Strategies and methods for implementing a community-based diabetes primary prevention program in Sweden

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SUMMARY
Non-insulin-dependent diabetes mellitus (NIDDM) is the most common type of diabetes with a prevalence of at least 4% in Sweden. There is convincing evidence that, besides a genetic predisposition, exogenous factors such as poor dietary habits (high fat, low fibre content), low physical activity and obesity are serious risk factors for NIDDM. Steps have been taken to develop a primary prevention program for NIDDM in Stockholm, Sweden. The program aims to reduce the incidence of NIDDM by 25% over a 10-year period, by influencing the risk factors in the populations of three intervention municipalities. The intervention will be developed through two approaches: ‘community intervention’, and ‘intervention within community’. Evaluation of the program will be performed by monitoring the prevalence and incidence of diabetes in the target population and by assessing the effects of strategies designed to increase physical exercise and improve diet. Furthermore, changes in awareness, knowledge, attitudes and practices related to prevention of diabetes, will be investigated. For this purpose, a baseline study is carried out in the three intervention municipalities and two selected control municipalities. The baseline study includes a sample of about 3200 men and the same number of women, aged 35–54 years, from intervention and control populations. A follow-up study after 5 and 10 years will be made.

Key words: community intervention; diabetes mellitus; evaluation; intervention within community

INTRODUCTION
Non-insulin-dependent diabetes mellitus (NIDDM) is the most common type of diabetes with a prevalence of at least 4% in Sweden (Andersson et al., 1991). The disease has a genetic background, and is characterized by chronic hyperglycaemia mainly due to impaired insulin secretion and action (insulin resistance). In most cases, NIDDM develops slowly through a stage with impaired glucose tolerance (IGT). Poor dietary habits (high fat, low fibre content), low physical activity and obesity constitute serious risk factors for NIDDM (Hamman, 1992;
Tuomilehto et al., 1992). The incidence is increasing and the annual health care cost for people with diabetes has been estimated to be as high as 15% of the total health care expenditure (Rubin et al., 1994). These costs are to a large extent accounted for by development of late microangiopathic complications and a several-fold increased risk for cardiovascular diseases in these patients [Kannel and McGee, 1979; World Health Organization (WHO), 1994].

Limited short-term studies addressing one or more of the risk factors for NIDDM have shown that it is possible to prevent the disease on the individual level. On the other hand, little is known about primary prevention of NIDDM aimed at populations, a model that theoretically could be very effective.

The Stockholm diabetes prevention program (SDPP) is now implementing a model for community-based intervention of NIDDM (Burström et al., 1994). The program will focus on improving dietary habits, reducing obesity and increasing physical activity for the general population. The program is planned to be carried out during a 10-year period. The design is unique as it combines an aetiologic cross-sectional study in the same population as the community intervention program, which gives the possibility to undertake both summative and formative evaluation.

DESCRIPTION OF PROGRAM DEVELOPMENT

Background
In early 1988 initial steps were taken to develop a primary prevention program for NIDDM by representatives from the Department of Endocrinology, Karolinska Hospital in cooperation with the Department of Social Medicine and Institute of Environmental Medicine, Karolinska Institute. The initial stages of the work were carried out with the help of research funds administered by the Health Directorate of Stockholm County Council. A group of researchers from those departments and from the Department of Cancer Prevention acted as consultants at the early meetings; these researchers are now members of the ‘scientific community’ of SDPP. The Department of Health Policy, London School of Hygiene and Tropical Medicine, the Department of Family and Community Medicine and the Department of Behavioral Epidemiology, Bowman Gray School of Medicine have also provided useful ideas for the design of the program. This early work resulted in the putting forward of a proposal for a program to the County Health Promotion Committee in June 1989. The proposal was accepted and in August the same year the County Board of Health and Medical Care decided to continue supporting the first phase of the program and allocate funds. When the first phase of the program was in progress, new funds for the intervention phase had to be sought. The Board of Health and Medical Care (Sjukvärdstyrelsen) for the Northwest Health Administration area decided to fund an intervention unit, at Karolinska Hospital. Later, the Southeast area entered into a partnership with the Northwest.

Study population
Stockholm’s county has a total population of 1.7 million divided into nine health administration areas with, altogether, 25 municipalities. The program focuses on the population of five selected municipalities. Of these five, three are intervention communities and two are control communities. The five municipalities selected are rather similar in size (between 21 000 and 35 000 inhabitants) and show demographic similarities.

Program objectives
The SDPP includes several objectives in order to address the different questions asked by researchers and founders (Burström et al., 1994b).

The ultimate program objectives are:

- to reduce the incidence of NIDDM by 25% during a 10-year period, by influencing the risk factors in the population of three municipalities;
- to reduce the prevalence of IGT correspondingly in the population during the same period of action.

Specific target objectives are:

- to alter the general population’s diet by reducing fat intake and increasing fibre and complex carbohydrate intakes. At least 50% of the population should adhere to a diet consisting of <30E% fat, >25g of fibre and >50E% starch per day;
- to increase by 50% the proportion of the population with normal weight [with a body mass index (BMI) of <26];
- to increase the physical capacity of the general
population through increasing by 50% the current rate of participation in organized physical activities.

The intermediate objectives for the community-based intervention are:

- to increase knowledge about risk factors, such as inappropriate diet, obesity and lack of physical activity;
- to change attitudes towards the consumption of low-fat, and fibre- and starch-rich foods in the population;
- to improve access to healthy foods in households;
- to ease access to physical activities in the community;
- to ease access to professional advice on weight reduction and dietary habits.

Research-related objectives for the aetiologic studies are:

- to study prevalence and incidence of NIDDM and impaired glucose tolerance;
- to study risk factors for NIDDM and IGT, such as heredity, dietary habits, physical activity and body mass;
- to map socioeconomic factors of putative relevance in the pathogenesis of NIDDM;
- to identify and characterize metabolically and genetically prediabetic subjects;
- to identify important predictors that influence the transition from prediabetes via IGT to manifest diabetes;
- to clarify the relationship between IGT and manifest diabetes on the one hand, and cardiovascular diseases on the other.

**Stages of the program**

SDPP is planned to comprise various stages with different study designs that also address different basic research questions. The program includes the baseline study, community intervention process studies, and the outcome study.

**Cross-sectional designs (baseline study)**

This stage was completed for men during 1995. A similar study is now being carried out for women. ‘Specific’ female factors such as pregnancy, menopause and oestrogen replacement therapy will be studied. The baseline study aims to understand basic relationships between risk factors and outcomes in terms of IGT and NIDDM.

In the baseline study, the age range 35–54 years was selected because it also encompasses those at risk of developing NIDDM during the study period, and it includes those for whom prevention is feasible. The study has been developed in two steps, including two different questionnaires and measurements of relevant physiological parameters. On the basis of questionnaire 1, distributed to about 13,000 men and the same number of women, which aims at clarifying the family history of diabetes, a group of individuals with diabetes heredity (∼12–15% of the initial group) and an age- and gender-matched group without heredity were selected to participate in the second part of the baseline study. This included an oral glucose tolerance test and questionnaire 2, with detailed questions regarding e.g. food habits, physical exercise and socioeconomic factors.

**Studies of a community intervention process in three communities**

This stage includes two different strategies for intervention—community intervention and interventions within communities. The aims of these studies are to understand which interventions are most effective with which groups of the population. It is also to test different types of interventions within different organizations—e.g. occupational settings, residential areas, specific target groups—and to refine efficient intervention methods. The process study is crucial to compare the different intervention methods in relationship to:

- expended resources and activities;
- participation in activities;
- participation as it relates to changes in behaviour.

**Outcome study**

The aim of this study is to understand how risk factors relate to disease, e.g. development of IGT and NIDDM. Follow-up of subjects will be done after 5 and 10 years.

**Model of planning and implementation**

Various models of community intervention programs have been developed in recent decades. Two models often referred to are: effect-models (how-it-works) (Sanderson et al., 1988; Green and Kreuter, 1991; Borland, 1992); and stage-models (how-to-do-it) (Johnston, 1980; Swedner, 1982; Bracht and Kingsbury, 1990). These models for health promotion programs imply an ordered set of activities, in which preparation
is less developed than analysis, initiating, implementing, maintenance and evaluation. A new model based on experience from heart disease, cancer and accident prevention, has been designed to help to combine the effect and stage models. This theoretical model has previously been described in detail (Sanderson et al., 1996).

The SDPP intervention program is developing according to his model (Figure 1). It recognizes that several types of program activities can take place concurrently, but that certain features depend on the completion of previous steps. The stages of development are (vertical bars): getting started, community analysis, program initiation, program preparation and development, implementation and review. Some of the stages in the model must be repeated when necessary. The categories of program development activities are (horizontal bars): organizational, strategic, target, evaluation and funds.

Getting started
In this stage, a review of the scientific background has been carried out to provide sufficient support for an intervention. Sources of funds have been explored, and those who should be involved in the program development have been identified. The intervention and control communities were selected. The capacity and the readiness of these communities were clarified. The scientific committee for the program development has been set up.

Community analysis
A community analysis has been carried out to identify important characteristics of the target group, and to develop means of gaining access for implementation in the three intervention municipalities (Burström et al., 1994a). Steps in the analysis are as follows:
- draw up a profile of demography and particular health risks in the municipalities;
- identify community and professional leaders in possible intervention areas and discuss the program with them;
- draw up a profile of potential collaborating organizations in intervention areas;

<table>
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<th>Initial program design</th>
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<td>O1 Form program development team’s</td>
<td>O2 Begin discussions with community &amp; professional leaders</td>
<td>O3 Assemble panel of program advisors</td>
<td>O4 Set up organisation for program implementation</td>
<td>O6 Begin program implementation</td>
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<tr>
<td>S1 Identify communal diseases for intervention</td>
<td>S2 Organisational profile &amp; investigate possible intervention channels</td>
<td>S3 Choose initial set of intervention channels</td>
<td>S4 Develop intervention strategy with intervention channels</td>
<td>S6 Continue strategy development with intervention channels, based on formative evaluation, diaries, surveys, focus groups, in-depth interviews</td>
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<tr>
<td>T1 Review scientific literature - natural history - epidemiology - effective intervention</td>
<td>T2 Community diagnosis: - community profile - health risks - health status</td>
<td>T3 Choose intervention strategies &amp; develop strategies</td>
<td>T4 In-depth interviews &amp; focus groups in intervention population</td>
<td>T6 Periodic review of objectives</td>
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<tr>
<td>F1 Find sponsorship &amp; seek sustainable finance</td>
<td>F2 Pursue funding for intervention and evaluation</td>
<td>F3 Develop evaluation strategy</td>
<td>F4 Baseline surveys in study population’s</td>
<td>F6 Periodic survey in study population for summative evaluation</td>
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Fig. 1: The SDPP-model for community intervention. From Sanderson et al. (1996) Effect and stage models for community intervention programmes; and the development of the model for management of intervention programme preparation (MMIPP). Health Promotion International, 2, 143–156, by permission of Oxford University Press.
• identify any aetiological issues that may be illuminated by such an intervention program.

One product of community analysis is increased awareness of channels of communication. This will form the basis for carrying out the intervention. A variety of channels will be used to increase the opportunities for reaching the members of the target population.

Program initiation
The key theme for this stage is prioritization. From the community analysis, the intervention population and groups have now been selected. The risk factors and the main channels of intervention have been chosen.

Program preparation and development
In this stage, the organization for implementation has been set up. Strategies for intervention and collaboration with the intervention channels have been developed. The local government boards have been involved in the program and a panel of representatives from these has been established. Local taskforces have been established and local project leaders employed. Presentations are made to management boards of local companies suggesting ways that physical exercise may be incorporated into the workplaces and residential areas. To improve diet and avoid obesity, the program will suggest ways that local restaurants and grocery stores can help in educating their customers in making healthy choices. In this stage, the evaluation strategy has become specific. The designs for summative and formative evaluations have been specified, and survey instruments and control groups chosen.

Implementation and review
The program is now in its active phase. The search for new collaborators and new approaches will continue. Obtaining regular opinions from formative and process evaluation studies will show how intervention activities may be reaching targets.

Strategies for intervention
In the planning and development of the SDPP intervention, theoretical and conceptual bases are drawn from experiences of similar projects (Farquhar, 1978; Luepker and Råstam, 1990; Bjärås, 1992). Mainly, five different models of theories are used to help in the development of the implementation. These are: a community adoption theory, diffusion theory, social learning theory, social marketing principles and a communication–behaviour change model (Kotler and Zaltman, 1971; Bandura, 1977; Farquhar, 1978; Rogers, 1983; Nix, 1987).

The intervention phase of the program will be directed at three of the major risk factors for the development of NIDDM: poor dietary habits, physical inactivity, and obesity (Jenkins, 1979; Ohlson et al., 1985; Blair et al., 1992; Hamman, 1992; Manson et al., 1992; Tuomilehto et al., 1992). These three factors have been selected because they appear to play a major role in the development of NIDDM, and because these factors are, according to previous studies, amenable to change (DeBusk et al., 1990; Helmrich et al., 1991; Tuomilehto et al., 1992; WHO, 1994). The objective of the intervention is therefore to bring about positive changes in dietary and physical activity habits. It is also to reduce the prevalence of obesity, under the assumption that this will ultimately lead to reduction of the incidence of NIDDM and of IGT in the target group.

The two main strategies used are community intervention and intervention within communities.

A traditional type of community intervention involves a comprehensive approach, focusing on the entire community and its elements. The objective is to create a supportive policy environment for interventions. It is also to obtain media coverage and inform the public about planned and ongoing activities. Mobilizing high-level political support for the intervention is necessary. It is on this level that the overall planning and realization of the program goals have to be made through the Municipal Board and the administrative organization. Measures have to be taken which can improve access to physical activities, and the conditions for change in lifestyles for the population.

Intervention within communities addresses smaller subgroups of the population in certain settings such as workplaces, residential areas, schools, etc. On this level, local taskforces and local project leaders are important when the networks for changes of a healthy lifestyle are going to be built up. Voluntary organizations, organizers of physical activity, purveyors of food, and employers are involved, in order to implement strategies relating to dietary change, weight reduction and physical activity.

The two models will be combined in SDPP. Figure 2 shows how the two strategies are working together, involving four levels of the
community structure: the political, administrative, organizational, and the population/individual level.

Program evaluation approaches
The SDPP will be evaluated with respect to its outcome and also its process; this will include both summative and formative evaluations. A summative evaluation (Figure 3) implies observations of effects of program activities on diabetes morbidity, early stages of diabetes, on weight and physical activities measured prior to start of intervention (observations $O_1$–$O_5$), and after 5 ($O_6$–$O_{10}$) and 10 ($O_{11}$–$O_{15}$) years of intervention, in all five municipalities. Intervention activities are carried out from year one, in the three intervention communities ($X$), whereas no intervention is introduced in the two control communities. The formative evaluation ensures that strategies, tactics and activities within the intervention are continuously evaluated and revised. The two control communities have to be followed during the period of intervention, in order to control for trends in diet and exercise habits and local activities influencing lifestyles.

A model of evaluation developed for the Stockholm Cancer Prevention Program will be used for SDPP (Sanderson et al., 1988). The model includes five stages in the evaluation of the program: the input, the activities, the exposure, $O = \text{observation, cross-sectional and longitudinal}$

$X = \text{intervention}$

$T = \text{time of measurement}$

$0,5,10 = \text{year}$

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Fig. 2: The framework for intervention strategies.

Fig. 3: The main study design of SDPP.
the attitudes/habits, and the morbidity/mortality (Figure 4). It also includes four possible elements of study design. First, the program management issue is to study ‘inputs’ in relation to ‘activities’. How successful has the program staff been in recruiting organizations and stimulating them to appropriate activity? A program definition will describe the planning, funding and organizational structure and system, clarifying the specific inputs, activities and projects in combination with SDPP.

Second, the program development issue relates ‘activities’ to ‘exposure’. How effective have the different activities been in affecting attitudes and behaviour in relation to dietary habits, obesity and physical activity? It will also measure, quantitatively and qualitatively, the intervention strategies and activities over time, related to exposure. Both of these two issues are parts of formative evaluation and the results from different studies are fed back to the participants while the program is in progress to improve its effectiveness and efficiency.

Third, the public health policy issue relates ‘exposure’ to ‘habits/attitudes’. Once the program has been initiated, how effective was it in changing the diet, physical activity habits and incidence of obesity? The outcome evaluation will look at what the program achieved in terms of changes over time. A process evaluation will try to describe how and why changes occurred. Is it worth initiating the program in other areas too?

Fourth, there are the aetiological and summative evaluation issues, to relate diet, physical activities and obesity to morbidity and mortality. Did the changes in diet, physical activity habits and obesity lead to expected changes in the incidence of NIDDM and IGT? The summative evaluation issues consider the relationship between changes in the incidence of NIDDM and changes in diet, physical activity habits and obesity. Finally, studies must be made of the relevance of the policy, and how others could benefit from the program.

**Program organization**

The program organization includes both scientific and intervention parts. The scientific part encompasses researchers from three main institutions in the scientific committee, which organizes research and evaluation issues.

Intervention is governed by a steering group with eight members. These are: two professional leaders of the cooperating Area Health Boards; the Chief Physician of the Department of Endocrinology and Diabetology, Karolinska Hospital;
the Chief Physician of Health Promotion from the Social Medicine Unit of Stockholm County; the Chairman of Stockholm County Diabetes Association; and representatives from the three intervention communities. The steering group outlines the intervention in the three municipalities. The Diabetes Prevention Unit at the Karolinska Hospital is the secretariat for this group. This unit is established to develop intervention strategies in collaboration with counterparts.

To coordinate the work in the two health administration areas and the three municipalities a coordination group has been established. The members of this group are professional leaders of the three municipalities, health planners linked to public health groups on local levels and the Diabetes Prevention Unit. This group meets to coordinate and discuss activities in the three municipalities.

The main community intervention work has to be done on the local level by health planners in cooperation with municipal public health groups, organizations and workplaces. A panel of program advisors for issues such as physical activities, obesity and diet, has also been established.

DISCUSSION

The planning process of SDPP has extracted experiences from population-based intervention programs. Community intervention directed at major public health problems has been successful in many respects (Farquhar et al., 1990; Spafka et al., 1990; Tuomilehto et al., 1992), but has also suffered problems. The process of initiating and sustaining a program through a comprehensive community approach is long and tedious. Mostly, only limited segments of the population take part in and benefit from activities. The design applied is called ‘quasi-experimental’ (Nutbeam and Catford, 1987). The evaluation of such programs also raises scientific problems. The unit of analysis being only one or a very few communities, standard procedures for evaluation cannot automatically be applied, and the statistical power of the analysis is usually low.

The ‘interventions within communities approach’ (Green and Kreuter, 1991), on the other hand, has other advantages and disadvantages. The concept implies working more intensively with various health promotion activities in and among restricted groups, such as in workplaces, schools, residential areas, etc. This approach makes it possible to direct efforts at certain selected groups, with interventions designed specifically for the intended group. Since it is on a smaller scale, it takes less time to carry out, and is easier to organize at a local level. Several smaller groups involved for each intervention increase the number of units of analysis and by that increase the power of statistical analysis, so that it is similar to that of regular clinical trials.

The advantages of a combination of the two strategies are that they mutually support and increase the efficacy and effectiveness of each other. A combination also eases the practical achievement of activities, and an evaluation of activities can be made more valid with a greater statistical power than previously. However, a combination of the two strategies may also be disadvantageous. Having two major strategies for intervention may lead to difficulties in ascribing success in the outcome to a particular intervention approach, and in establishing a cause–effect relationship. Another negative consequence of a combination could be that resources for intervention are spread too thin.

The central ideas and issues which have to be addressed by the program are, first, that physical activity is an important component of a healthy lifestyle for all of us, but particularly important for those at increased risk of chronic diseases such as NIDDM. Second, that healthy dietary habits (e.g. low fat and high fibre consumption) decrease the risk for NIDDM.

To fulfil the goals for program implementation, it is crucial to have a strong and competent organization. Building up the organization and the network to enable the activities mentioned above will take time and will have to continue as long as the program is running. The local activities will concentrate on improving access to healthy food in households, to physical activities, and to professional advice on weight and dietary habits.

In long-term programs, many trends and ideas extraneous to our study may influence the outcome. Trends already exist in the municipalities regarding attitudes to and demands for physical activity, and dietary habits. We do not know how these trends are related to social stratification and we do not know if intakes of ‘healthy food’ are related to concern about maintaining a high level of physical activity.

It is difficult to assess lifestyle changes occurring beyond our control in the municipality, and
to realize how these may affect the outcome of the intervention. Another problem could be the potential for contamination from intervention to control communities. All the communities share the same national mass-media sources (television, radio and newspapers). It is of importance to control also for certain trends and activities ongoing in the two control communities.

Interest in evaluation of SDPP varies depending on whom it concerns. Public health focuses on how effective a community intervention program can be in changing the fat and fibre intake in the diet, and in increasing physical activity in the population in focus. The main interest for the scientific researchers is if the program might provide data linking change in diet, obesity and physical activity to the incidence of NIDDM. The scientific committee and the health services are concerned that the SDPP should be shown to be cost-effective in reaching the population with its message.

A process evaluation makes it possible to detect success and failure of intervention efforts in time to make any necessary changes. Without process evaluation, it is impossible even to have a chance of finding out why the intervention succeeded or failed to succeed as anticipated.

SDPP is unique, as it combines an aetiological cross-sectional study in the same population as that in which the intervention program is running. This combination and the long-term program strategy offer the possibility of undertaking outcome studies that increase our knowledge of the aetiology of NIDDM.

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