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EDITOR: GEORGE P. CERNADA

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SPECIAL ISSUE

Community Intervention Trial for Smoking Cessation: COMMIT

(Continued on back cover)

ROUTLEDGE

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The *International Quarterly of Community Health Education* is committed to publishing applied research, policy and case studies dealing with community health education and its relationship to social change. This rigorously peer-refereed journal will consider all manuscripts but will especially encourage stimulating articles which manage to combine maximum readability with scholarly standards. The journal will stress systematic application of social science and health education theory and methodology to public health problems and consumer-directed approaches to control of preventive and curative health services. Environmental and structural changes will be emphasized and *victim blaming* approaches will be closely examined.

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EDITOR'S FOREWORD

This special issue is devoted exclusively to the Community Intervention Trial to Reduce Heavy Smoking (COMMIT). This eight year, $45 million program, sponsored by the National Cancer Institute, is the largest community smoking intervention ever attempted. The eight articles provided here present a comprehensive overview of the project's rationale, intervention, and evaluation plan.

COMMIT is of special interest to health educators because it endeavors to integrate research, community organization, and rigorous evaluation to address a significant world health risk. We are grateful to this issue's co-editors for providing our readers with these articles which emphasize the importance of community mobilization, ownership and partnership in educational intervention as well as the difficulties of balancing standardized research protocols against the need to design interventions suitable to a particular and often unique community setting.

This issue of the Journal is our first devoted to a single topic. Deciding to try this format after more than fory issues may have been influenced by our recent experience at the School of Public Health at the University of Massachusetts in Amherst. As our readers know from our last volume, we are implementing a large-scale smoking intervention study sponsored by the National Cancer Institute to test out the merits of a community-based and community-organized educational intervention versus a mass media-oriented campaign. This ongoing study is taking place in four large U.S. cities: Columbia, South Carolina; Durham, North Carolina; Hartford, Connecticut and Springfield, Massachusetts. Implementing agencies include, in addition to the School of Public Health at Amherst, the Connecticut State Health Department, Benedict College in Columbia and North Carolina Central University. The population in this study differs from COMMIT in being primarily black.

A description of preliminary results of the pilot baseline study related to mass media readership, viewing and listening habits and references on the overall study may be found elsewhere [1, 2].

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George P. Cernada

ACKNOWLEDGMENTS

The Community Intervention Trial to Reduce Heavy Smoking (COMMIT) is a large scale, multi-site project involving the efforts of many people. The articles in this issue represent the contribution of a host of people beyond the listed authors. Colleagues from the coordinating center, Information Management Services, Inc., National Cancer Institute (NCI), each of the eleven cooperating research institutions, and field staff from each of the eleven intervention sites all deserve to be recognized for their contribution. The COMMIT project contract is supported by NCI.

We are especially indebted to Joseph W. Cullen. Dr. Cullen, as Deputy Director of NCI's Division of Cancer Prevention and Control and Head of the Smoking Tobacco and Cancer Program, was the force behind the initiation of COMMIT and provided support for the trial in its critical formative period. His untimely death is an enormous loss to all those concerned with cancer prevention.

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INTRODUCTION TO THE COMMUNITY INTERVENTION TRIAL FOR SMOKING CESSATION (COMMIT)

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ABSTRACT

The Community Intervention Trial for smoking cessation (COMMIT) is sponsored by the National Cancer Institute and involves eleven pairs of communities in North America. COMMIT emphasizes a partnership between the eleven research institutions and their respective intervention communities in developing the structures needed to implement the intervention protocol. We summarize the epidemiological data and describe the prior community interventions that set the stage for COMMIT, and discuss how COMMIT may inform state-wide tobacco reduction demonstration programs. An overview of the articles that describe the COMMIT intervention and evaluation plan is presented.

RATIONALE FOR COMMIT

Goals for Disease Reduction

Thousands of epidemiologic and animal studies have provided conclusive evidence that tobacco use increases a person's risk of developing cancer at a

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variety of sites; in particular, smoking causes lung cancer [1]. Smoking is also a proven risk factor for cardiovascular disease [2, 3]. The weight of the evidence linking tobacco use to cancer and heart disease is so uniformly persuasive that the Surgeon General of the United States has stated, "Cigarette smoking is the chief, single, avoidable cause of death in our society and the most important public health issue of our time" [1].

Consequently, the National Cancer Institute's "Cancer Control Objectives for the Nation: 1985-2000" [4] identifies a reduction in smoking and use of tobacco products as one of the primary objectives in the goal to reduce cancer mortality by 50 percent by the year 2000. If a reduction in the use of tobacco products can be achieved, thousands of lives can be saved each year. However, the addictive nature of tobacco makes cessation of tobacco use extremely difficult, especially for the heavy user. Significant progress has been achieved in the study of smoking and smoking cessation; nevertheless, major questions exist concerning the most effective methods to reach and involve large number of smokers in the cessation process. The problem is particularly acute for heavier smokers.

The risk of cancer and heart disease among heavy smokers is substantial. Both the 1982 Surgeon General's report, *The Health Consequences of Smoking: Cancer* [1] and the comprehensive review of causes of cancer by Doll and Peto (1981) have reviewed the major prospective studies of the epidemiology of smoking and confirm that middle-aged smokers using twenty-five or more cigarettes per day have a relative risk of lung cancer that is fifteen to twenty-five times greater than for non-smokers. The more recent risk estimates from the American Cancer Society's Cancer Prevention Study II show that these relative risks may have *doubled*, since *all* smokers combined now have an estimated relative risk of over twenty-two for men [3]. These heavy smokers have a similarly elevated relative risk for cancers of the larynx, oral cavity, and esophagus [1]. Additionally, the risks of morbidity and mortality from cardiovascular and respiratory diseases are also dose-related [2, 5] and are highest for the heavy smoker. Heavy smokers represent about one-quarter of all smokers but account for nearly half of all the lung and smoking-related cancers among smokers [1]. Hence, heavy smoking is a pressing public health problem.

Readiness for a Community Approach: Phases of NCI Research

COMMIT is funded by the National Cancer Institute (NCI) and is designed as a Phase IV trial within the NCI's programmatic approach to prevention [6, 7]. Phase I and Phase II research involve developing hypotheses about promising risk reduction strategies and developing needed measures and procedures. Phase III studies are randomized trials in samples of convenience wherein the efficacy of a given risk factor reduction program is evaluated. These are outcome studies comparing different risk factor reduction strategies–e.g., for changes in diet, smoking, or screening behaviors–that are generally familiar to behavioral

scientists. Phase IV involves the systematic application of previously tested risk factor reduction programs within randomized trials using large, well-defined population samples drawn from entire workforces, neighborhoods, health care plans or communities. These Phase IV studies normally include an assessment of the impact of the risk factor reduction program on disease rates unless the link between behavioral changes and disease outcomes is very well documented (e.g., as with smoking). Phase V in the NCI approach involves disseminating the risk reduction program broadly enough to have an impact on national disease rates. The American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) described below is an example of a Phase V effort. It is at the fourth and fifth phases that community interventions are most appropriate.

Need for a Community-Based Approach

Community-wide smoking cessation approaches are based upon the assumption that many of the important circumstances supporting smokers' decisions to quit, to initiate quitting, and to maintain abstinence are social circumstances [8, 9]. An important aspect of these community-based intervention strategies is that they provide a sustained intervention effect on a large segment of the smoking population, as opposed to a sporadic high-intensity contact with only a small segment of smokers willing to attend clinic-based programs [10].

A variety of community-wide cessation programs have been conducted (e.g., [8, 11-19]). Often, these smoking cessation campaigns have been mounted as a component of community-wide heart disease prevention studies or other national health promotion initiatives. The early data from these community-based smoking cessation efforts have shown modest success but are generally encouraging. The results from the Stanford 3-Community Study demonstrated an impressive quit rate in the intensive instruction community sample [20] though not for the community which received only the media campaign. However, the feasibility of applying a similar type of intensive intervention protocol in other communities as well as the generalizability of the study design have been questioned [21, 22]. Similarly, results from the landmark North Karelia Study are generally favorable but qualified due to a variety of technical issues [23]. While these early community studies were able to measure some positive smoking cessation effects in cohorts, their inability to demonstrate actual changes in smoking prevalence in the intervention versus the comparison communities make it difficult to draw firm conclusions.

Several recent community-based interventions have shown more definitive population-wide cessation results. The Australian North Coast Program [12] utilized a design similar to the Stanford 3-Community Study, but the evaluation of the community-wide cessation rates was stronger since the effect was measured on independent population samples. The 15 percent net reduction in smoking in that study provides an estimate of the level of treatment effect which can be achieved

by a community-based cessation intervention. However, this study suffered from the methodological problem of non-random assignment of communities and a small sample of sites; hence, the results still must be interpreted with caution. Data from the more recent Australian "Quit for Life" media-based campaigns provide a basis for optimism for a sustained anti-smoking effect [17] although the impact was primarily among men [24]. The stronger evaluation methodology of this study increases the confidence in concluding that population-wide effects on smoking prevalence were produced [11].

Preliminary data from the current generation of U.S. Community Heart Disease Prevention trials also are encouraging. Recently published data from the Stanford 5-City Project [25, 26] demonstrate a progressive pattern of smoking cessation in the communities, with the two treatment sites consistently exceeding their matched comparison site during the five-year project. While the quit rate difference between the treatment and control sites within the population-based cohorts increased to 13 percent by the final follow-up, no differences were observed in the independent, cross-sectional surveys of smoking prevalence. The magnitude of changes reported within the Stanford 5-City Project are similar to those projected for COMMIT.

Preliminary data from the Minnesota Heart Health Program [27] suggest that a large proportion of smokers can be recruited to participate in cessation activities and that heavy smokers can be successfully recruited and aided in quitting [8]. While the data analyses of smoking cessation rates in both the Minnesota Heart Health Program and the Pawtucket Heart Health Project [16] are not yet complete, the community heart disease prevention trials have demonstrated that smokers can be reached and involved in community-based cessation programs [8, 28-30].

Smoking's proven status as the major, preventable cause of morbidity and mortality in developed as well as many developing countries around the world makes it the prime candidate for risk reduction interventions. Extensive clinical trial research (Phase III) has yielded a number of promising interventions which can be implemented within specific channels found in a community (e.g., media, worksite, health care providers, schools) while also suggesting that single strategies have limited potential in reaching large populations [31]. COMMIT was initiated in September of 1986 to establish a cooperative intervention trial in twenty-two communities in North America and is the largest smoking intervention trial in the world, involving over two million people. Intervention with heavy smokers (25 or more cigarettes per day) is emphasized due to the greater cancer and cardiovascular risk among this group and difficulty in quitting.

STRUCTURE OF COMMIT

At the national level, COMMIT is a partnership among eleven participating research institutions (one for each site), a coordinating center charged with responsibilities for data management and analysis and logistical support, and NCI

program staff. A thirteen-member steering committee composed of the principal investigators from each of the eleven field sites, coordinating center and the NCI project officers, and chaired by an outside expert, is responsible for the scientific management of the trial. The steering committee has an executive committee responsible for overall coordination and charged with handling matters requiring action between steering committee meetings, and three subcommittees to carry out needed work: 1) community organization and intervention; 2) design and evaluation; and 3) publications and presentations. A policy advisory committee composed of national smoking control and health promotion experts is maintained by the NCI to provide broad policy and scientific oversight of the trial and to advise NCI management on trial status and progress.

At the local level, COMMIT is a partnership between the eleven research institutions and their respective intervention communities. The conceptual premise of the trial is that permanent large-scale behavior change is best achieved by community-owned, multi-channel programs that enhance community resources and alter community norms [10, 32-34]. The protocol stipulates that a community board will be formed along with at least four task forces representing the major channels of intervention. Citizen volunteers staff the board and task forces supported by paid staff people hired from the community: a field director, a community organizer, and an office manager. Additional funds are available for materials, subcontracting with local resources, or hiring additional personnel for specific tasks. The number of staff and other resources available to the communities varies according to population and complexity of the local intervention channels.

Figure 1 depicts the organization of COMMIT focusing on the relationship between the research institution and local communities. While no single graphic can accurately portray the actual relationships for all eleven sites, the partnership nature of the organizational structure is a critical element of the trial [35].

PLANNING AND PROTOCOL DEVELOPMENT

During the initial planning and protocol development phase from fall 1986 to summer 1988, trial investigators defined a "state-of-the-art" package of community-based smoking cessation strategies. During the four-year intervention phase which began in fall of 1988, this package is being implemented in all eleven communities. The intervention period will be followed by an eighteen-month phaseout, when data analyses will be performed and final results reported. Figure 2 depicts this overall study timeline.

The intervention protocol was based on prior clinical trials research and focused on four primary intervention channels: public education through the media; health care providers; worksites and other organizations; and cessation resources. Another requirement, consistent with basic tenets of community psychology [36], was that protocol activities be defined such that they largely could be carried out

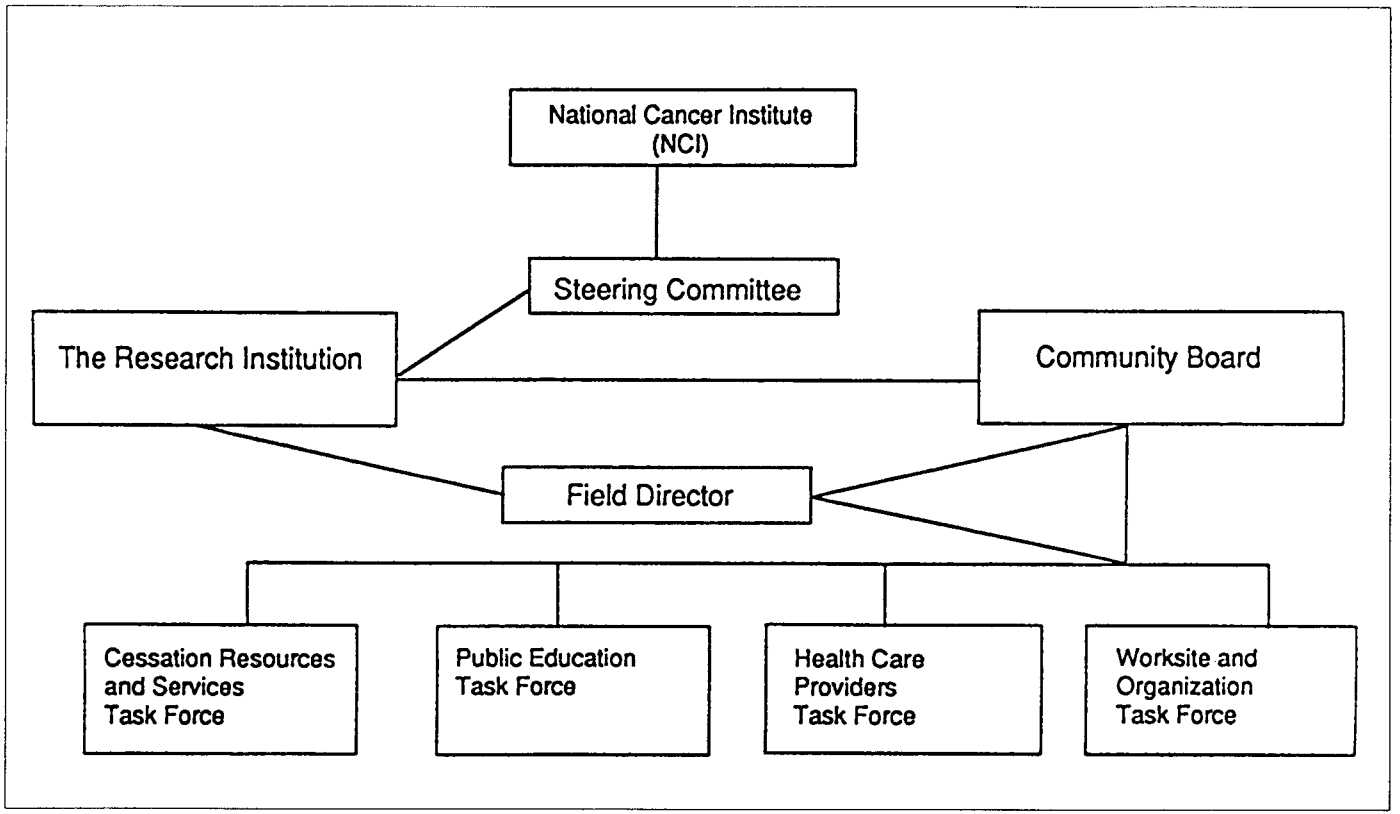

Figure 1. Commit Community organization chart.

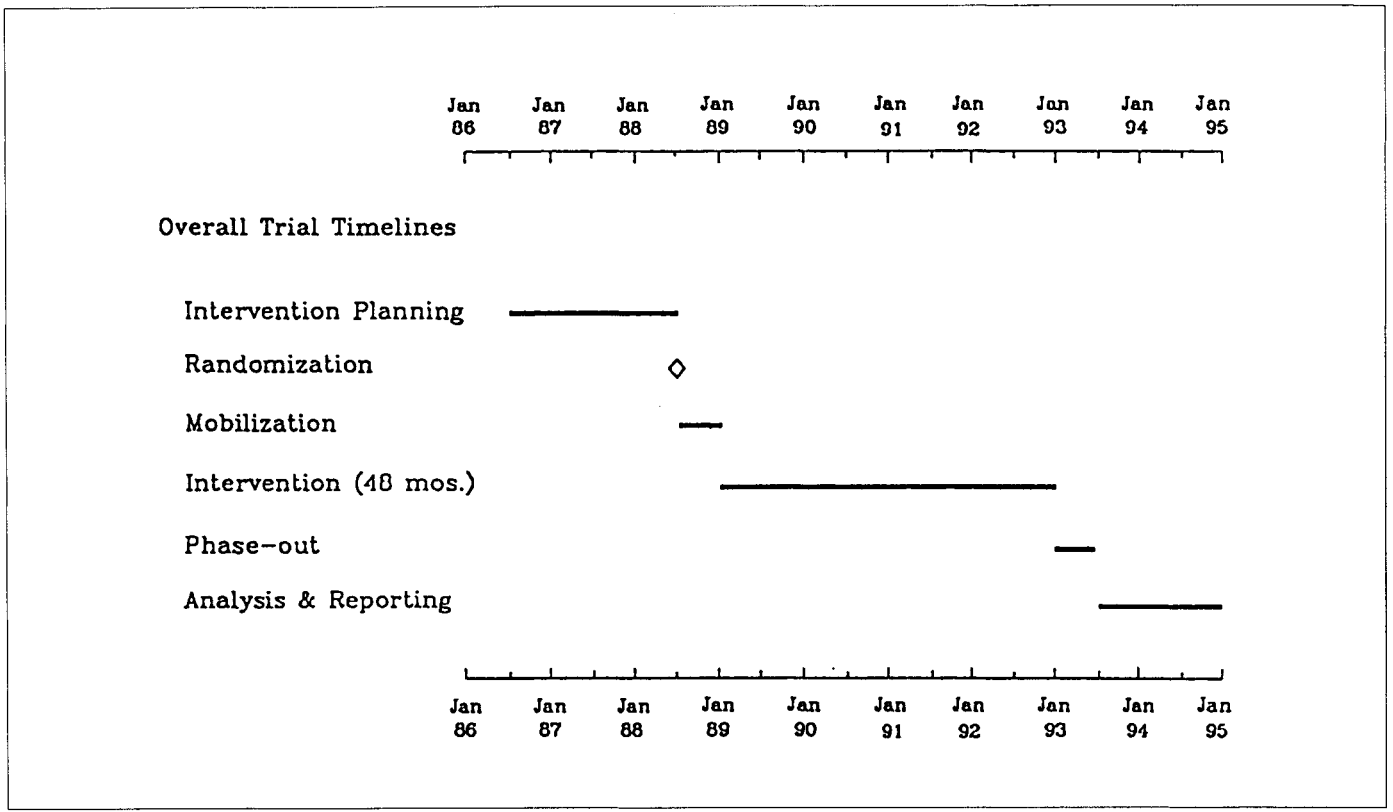

Figure 2. Study timeline.

by community volunteers or local staff or agencies. The research institutions, NCI program staff and other experts provide consultation, training, technical resource materials, and exemplar intervention strategies for the community staff and local volunteers. The decision to emphasize implementation with local resources was guided by the consideration that the *intervention* package being tested must be generalizable to other communities which might not have external resources.

While the research nature of the trial required a standardized level of protocol implementation across all eleven sites, the investigators incorporated a variety of recommendations and protocol adaptations to help communities adopt the protocol to their local conditions [37]. Ultimately, the trial investigators struck a balance between standardization and the principles of community mobilization. Throughout this process, the community and public health aspects of the smoking program were stressed, and are reflected in the trial-wide goals of COMMIT [35]:

- increase the priority of smoking as a public health issue;
- improve the community's capacity to modify smoking behavior;
- increase the influence of existing policy and economic factors that discourage smoking; and
- increase social norms and values supporting non-smoking.

BEYOND COMMIT

COMMIT is a very large scientific undertaking, but it is only one major step toward the ultimate purpose of all of the National Cancer Institute's research on strategies to reduce the use of tobacco: the public health application of proven tobacco control methods [4, 6]. Using the results of its clinical trials and other research efforts, NCI has joined forces with the American Cancer Society to launch the world's largest demonstration project for tobacco control and health promotion ever conducted–the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST).

While COMMIT intervention communities range in size from 57,572 to 163,036, any state, regardless of population, is eligible as an ASSIST site, as are metropolitan areas with a population of at least 2 million. Nevertheless, the organizational structure within an ASSIST site will build upon the COMMIT community mobilization experience [36]. Each ASSIST site is required to form a community-based tobacco control coalition that will be responsible for developing comprehensive tobacco prevention and control plans and implementing these plans in a coordinated fashion throughout the demonstration site. State and local health departments, because of their overall responsibility for the state's or metropolitan area's public's health, will serve as the fiscal agent for the ASSIST coalitions. Within COMMIT, all eleven communities are implementing a common intervention protocol. Within ASSIST, sites will be given more flexibility in