ABSTRACT: Among the different approaches to the study of cardiovascular disease prevention are community-based programs. This type of program concerns a whole community and the intervention takes advantage of the existing service structure and community organization. The evaluation assesses the feasibility, effects on risk factor and disease reduction, costs, process, and other consequences associated with the program. Several such programs have recently been launched in the United States and some other countries. The first major community-based control program was the North Karelia project in Finland, started in 1972 and recently evaluated for its first five-year period. This paper discusses the problems in evaluating community-based CVD control programs on the experiences obtained in the North Karelia project.

In the search to control the present cardiovascular disease (CVD) epidemic, research has proceeded along many lines from basic sciences to epidemiological studies. Several large-scale intervention studies were started during the seventies. Among the strategies was the community-based study. The first major one was the North Karelia project in Finland that was launched with the help of the World Health Organization (WHO) after the local people petitioned the government to do something about the severe CVD problem. After that, several community-based studies have been launched in different countries. In the middle of the seventies, WHO started to coordinate and promote the establishment of comprehensive community-based CVD control programs as pilot projects for possible nationwide applications.

The design and evaluation of the community program faces many challenges and problems. Some of the major problems are discussed here with experiences from the North Karelia project, recently evaluated for its original five-year period. A classical intervention trial based on random allocation of individuals into experimental and control groups has several well-known limitations: Clinical intervention on risk factors is expensive, deals with people
outside of their natural living conditions, and is unrealistic for nationwide application. It is also not possible to restrict the changes in the intervention group to the isolated risk factors. Concurrent changes in other factors will often occur because of more general impact of the intervention that cannot easily be controlled.

The community-based approach overcomes these problems to a great extent. The strategy is to intervene on the community social organization, rather than on individual persons. It also tests the effects of a comprehensive package applied in a community setting. The intervention takes advantage of existing community influence channels, community organization, and of natural interactions in the community. This strategy may reduce costs significantly and, in some cases, obviate ethical problems which might otherwise exist. However, compared with the clinical trials, the epidemiological inference from a community program may be restricted because use of large units may reduce the study’s statistical power. Because of the advantages given above, the community programs may, however, contribute considerable to reducing the uncertainty surrounding CVD risk factor causality. The community programs also aim for demonstration models in better use of existing health services and other community resources. 

**STUDY DESIGN**

A “quasi-experimental” study design is used. One or several communities are chosen where the experimental intervention will be carried out. In other words, the best possible knowledge, both from epidemiological and socio-behavioral points of view, for risk factor and CVD control, is applied to the whole community. One or several other communities are chosen for “reference” areas. These communities represent the “natural” development. Other than the experimental project activities, the reference community is in no way deprived of any development that might occur there.

The observation unit is the community. Several communities may be used to increase the population but it is not realistic to have enough communities to use “community” as a unit in the statistical analysis. Use of two or more communities may cause problems in the interpretation in the case of a positive result in one and negative result in another community. This situation may arise because of possible community preferences of unequal efforts among the intervention team. On the other hand, use of several reference communities, if feasible, could reduce the possibility of detecting a spurious result as a consequence of random variation over time, especially concerning disease rates.

In all quasi-experimental designs, where the assignment into experimental and control units is not random, there is the possibility of both biased sampling (selection of study units) and biased selection of experimental and reference units. In the case of the North Karelia project the intervention area was given by the original popular petition (the county of North Karelia). The only choice was then the reference unit selection. Another county was chosen as the reference community.