system would appear to be so duplicative, disruptive, and costly that a careful examination of the North Karelia program for elements pertinent to a less well organized health care system is clearly in order. The establishment of community-wide registries to facilitate surveillance and the expanded use of public health nurses in close coordination with physicians would appear to be reasonable approaches, for example.

The North Karelia Project will not answer the fundamental epidemiologic and clinical questions about whether intervention for a specific risk factor is justified or which are the most effective and efficient methods of intervention. The words of McAlister, et al, that "the North Karelia Project must be viewed as a promising case study rather than a critical test of the effects of health promotion," would appear to be a prudent and fair assessment. It is, however, a rich source of ideas and experiences gathered in the real world which, when considered alongside the results of the more rigorous but more limited experiments, provide a solid foundation for the design of the next generation of experiments.

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## Some Lessons from the North Karelia Project

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Dr. McAlister and his Finnish coauthors who are all participants in the North Karelia Project provide a highly valuable service because their paper is the first American publication to summarize all the efforts of the North Karelia Project. Moreover, they attempt to provide conceptual and theoretical analyses of the six major classes of goals that have guided the Finnish effort; that is, preventive services, information, persuasion, training, community organization,

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Editor's Note: See also related article p 43 and related commentary p 51 this issue.

and environmental change. Finally, the authors attempt to summarize the evaluation of the five-year effort and to consider the implications of the North Karelia Project for the United States. Because the comprehensive report on the Project, published by the World Health Organization,<sup>2</sup> requires several hundred pages, the potential value of a brief paper is great.

The authors succeed in achieving some of their goals while failing in the achievement of others. To begin, a careful reading of the paper should persuade many readers that many intervention strategies can be combined in efforts to improve health; including reorganization of health services, the introduction of environmental changes, the education of individuals and the public, and community organization. Many health workers take positions in favor of environmental modification and exclude public education as a feasible strategy for intervention. Other health workers are equally

extreme in promoting individual and public educational approaches to the exclusion of environmental change. It should be clear, that both approaches may be combined, and may be more effective than either alone.

It is the "may be" in the previous sentence that reflects the most serious flaw in the report of the North Karelia Project; namely, the evaluation design.

Evidence for program effectiveness was obtained using a separate sample, pretest-posttest design with a nonequivalent "reference" (i.e., comparison) group, which was a nearby county. The pre and post samples are separated by a period of five years, the intervention components being introduced at various points in the interim.

This evaluation design does not permit us to distinguish population changes which are due to program impact from those due to other forces affecting the population. For example, an apparent change in the diet of North Karelia could have come about less as a result of the program than of immigration to the region after the pretest. Although neither the monograph<sup>2</sup> nor the McAlister paper<sup>1</sup> is completely clear on this point, it seems that any immigrants to the county were automatically entered into the treatment population if they become permanent residents of North Karelia. As a matter of fact, the term "permanent resident" is never defined in either publication. If these new residents, by virtue of previous life-style, were already consuming low-fat foods, the study design would permit a mistaken attribution of their diet to the effects of the program. This problem is due to selecting two independent samples for the pretest and posttest, since population membership is likely to have changed in both counties over the five-year period.

Moreover, this evaluation design does not require any evidence that behavior was actually changed by the intervention although behavior change, after all, was the immediate target of the program. It was probably hypothesized, for example, that dietary advice would lead to changed dietary practices and the changed practices, in turn, would lead to reduced cholesterol levels. However, no determination was made of whether dietary advice did in fact modify dietary practices. The authors state that the advice was given, but we have no evidence that it was received, understood, or followed. As a consequence, changes in cholesterol, if any, are not necessarily attributable to the program. Clearly, something influenced people in the experimental population, since some effects were noted, but the measurement design leaves the effectiveness of the specific intervention open to question.

Another shortcoming in the design is the reliance on a single base line measure and a single post measure. There is thus the possibility that any observed changes in risk factors were due to trends already in operation prior to the base line measurement. This is especially likely when we consider that public awareness of the CVD problem was a factor in initiating the North Karelia Project in the first place; it is

possible that many individuals were already taking steps to change life-styles to lower the risk of later problems. Repeated measurements in a time-series design would have detected trends and eliminated competing hypotheses of this kind.

One question which is never addressed is that of the relative impacts of the various intervention components. Changes in the health service system, establishment of information dissemination systems, and the widespread use of small group behavior change techniques are all interventions on their own; each is costly to implement. Yet, a program planner who wishes to make use of the North Karelia example must, in the absence of more detailed information, consider the entire expensive package as a single intervention.

As a matter of fact, McAlister, et al, make no comment whatever on costs of the program, although the WHO monograph does discuss costs, at least in a cursory way. It is from the monograph that one learns that approximately 1.1 million US dollars were spent on direct costs for eight year's planning and intervention. This is said to be the cost of operating four to five beds in a Finnish university hospital during an equally long period. Approximately half the programmatic cost was attributable to the costs of obtaining evaluative data.

One wishes that more information on program effectiveness had been reported. We are provided with only one table which shows pretest-posttest mean changes in risk factors. The major measure of effect used in the Project was "net reduction"; that is, any change in a risk factor in North Karelia between base line and terminal survey, minus the comparable change in the reference county. For example, a mean difference of 1.8 cigarettes/day is noted between the base line and terminal surveys in North Karelia and .8 cigarettes in the reference county. Using the Project's measure of net reduction, this represents an effect of 1.0 cigarettes/day. Now, one may ask whether a reduction of one cigarette per day is a meaningful reduction in smoking behaviors. Similarly, other reductions in risk factors need to be questioned, with attention turned away from statistical significance and toward the issue of medical and public health significance.

Undoubtedly a study of this scale will serve as a rich source for future publications; Dr. McAlister and his coauthors have provided a valuable orientation to a highly complex public health intervention.

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