intervention and comparison communities in 1990 and 1993. A random sample of approximately 18 ninth-grade classrooms per community, involving approximately 450 students, was surveyed in 1990 and again in 1993. The sample size of the youth survey was designed to permit detection of a 5-percent net change (e.g., from 10 to 15 percent) in surveyed adolescent smoking prevalence between intervention and comparison matched communities.

PROCESS EVALUATION Another level of evaluation revolved around the activities that were developed to meet the impact objectives. The activities had process objectives attached to them that were designed to achieve the impact goals. Process objectives specified what was considered to be the minimal amount of intervention change required to contribute to the achievement of the overall trial goal. Information was collected on the implementation of each protocol activity, including when events were held, number of attendees, materials distributed, and miscellaneous information. This information was collected through a computerized tracking system developed for this project (Corbett et al., 1990-91).

The COMMIT Program Records System (PRS) was a computerized relational database that had two major purposes: (1) data collection of activities and participation by local groups and individuals and regular updating of the denominators for the various process objectives; and (2) provision of an efficient system to capture, retrieve, display, and report information both locally and trialwide. Centralized quality control procedures were followed.

The data collection process was based on standard forms completed by field staff members as specific activities were initiated, planned, and implemented. The data from the forms were then entered into the system, using preexisting screens and prompts. During the initial stages of the local operations, field staff members also entered the names, addresses, and other contact information for the various groups that were the targets for intervention (e.g., physicians and dentists, hospitals and clinics, worksites, schools, cessation resources and services providers, and religious organizations). These files were named the "affiliate" files and were used to produce sampling frames for surveys and mailing labels and to provide the denominators, updated annually, for each of the targeted groups. The system also allowed recording of data related to other trial objectives, such as monitoring of media (newspapers, billboards, and some electronic media) and optional activities conducted by the community.

The system produced, on request, a status report for process objective attainment. Summary scores of process objectives attained were calculated by community, intervention channel, and the overall trial.

Another part of process evaluation was the development of a method to collect regular qualitative data on trial activities, which was done through a quarterly report that described various interactions with the community volunteers working on the trial, monitored legislative events, kept track of changes in the community context, and documented case studies within the communities (Corbett et al., 1990-91).

ECONOMIC EVALUATION The final level of evaluation for the trial was an economic analysis to estimate the costs of the trial. The primary outcome of this analysis would be the estimated marginal societal costs of increased smoking cessation (Mattson et al., 1990-91). The analysis also would examine the resources provided by the funding agency and estimate the extent to which those agency resources generated additional community resources for smoking cessation.

SUMMARY The COMMIT evaluation was as ambitious as the trial. Trial investigators developed a multilevel approach to the project evaluation. Each level down from the outcome evaluation in the cohort of heavy smokers provided a richer and more indepth understanding of what happened in the trial. In a symposium held more than a decade ago, researchers acknowledged that community interventions presented unique problems for assessment of results because the interventions were designed to reach further than the individuals being evaluated (Hulley, 1978; Syme, 1978). Using the multilevel evaluation plan described here will allow researchers to ascertain the "dose" of intervention delivered to each community, the association between the dose and the intermediary agents that were expected to change their activities and behavior to encourage smokers to quit (e.g., policies advocated by physicians and dentists, worksite policies), the receipt of the interventions by individuals (change in attitudes and community norms around smoking), and the change in behavior (smoking cessation).

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