Community Intervention Trial for Smoking Cessation: Development of the Intervention

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INTRODUCTION   The Community Intervention Trial for Smoking Cessation (COMMIT) intervention protocol was developed by collaborating trial investigators during a 24-month planning phase. To select the specific intervention methods included in the COMMIT protocol, the investigators used a wide variety of data from controlled and demonstration trials of smoking control strategies as well as advice from public health experts and their own experience in large-scale behavior change efforts. The protocol took into account several theoretical perspectives on health behavior change, including social learning theories (Bandura, 1977 and 1986; Abrams et al., 1986; Elder et al., 1986), persuasion models for communication and social influences (Bandura, 1977; Flay et al., 1983; McAlister et al., 1982; Rogers, 1973), the health belief model (Green et al., 1980; Rosenstock, 1974), action research models for community organization and innovation diffusion (Rothman, 1979; Grusky and Miller, 1981; Gusfield, 1962; Rogers and Shoemaker, 1971), and others.

In evaluating smoking control literature, it was obvious that the vast majority of the published literature had focused on individual-oriented strategies as discussed in Chapter 2 of this monograph. Although these interventions were viewed as efficacious in many settings, especially clinical settings, most COMMIT investigator team members saw them as inefficient and inconsistent with the overall intervention philosophy of this trial, which is intended to achieve large-scale change within the community. In addition, enhancement of traditional cessation services (i.e., quit-smoking programs and self-help materials) was deemed as supportive of the overall goals of the trial but insufficient to achieve the breadth of change desired. The consensus of the investigators was that other primary intervention strategies were needed to reach large portions of the smokers in the community; furthermore, such strategies needed a high potential of increasing both the frequency and success rate of self-initiated quit-smoking attempts.

The investigators were guided in the development of the COMMIT protocol by the fundamental assumption that a community approach to smoking control must focus on the social and environmental factors that influence smokers' contemplation of quitting, efforts to initiate quitting behaviors, and ability to maintain abstinence on a permanent basis (Farquhar, 1978; Farquhar et al., 1981; Blackburn and Pechacek, 1986; Thompson and Kinne, 1990). It also was expected that communitywide intervention strategies would be more effective because they would provide a sustained intervention effect on a large segment of the smoking population, as opposed

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to sporadic higher intensity intervention contacts with only the small segment of smokers willing to attend or participate in more traditional smoking cessation interventions (Leventhal et al., 1980; Schwartz, 1991). A significant portion of the trial intervention effort was expected to focus on changing the community's social norms regarding smoking as well as the overall informational environment so that it would be difficult for any smokers in the community to escape the consistent and repeated messages about the benefits of cessation; simultaneously, they would be provided with ongoing cues and opportunities to initiate quitting behaviors (Lichtenstein et al., 1990-91; Thompson and Kinne, 1990; Thompson et al., 1990-91).

Nevertheless, it also was recognized that few tried-and-tested interventions existed that were not individual oriented. A few community studies, such as the North Karelia Project (Puska et al., 1983), the Australian North Coast Healthy Lifestyle Programme: Quit for Life (Egger et al., 1983), and others discussed in Chapter 2, targeted smoking cessation as one of their endpoints. The projects used several strategies, including mass media and skills training, which were examined in the development of the COMMIT interventions. However, the COMMIT interventions were developed primarily from existing programs within the Smoking and Tobacco Control Program of the National Cancer Institute (NCI). The trial investigators selected the best individual or small-group interventions that existed and grouped them together in an intervention package that was expected to reach all facets of the community. Channels of intervention that were thought to be key for reaching heavy smokers were identified and provided an organizing structure for specific activities. The interventions were designed to be delivered through a community-organization approach so that they would become an integral part of the everyday lives of the community's smokers.

INTERVENTION GOALS AND OBJECTIVES   The evaluation of COMMIT specified one primary outcome goal— an increased cessation rate by heavy smokers in the intervention communities. However, for that goal to be reached, several other community changes had to occur. Using a public health perspective and a community focus of intervention, the investigators defined four general intervention goals to guide the COMMIT effort:

1. *Increase the priority of smoking as a public health issue*. As previously discussed, most intervention efforts have focused on smoking as

an individual's problem behavior, resulting in primarily clinically oriented cessation methods rather than interventions that involved the broad social and environmental networks in which a smoker lives and smokes. The COMMIT intervention defined smoking as a community problem that requires public health action by the community at large. Although the COMMIT intervention was focused primarily on adult smoking cessation, smoking prevention also must be addressed; hence, activities focusing on youth and prevention were incorporated into many trial interventions.

2. *Increase the community capacity to modify smoking behavior.* When smoking has been viewed as an individual problem, community resources to assist smokers have tended to be relatively sparse. In conjunction with efforts to meet the first goal, it is acknowledged that individual smokers who seek assistance need to have an adequate system of resources and services available. These resources and services need to be fully integrated into community institutions and groups so that the logistical barriers to their use can be reduced and delivery of these services by the community can increase the overall capacity to address the smoking problem. The investigators recognized that traditional clinical programs are used by a small minority of smokers and that the community resources and services promoted by COMMIT need to include any and all methods that may interest smokers. Furthermore, mechanisms must be in place to remind smokers of the available opportunities to seek help with cessation.

3. *Increase within a community the influence of existing policy and economic factors that discourage smoking.* Local and State laws and ordinances controlling smoking in public places and limiting tobacco sales have become common in the United States and Canada (U.S. Department of Health and Human Services, 1993). It is clear that such policies and economic factors can be an important part of the social environment of smokers and their decisions to attempt cessation. Factors that

can influence smoking rates include cigarette taxes; constraints on advertising and promotion of tobacco products; policies related to the sale and distribution of cigarettes, especially to minors; and restrictions on smoking in public places, worksites, organizations, and other settings where smokers tend to congregate.

4. *Increase social norms and values supporting nonsmoking.* The social acceptability of smoking is steadily declining in the United States and Canada (U.S. Department of Health and Human Services, 1989). Although a social norm supporting nonsmoking is emerging, progress in many communities is still hampered by the prevailing perception that smoking is a problem of an individual. As intervention efforts attempt to highlight smoking as a public health and community problem, opportunities will arise to strengthen the perception that nonsmoking is normative and to be valued and that smoking is harmful to the community at large. As the social acceptability of smoking declines, the negative social consequences of smoking increase and further reinforce both quitting behaviors and maintenance of abstinence in recent quitters.

These four overall trial goals led to the establishment of several objectives that, if reached, could be expected to help meet the goals. Similarly, the identification of trial activities was predicated on the relationship between those activities and the objectives they were intended to attain. The philosophy that a hierarchical association exists between the overall trial goal, intermediate trial goals, impact objectives, mandated intervention activities, and process objectives led to a systematic development of goals and objectives.

Intermediate goals were directed at the various channels of intervention identified as being critical to achieving community change. The channels contained intermediary agents that were likely to come into regular and repeated contact with smokers. In addition, the intermediary agents also were thought to be amenable to new practices that would encourage smoking cessation. An example is found in the health care provider channel. Because the majority of smokers see a health care provider annually, a relatively simple change on the part of providers—reminding smokers to stop or setting quit dates with smokers—may be sufficient to lead many smokers to attempt cessation. The intermediate goal, then, is to build a critical mass of health care providers who give such regular encouragement. To achieve that goal, several impact objectives were established; for example, 80 percent of community physicians and 65 percent of community dentists should receive training in basic smoking cessation practices, and 30 percent of physicians' offices should receive training in setting up office systems to track smokers and document that cessation encouragement was given.

Similar impact objectives were established for each of the four major channels of intervention (i.e., health care providers, worksites and organizations, cessation resources and services, and public education), plus a fifth overarching channel of community mobilization. Attempts also were

made to quantify the degree to which objectives had to change to achieve the trial goals. Through the use of existing literature, previous intervention experience, and advice from experts in the smoking field, consensus was reached among the trial investigators concerning the quantification of the impact objectives (Wallack and Sciandra, 1990-91; Ockene et al., 1990-91; Sorensen et al., 1990-91; Pomrehn et al., 1990-91).

Impact objectives, in turn, led to the mandated activities required by the protocol. The extant literature, experience of investigators, and much discussion resulted in the identification of a set of activities for each intervention channel considered likely to lead to realization of the impact objectives. Assessment of the implementation of intervention activities was accomplished through the completion of process objectives that documented various components of the activities. A computerized system for tracking process objective achievement also was developed (Corbett et al., 1990-91).

INTERVENTION AREAS   The intervention protocol was divided into five major sections corresponding to the channels of intervention: Community Mobilization, an overarching section to organize the community around tobacco control; Health Care Providers; Worksites and Organizations; Cessation Resources and Services; and Public Education. Each of the five channels was selected for its potential contribution toward achieving the trial outcome. Most mandated intervention activities within each channel area had proved efficacious in other settings, and the investigators believed that combining such intervention activities would result in a synergism that would lead to change. Each channel is described below.

Community Mobilization Channel   COMMIT's overall goal of community mobilization was to build the capacity of communities to address smoking control issues. Community mobilization also was intended to facilitate the implementation of smoking control activities and ensure maintenance of these activities.

Achieving citizen participation and community partnership requires mobilization of a community. Mobilization is a process through which community members become aware of a problem, identify the problem as a high priority for community action, and institute steps to resolve the problem (Thompson and Pertschuk, 1992). Each community has its own structures, history, and resources necessitating some variation between communities in the process of mobilization. The logic and philosophy of the trial provided each community, through standard mobilization features, with some discretion in local trial management. The basic mobilization model was designed to provide scientific integrity while allowing some local flexibility to establish structures and implement activities in a manner congruent with local practice.

The mobilization plan began with a strong understanding of the community gained through a community analysis designed to yield a systematic understanding of community history, social climate, culture, structures, resources, organizations, and key individuals. Research staff

identified several key individuals as candidates for an initial planning group, where members were introduced to the trial's rationale, design, and protocol. Depending on their enthusiasm and availability, they were asked to serve on a short-term Community Planning Group charged with developing a more comprehensive and long-lasting community Board. Each intervention community had to form a new community Board, which was required to provide project legitimacy, access, and overall management support to the community; to represent the key sectors considered to be important in all communities (i.e., health care, business and labor, health voluntary organizations, media, education); and to accurately represent the community. Rules were established to maximize community involvement in intervention planning and implementation. Wherever local groups or organizations existed that could conduct an intervention activity, they were given highest priority to do so, even if required training of staff or enhancing the resources that were already dedicated to the activity was required. Similarly, rules were established for resource allocation in accordance with the philosophy that the resources available through the trial were by themselves insufficient to implement the protocol but should be perceived as "seed" resources to develop existing or new community mechanisms for smoking control.

The trial protocol was developed by the investigators before the communities were randomized; therefore, the community had no input into the content of the protocol. However, communities were expected to develop their own plans, consistent with the protocol, to achieve a social climate that would support non-use of tobacco. To maximize the potential of communities to make a permanent change, external resources (NCI funded), both fiscal and human, were limited and considered seed resources. Limiting resources would encourage the communities to contribute some of their own resources and thereby eventually incorporate some tobacco control activities into their own organizational structures.

Health Care Providers Channel   Health care providers and the settings in which they work are important to reaching heavy smokers in the community (Ockene et al., 1990-91). Targeted health care providers included physicians and dentists, although it also was considered desirable to involve pharmacists, nurses, respiratory therapists, and other health care providers. The mandated intervention activities focused on involving community health professionals in smoking cessation intervention activities in their practices and in their roles as community leaders. Each community identified key influential health

professionals who were interested and able to play leadership roles in the COMMIT intervention. National training equipped these influentials to persuade their colleagues indirectly through discussions at meetings and social events and directly through presentation of types of training events to make smoking cessation counseling part of their regular practice. An important component of this task force was the policy change expected to take place in all health care facilities in the communities. Intervention objectives included smoke-free hospitals, medical offices, nursing homes, and substance abuse treatment centers. Enhancing the availability of cessation information and antismoking promotional messages was also an important goal of this channel.

Worksites and Organizations Channel   Worksites are an ideal location for promotion and support of smoking cessation efforts, including both programs and policies. Seventy percent of adults between the ages of 18 and 65 are employed (Sorensen et al., 1990-91). Worksites and community organizations are opportune places to publicize project activities, offer quit-smoking programs, promote policy changes, and foster environments supportive of successful quitting. They also are important as sources for personnel and local resources to support project activities, particularly large-scale community events. Intervention activities described for worksites and organizations were to be offered widely in the community; however, activities were targeted particularly to sites in which heavy smokers could be reached most effectively. Worksites offered great potential for reaching less educated and less motivated heavy smokers who might not volunteer for or be reached by other community antismoking activities. Restrictive smoking policies were seen as having much to contribute to the social environment; therefore, many COMMIT intervention activities in this channel were oriented to presentations and consultations with worksites to assist them in implementing policies.

Other organizations also were targeted for intervention. Fraternal organizations, civic groups, religious organizations, and so forth were used both for promotion of smoking cessation policies and activities and as targets for such interventions. The protocol called for intervention activities such as presentations to encourage more restrictive policies, provide information to such groups, and attempt to involve these groups in promotion activities.

Cessation Resources and Services Channel   In addition to the powerfully addictive nature of tobacco, there are many barriers that contribute to the continuing high smoking rate among adults. Although knowledge of the hazards of smoking and the benefits of quitting provide reasons for cessation, barriers to quitting include willingness to take a risk, paucity of cues to quit smoking, difficulty

45

in obtaining self-help materials, low awareness and use of existing smoking cessation services, high relapse rates among smokers trying to quit, and inadequate social support for smokers who are motivated to quit. A wealth of information exists regarding methods and techniques that can aid smokers who are trying to quit (Schwartz, 1991; Thompson and Hopp, 1991). Much is available in self-help formats, including books, pamphlets, audiotapes, and videotapes, and most of these materials are available from voluntary health agencies free or at minimal cost. Numerous programs to help smokers have been developed and refined over the past three decades. Programs offered by the major health voluntary organizations, local hospitals, and other community agencies have benefited from the thousands of research projects on smoking cessation conducted in recent years.

A fundamental assumption underlying COMMIT intervention activities was that an increase in cessation rates requires a change in the social circumstances surrounding smokers' decisions to quit, to initiate quitting, and to maintain abstinence (Pomrehn et al., 1990-91). The aim of COMMIT was not to provide cessation services; rather, the aim was to increase the demand for cessation resources and services as smokers became more willing to attempt cessation. Thus, activities in this channel were limited to those that provided the regular, inescapable messages about opportunities for cessation. Specific intervention activities, such as a voluntary smokers' registry, newsletters, and publication of guides promoting cessation resources and services, were undertaken to increase the quantity and utilization of existing services. Those activities also were designed to enhance the efforts of other trial interventions, particularly worksite, organizational, and health care provider interventions.

Public Education Channel   Communitywide public education efforts were central to the trial's activities to meet overall intervention goals. Educational efforts focused on mass media campaigns promoting smoking as a public health problem, smoking prevention, and communitywide cessation activities. The media contribute significantly to the overall context in which personal decisions about initiating, continuing, or quitting smoking occur. The media are a key source of social-environmental cues regarding nonsmoking behavior (Wallack and Sciandra, 1990-91). An important function of this channel was to establish and maintain the visibility and credibility of COMMIT in the communities.

Mass communication plays a significant role in the ongoing effort to control smoking. The media can perform an important agenda-setting

function, they can confer status and legitimacy, and they can activate public discussion. In addition, the media can reinforce nonsmoking behavior (among both smokers and nonsmokers), generating further help-seeking behavior (e.g., calling a toll-free number) and recruiting smokers into treatment programs, and can advertise and promote opportunities for cessation. The media also can promote norms that are supportive of nonsmoking and quitting.

Smoking prevention among youth was not a primary program focus in COMMIT. However, activities targeted at youth have the potential for increasing the community's awareness of smoking and health issues and for shifting social norms. Health promotion through educational, policy, and regulatory activities aimed at youth have traditionally been noncontroversial and can provide leverage for community organizing efforts. Tobacco education activities for youth were used to enhance the visibility, credibility, and acceptability of COMMIT. Although school-based, tobacco use education was not emphasized in COMMIT, it is hypothesized that the overall intervention can decrease the prevalence of adolescent smoking, can have an effect on smokeless tobacco use among adolescents, and will modify the precursors of adolescent smoking behavior.

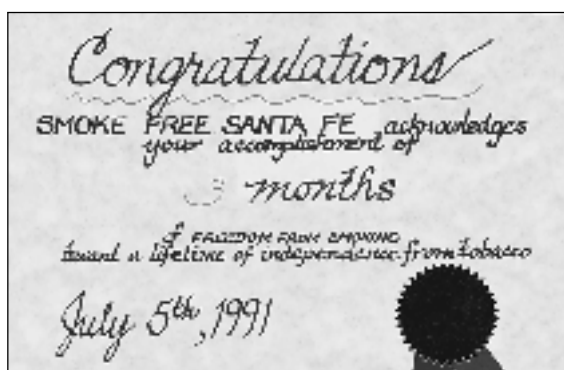**SPECIAL CONSIDERATIONS OF THE INTERVENTION DESIGN** An important factor in the COMMIT intervention was the necessity to constrain the intervention to relatively small communities so that a rigorously designed trial could be implemented. However, it is important to note that communities are not independent social systems. They exist also in a larger social context, and external events or changes in the broad social system can have a substantial effect on the local community. As a conceptual framework, a system's perspective provides a useful model. In such a perspective, the community is made up of many different components, including political, economic, and health sectors (Thompson and Kinne, 1990). Changes in any part of the system or changes external to the system reverberate throughout the system and result in adjustments or responses that will ultimately affect the entire system. Social norms change along with the system to provide new rules of conduct (Robertson, 1977).

Just as the North Karelia Project showed that an implemented national policy could affect smoking behavior nationally (Puska, 1983) and just as the Minnesota Heart Health Program indicated a large secular trend that may have overwhelmed any intervention effect (Luepker et al., 1994), several external factors were present during the COMMIT trial that could have had an impact on the communities involved. For example, California passed Proposition 99, which released huge amounts of resources for antismoking activities, including mass media campaigns that directed attention to minorities, members of low socioeconomic groups, and other subgroups of smokers. Another example is Canada's passing an excise tax that raised the price of a package of cigarettes to new highs and resulted in a decrease in the prevalence of smoking. Within New York State, policies on smoking in public places, including worksites, were strengthened.

Nationally, the U.S. Environmental Protection Agency classified secondhand smoke as a Class A carcinogen (U.S. Environmental Protection Agency, 1992), making employers think more seriously about the liability associated with smoking in the workplace. National fast-food restaurant chains became at least particially smoke-free to to project an image of protecting youth. In short, the broad social environment within which the pairs of communities were located may have changed substantially, making it difficult to determine what the effects of the COMMIT intervention alone were.

The COMMIT interventions initially were formulated to provide synergy between the various activities. Synergy is the cooperation among various parts of the system or the way the components of a system act together. When activities are oriented toward a common goal, synergy makes the net effect of the forces greater than the sum of its parts. Synergy makes it impossible to separate out the contribution to the outcome of the various parts of the COMMIT intervention. The investigators had to be satisfied that the package they developed produced synergy, which meant that no channel could be emphasized over another and that subsequent analyses to account for the contribution of specific channels were not possible. This approach was further complicated by issues of measurement. Only the achievement of process objectives was measurable; it was not possible to assess the interaction between various activities or process objectives.

Another key consideration involved the group of investigators involved in the project. Because the individuals came from a variety of disciplines, backgrounds, and experience levels, there was initially considerable controversy over the approach to take. The options were reduced to two basic approaches: In one approach, the 11 intervention communities would simply be given resources to design their own studies, whereas a standardized protocol would be followed in the other. The first approach would produce a purer community study but would likely result in many different interventions. This could not be regarded as a rigorous randomized controlled trial. The second approach fulfilled the requirements of scientific rigor but greatly constrained the role of the community in designing interventions. The limited time for planning and discussion of these issues made it difficult for investigators to come to consensus. The design process of the trial alienated various "stakeholders," and this resulted in wasted effort and time.

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SUMMARY   The theoretical base for COMMIT used existing knowledge, state-of-the-art interventions, and the wisdom of investigators in the field to develop an intervention strategy and protocol oriented to meet the trial's overall goals

and impact and process objectives. Mandated activities were intended to lead to achievement of the impact objectives, which in turn would lead to attainment of the intermediate and overall trial goals. A number of lessons were learned in the development of the protocol.

1. The intervention strategies implemented in COMMIT were designed to have a large effect on the communities' attitudes to and behaviors regarding cigarette smoking, yet there was little in the literature to provide insights on how best to do this. Even media studies that had been conducted previously showed only marginal changes in knowledge and attitudes.

2. Although the COMMIT protocol was built on the best knowledge available from randomized clinical trials in the area of smoking control, it is not clear how those experiences can be extrapolated to a randomized community trial.

3. A unique feature of COMMIT was that the diverse and extensive interventions were combined in such a manner that a communitywide effect was anticipated. Based on the supposition that people are more likely to stop smoking when the policies regulating smoking, the opportunities for cessation, and the messages about the dangers of smoking for both smokers and nonsmokers are predominant within a community, COMMIT wished to create a social environment in the intervention communities where smoking was nonnormative. Despite these ambitious goals, it was unclear how best to change policies and get messages to the target group of heavy smokers.

4. It was assumed that implementation of the mandated activities through the five intervention channels would make it difficult for any smoker to avoid messages about or opportunities for smoking cessation. Again, there was not strong evidence from the results of other trials to support the assumption.

5. The community is not an entity in and of itself; rather, it exists in a broader social context that also may be changing. When a community rides the secular trend, it is difficult to judge the effects of an intervention; it may have been better to build more flexibility into the protocol so that different tactics could have been used when the external environment changed.

6. Synergy is an excellent construct but was impossible to measure in this trial. That may not be completely negative, but if efficient trials or interventions are to be devised, it would be helpful to be able to identify the components of the intervention.

7. Lack of attention to stakeholders in the development of the protocol led to considerable controversy. More time should have been allowed to reach consensus in a trial of this magnitude.

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