

EFFECTIVENESS OF COMMUNITY-DIRECTED DIABETES PREVENTION
AND CONTROL IN A RURAL ABORIGINAL POPULATION

by

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ABSTRACT

In response to the increasing prevalence and impact of non-insulin-dependent diabetes mellitus (NIDDM) in Canadian Aboriginal populations, a community-based diabetes prevention and control project of 24 months duration was implemented in the interior of British Columbia. A participatory approach was used to plan strategies by which diabetes could be addressed in ways acceptable and meaningful to the intervention community. The strategies emphasised a combination of changing behaviours and changing environments. Project workers implemented programme initiatives. Researchers served as facilitators and advocates for community change processes.

The project was quasi-experimental. The intervention community was matched to two comparison communities. Workers in the intervention community conducted interviews of individuals with or at risk for diabetes during a seven-month pre-intervention phase ($n = 59$). Qualitative analyses were conducted to elucidate strategies for intervention. Baseline measures were obtained in each community, and implementation began in the eighth month of the project. A population approach was taken to diabetes prevention and control.

Trend measurements of diabetes risk factors were obtained in each community for "high-risk" cohorts (persons with or at familial risk for NIDDM) ($n = 105$). Cohorts were tracked over the 16-month intervention phase, with measurements at baseline, the midpoint and completion of the study. Cross-sectional surveys of diabetes risk factors were conducted in each community at baseline and the end of the intervention phase ($n = 295$). Surveys of community systems were conducted during the pre-intervention and early and late intervention phases.

The project yielded few changes in quantifiable outcomes. Activation of the intervention community was insufficient to enable individual and collective change through dissemination of quality interventions for diabetes prevention and control. Theory and previous research were not sufficiently integrated with information from pre-intervention interviews, nor were qualitative results brought to bear on activation and intervention planning. Interacting with these limitations were the short planning and intervention phases, just eight and sixteen months, respectively. The level of penetration of the interventions mounted was too limited to be effective. Attention to process is warranted, as is the feasibility of achieving effects within 24 months.

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DEDICATION

To my family.

*Read not to contradict and confute, nor to believe and take for granted,
nor to find talk and discourse, but to weigh and consider.*

– Francis Bacon

PREFACE

This dissertation reports on and evaluates the effectiveness of the Okanagan Diabetes Project, an initiative funded by the National Health Research and Development Program (NHRDP), Health Canada (NHRDP #6610-2022-ND). A preliminary evaluation of the project was undertaken and submitted to the NHRDP in September 1996 (Daniel & Gamble, 1996). Aspects of the preliminary report are reviewed in this dissertation. This dissertation, however, with the prior knowledge and approval of the NHRDP, constitutes the main evaluation and statement on the effectiveness of the Okanagan Diabetes Project. Although the statistical techniques differed and the scope of the preliminary report was limited, its main conclusions are not altered by the additional data and broader review set forth in this dissertation. This evaluation builds on the preliminary report through a detailed appraisal of the circumstances and conditions associated with the project.

CHAPTER 1

INTRODUCTION

Policy Background

In 1965 the World Health Organisation (WHO) released its First Report on diabetes mellitus* (World Health Organisation, 1965). Perhaps because the emphasis in public health at that time continued, at least in the WHO and developing countries, to be on communicable diseases, the First Report was of little consequence. Virtually all bodies ignored its recommendations (Alberti, 1980). The WHO's Second Report on diabetes, released in 1980 (World Health Organisation, 1980), had considerably more impact. Influenced by the International Conference on Primary Health Care, held in Alma Ata in 1978 (World Health Organisation, 1979), the Second Report emphasised community level preventive, promotive, diagnostic and rehabilitative aspects of diabetes. Recommendations detailed in the WHO's Second Report have been widely implemented. Nevertheless, in Canada, the specific recommendation of the Second Report that "the concept of primary prevention should be vigorously explored with particular attention to high-risk people and to environmental factors" (World Health Organisation, 1980) received little emphasis until recently. Only limited diabetes research had been undertaken in Canada in 1989, when the World Health Assembly adopted the landmark "Resolution on the Prevention and Control of Diabetes" (World Health Organisation, 1990).

The Assembly resolution served to provide a mandate for joint action on diabetes involving governments, health care providers and diabetes organisations. As a basis for action the resolution made the points that diabetes is a chronic, debilitating and costly disease attended by severe complications, and that diabetes imposes a growing burden on public health in all countries. Accordingly, the Assembly invited member states to assess the national importance of diabetes and to implement population-based measures appropriate to the local context to prevent

*The term *diabetes* is used hereafter, rather than *diabetes mellitus*, in reference to the disease.

and control the disease. An aim of these actions was to establish models for an integrated approach to diabetes prevention and control at the community level.

The growing problem of diabetes in the Canadian Aboriginal population requires a strong public health response, in keeping with the challenges laid out by the World Health Assembly. Since 1986, this need has been recognised by the National Health Research and Development Program (NHRDP) of Health Canada, through conferences and working groups. A national survey was undertaken in the late 1980s on the extent and impact of diabetes in the Canadian Aboriginal population (Young *et al.*, 1990). Population-based actions were few, however, until the 1992 NHRDP Special Initiative on Research on Diabetes in the Canadian Aboriginal Population. This was a special research competition intended to support community-based diabetes interventions with strong evaluation components (Young & Ross, 1991).

Purpose and Orientation

This dissertation undertakes an in-depth appraisal of the issues associated with diabetes and its prevention and control in the Canadian Aboriginal population,^{*} and reports on and evaluates the effectiveness in a rural Aboriginal population of a community-directed project that arose from the 1992 NHRDP Special Initiative to prevent and control diabetes. Methodological issues specific to undertaking and evaluating community-based research are also reviewed in detail.

A prevalent theme throughout this dissertation is that diabetes in the Canadian Aboriginal population is both a consequence of environmental changes associated with acculturation, as

^{*}Different terms are used to describe broad ethnic groups (Young, 1994). In keeping with common usage, the term *Native American* refers to the indigenous populations of Canada and the United States, which are distinguished by country through the descriptors *Aboriginal Canadian* and either *American Indian* or *Alaska Native*. In differentiating Aboriginal Canadians, reference is made as necessary to *Indians* and *Inuit* for those whose health care services are administered by the federal government (i.e., "registered" Indians and Inuit), versus *Métis* and others reporting Aboriginal identity who are neither registered Indians nor Inuit.

The above terms are used to simplify and ease communication, but it is acknowledged that the appropriateness of any particular term falls to the groups being discussed, and therein lie many group and individual differences. Any one term may be offensive to some people. For example, tribal names with a history of use (e.g., Cree, Ojibwa, Dogrib, Haida, and so forth) are used instead of less familiar tribal names given by individual Aboriginal languages, though there is a growing tendency, especially in British Columbia, towards the use among Aboriginal people of language-specific tribal names. The descriptor *First Nation* for Indian people has been avoided because it is awkward and does not include Inuit and Métis, though it is often used in a manner suggesting simultaneous reference to all Aboriginal peoples of Canada.

well as an inherent genetic predisposition. In this context, acculturation is the rapid process by which the cultures of Aboriginal peoples are exposed to, diluted and made dependent on modern, “western” ways of living and external resources inconsistent with traditional patterns. It reflects the tremendous political, economic and social challenges faced by Aboriginal people primarily during the second half of the 20th century (Young, 1994). The impact of acculturation and the stress of rapid environmental change on the risk of developing diabetes is supported by ecological data from several migrating populations traditionally free of the disease (Dowse *et al.*, 1990; Fujimoto *et al.*, 1987; Kawate *et al.*, 1979; Medalie *et al.*, 1975; Shanghai Diabetes Research Co-operative Group, 1980; Tai *et al.*, 1987). Thus, despite the important role of genetic factors, diabetes (at least the non-insulin-dependent type) can — and should — be considered a largely preventable disease (Manson & Spelsberg, 1994).

An emphasis on acculturation is not to suggest that Aboriginal people are in some way deficient or incapable of responding effectively to environmental change. A litany of “culture bound syndrome” stereotypes (Webster & Nabigon, 1993) suggests that the health problems and social pathologies affecting indigenous populations represent a failure of the Aboriginal culture to adapt to stressful socio-economic conditions. This position assumes an unrealistically high level of self-responsibility for health, and ignores the role of environmental forces over which Aboriginal peoples have had little control. Rather, the stress of acculturation, and political, economic and social subjugation and relegation to low status identity, reflect the general failure of Canadian society to validate Aboriginal culture and, in doing so, promote Aboriginal health.

There is an intimate relationship between culture and health. Devaluation of Aboriginal culture and the imposition of non-Aboriginal “solutions” for ill health associated with loss of culture and cultural identity does not recognise Aboriginal people as legitimate citizens with a history, traditions and values that may offer other solutions that are relevant, meaningful and effective (Colorado, 1988). For example, a deterioration in health status followed the loss of tribal status of the Klamath Indians of Oregon in 1954. Thirty years later, their level of unmet need and their absolute health status, relative to age, was poorer than that of the general population and other American Indian groups that retained their cultural identity (Joos & Ewart, 1988). The effects of

acculturation on health are evident through Aboriginal versus non-Aboriginal population contrasts, as well as in variability within Aboriginal populations.

Evidence from other populations of marginalised people (e.g., Hispanics in the United States) indicates that acculturation is a multi-dimensional phenomenon (Berry, 1980; Padilla, 1980). Among Hispanic samples, acculturation is associated with poor mental health status (Griffith, 1983), low levels of social support (Griffith & Villavicencio, 1985), alcohol and drug abuse (Graves, 1967) and premature mortality (Wei *et al.*, 1996). Scribner and Dwyer (1989) found that acculturation among Hispanic women significantly predicted low birthweight status. In this study, U.S.-oriented mothers had a risk of ever having delivered a low birthweight infant that was 1.64 times greater than that of Mexican-oriented mothers. A secondary analysis of the same study using structural equation models indicated that smoking and dietary intake mediated indirectly the effect of acculturation on low birthweight status (Cobas *et al.*, 1996). Psychosocial influences related to acculturation mediate determinants of smoking (Deosaransingh *et al.*, 1995). Whether all dimensions of acculturation are equally relevant to particular health outcomes is unclear, as is the nature of the process by which acculturation influences health.

As used throughout this dissertation, the term "health" refers to a state of physical, mental and social well-being. This conception derives from the Ottawa Charter for Health Promotion (1986), which defines health in relation to health promotion:

Health promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and realise aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasising social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy lifestyles to well-being. (Ottawa Charter on Health Promotion, 1986)

This and other contemporary definitions of health differ from earlier conceptualisations in that (a) health is not simply the absence of disease and (b) health is linked to the social and economic environment, and to the way society operates. Health refers to a dynamic quality both individually and socially valued, with simultaneously objective and subjective dimensions. Overall health is a global quality, but health consists of particular qualities as well (e.g., physical,

psychological, and social well-being and functioning) (Noack, 1991). "Sickness" is the sum of disease and illness, where "disease" is the objective, measurable aspect of sickness, and "illness" is the subjective, difficult-to-measure experience of disease (Eisenberg, 1977).

Health status may be improved by attention to culture where its denial or oppression is associated with alienation (Axelos, 1976), anomie (Durkheim, 1933), or normlessness (Merton, 1949). That these conditions are relevant to the situation of Canadian Aboriginal people is supported by testimonials (Harris, 1995a; Mussell, 1992). It is also supported by demographic data describing outcomes and circumstances in keeping with those predicted by sociological theory (e.g., suicide, drug and alcohol abuse, mental illness, high rates of chronic disease and early mortality) (Cooper, 1995; Foster *et al.*, 1995; MacMillan *et al.*, 1996), as well as Aboriginal position papers and policy documents (Mardiros, 1987). For example, in a discussion paper written for the Assembly of First Nations Health Secretariat, Lemchuk-Favel (1995) distinguished the impact of socio-economic circumstances on health. It characterised these as interactive with

... cultural alienation or cultural stress ... caused by oppressive experiences such as loss of land, loss of control over living conditions, restricted economic opportunity, suppression of beliefs and spirituality, weakening of social institutions, displacement of political institutions, pervasive breakdown of cultural rules and values and diminished self-esteem, discrimination and institutional racism and their internalised effects, and voluntary or involuntary adoption of elements of an external culture and loss of identity. (Lemchuk-Favel, 1995, p. 7)

Changes in behaviour and lifestyle interact with specific reactions associated with social, cultural and economic stress in predisposing the development of diabetes in vulnerable populations (World Health Organisation, 1994). Among indigenous peoples around the world, a growing body of evidence suggests that diabetes and other chronic diseases are a consequence of lifestyle changes associated with acculturation. In this context, the notion of "lifestyle" implies more complex, repetitive, if not habitual, patterns of behaviour conditioned by living standards and the set of social conditions that surround a social group, including cultural history and socio-economic circumstances (Green *et al.*, 1996). Lifestyle is a composite expression of enduring patterns of behaviour that reflect the social and cultural circumstances that condition and constrain behaviour, as well as the consciously chosen, personal behaviour of individuals (Green & Kreuter, 1991). The public health application of this construction of lifestyle has been to seek policies and

environmental regulations to support healthful living. The mechanisms for achieving change in lifestyle such as the development of personal skills and the strengthening of community action supported by social and economic policies, however, continue to be difficult to attain at both local and national levels (Gunning-Schepers & Gepkens, 1996).

More than any other chronic disease, diabetes exemplifies the interaction among the four determinants of health — human biology, the environment, lifestyle and behavioural factors, and the health care system — considered in the milestone federal report “A New Perspective on the Health of Canadians” (Lalonde, 1974). The emergence of diabetes as one of the most pressing health issues facing Aboriginal Canadians today represents the outcome of an interaction among genetic factors, environmental, lifestyle and behavioural factors associated with acculturation. These, in turn, interact with the limited capacity of western biomedicine and the traditional health care system to meet the needs of Aboriginal peoples in culturally relevant and meaningful ways. The development of prevention and control strategies for diabetes among Aboriginal Canadians has become increasingly important because of its significant morbidity and mortality and the human and economic costs associated with its complications. A health promotion framework offers the potential to research culturally sensitive control and prevention initiatives to counter diabetes in Aboriginal communities. Uncertainties regarding the precise aetiological role of risk factors such as obesity, physical activity and diet in the development of diabetes lend support to a multiple-risk-factor intervention approach, through a healthful lifestyle strategy, for prevention and control. This approach has the potential to impact on other chronic diseases also influenced by lifestyle.

Statement of the Problem

This study responds to three problems: (a) the high prevalence of diabetes and the impact of the disease among the Canadian Aboriginal population; (b) the limited effectiveness of traditional health care approaches as applied to meet the needs of Aboriginal populations; and (c) the need to address through prevention the role of behavioural, lifestyle and environmental factors. It addresses a need to develop and implement, in collaboration with Aboriginal people, community-based, community-directed, culturally sensitive diabetes prevention and control programmes. It

also seeks to evaluate the impact of such programmes on health outcomes, broadly defined to include psychosocial constructs and indicators of well-being, and on behavioural, environmental, physiological and metabolic risk factors for diabetes.

Outline of the Dissertation

This dissertation is organised according to the traditional format. Following the policy background, stated purpose and orientation provided as an introduction, it contains a literature review, a presentation of the methodology and procedures used, a presentation of results and a concluding discussion. Some flexibility has been required, however, with respect to form. This need is met by grouping chapters into two parts.

Part One provides a systematic review of the literature, and a rationale for the development, implementation and evaluation of the project reported here. This review has three components, corresponding to Chapters 2, 3 and 4, respectively: (a) diabetes in the Canadian Aboriginal population; (b) theories accounting for a relationship between diabetes and acculturation and by which to explain and predict behavioural and environmental change; and (c) methodological issues involved in the design and analysis of community-based trials.

Chapter 4 (the methodological review) could be skimmed in a general reading. The chapter exists to provide an orientation to methodological challenges peculiar to evaluating small-scale social interventions as applied research, and an explanatory background justifying decisions made in the design and analysis of the trial reported here. Were such issues to be reviewed in the description of the methodology used, the number of footnotes, qualifying statements, historical asides and other explanations would surely have compromised readability. The methodological review is relevant to this dissertation because there is no established orthodoxy to fall back on to evaluate small-scale community trials. Options for reconciling methodological difficulties are not widely known or well-accepted. Relevant strategies arise from and reflect a variety of paradigms, assumptions, methods and kinds of data that share some broad resemblances. Together, these do not suggest the coherence and consensus among researchers that would constitute a single paradigm. As the science of epidemiology provides an organising framework for this dissertation, it was necessary to integrate, from this perspective, diverse methodological strategies with roots

in other disciplines, primarily the social sciences. The challenges involved in the work reported here required use of methods and analytic techniques not widely applied in epidemiological research.

Part Two describes the community-based initiative evaluated here, known as the Okanagan Diabetes Project. Chapter 5 summarises the demographic characteristics of the population and communities involved in the project. Planning and organisational issues are reviewed, and the chapter concludes with a statement of goals and research questions.

Chapter 6 covers the methodology used. The design of the project and sampling strategies are described first. This is followed by a review of the theoretical model on which the project was founded. A section on methods and procedures covers issues pertaining to each phase from the development and implementation of interventions to monitoring and programme evaluation procedures, data preparation and statistical analysis. Measurement procedures are described in detail. Chapter 7 presents the results of the project. Chapter 8 begins with a summary of results, and discusses the implications of these in relation to implementation and methodological issues. Contextual factors and previous research are also considered. The dissertation concludes with recommendations for future intervention research on diabetes or other health issues in indigenous populations.

PART ONE — REVIEW OF LITERATURE

CHAPTER 2

DIABETES IN THE CANADIAN ABORIGINAL POPULATION

Native Americans are a heterogeneous collection of indigenous peoples at substantial risk for the development of diabetes. Diabetes is an "indicator" disease of the "epidemiologic transition" that all societies undergo (Crews & McKeen, 1982; Kuberski & Bennett, 1980; Schooneveldt *et al.*, 1988). Along with a decrease in the morbidity and mortality of infectious diseases over the last several decades has been an increase among Aboriginal Canadians in chronic diseases including diabetes (Muir, 1991; Young, 1988). Diabetes is a debilitating condition associated with severe complications that occur at frequencies often greater in Aboriginal than in non-Aboriginal populations (Bennett & Knowler, 1984). Further, the medical case-load associated with diabetic Native Americans is more than twice that of non-diabetic Native Americans, as determined by comparisons of rates of outpatient and inpatient utilisation patterns (Reinhard & Greenwalt, 1975).

Complications observed among Aboriginal populations include those that arise from damage to arteries (macrovascular complications) such as cardiovascular disease (i.e., ischaemic heart disease, cerebrovascular disease and peripheral vascular disease) (Hoy *et al.*, 1995; Macaulay *et al.*, 1988; West *et al.*, 1983) and hypertension (Montour & Macaulay, 1985; Young *et al.*, 1985). Other complications arise from impaired blood supply to specific organs (microvascular complications) such as retinopathy (Lee *et al.*, 1992; Nelson *et al.*, 1989), nephropathy (Dyck & Tan, 1994; Newman *et al.*, 1990; Young *et al.*, 1989) and neuropathy (Nelson *et al.*, 1988; Ross & Fick, 1990). The relative prevalence of these conditions in the general population, comparing diabetes cases with non-diabetics, ranges from 2.5 for hypertension to 10.3 for blindness (Huse *et al.*, 1989). The prevention of complications is the primary rationale for glucose control among persons with established diabetes (Benjamin & Sacks, 1994; Nathan, 1992; Rossetti *et al.*, 1990).

The microvascular complications of diabetes are severe, and the macrovascular complications ischaemic heart disease and cerebrovascular disease are the leading causes of death in developed regions of the world. These causes of death are not always related to

diabetes, although reducing the incidence of diabetes has the potential to avert more of the disease burden (both deaths and the impact of premature death and disability on a population) in developed regions than reductions in any other chronic disease (Murray & Lopez, 1996). Notwithstanding the WHO's Second Report on diabetes mellitus (World Health Organisation, 1980) and the World Health Assembly's "Resolution on the Prevention and Control of Diabetes" (World Health Organisation, 1990), the extent of the problem among Canadian Aboriginal peoples indicates a clear need for research on community level preventive, promotive and rehabilitative aspects of diabetes (Daniel & Gamble, 1995). This research should parallel enquiry into genetic and environmental determinants of the disease.

The purpose of this chapter is as follows:

- To define diabetes and to describe its diagnosis;
- To ascertain the importance of diabetes in relation to the health of Aboriginal Canadians and to justify the use of resources to develop and implement prevention and control strategies to counter diabetes among Canadian Aboriginal populations;
- To outline aetiological factors related to the prevention and control of diabetes among Aboriginal and other populations;
- To review the extent of support for population-based approaches to diabetes prevention and control, including an appraisal of programmes known to have been undertaken in Canada;
- To consider cultural characteristics of Aboriginal people, and illness interpretation, health belief and value systems relevant to meaningful and acceptable diabetes prevention and health promotion initiatives; and
- To appraise the problem in relation to quality of life.

Nature of the Disease

Blood glucose concentration is normally tightly regulated by the action of insulin and counter-regulatory hormones (primarily epinephrine and glucagon), with a balance maintained between glucose production by the liver and glucose clearance into peripheral tissues. Insulin released

from β -cells of the pancreatic islet is constantly adjusted so that normoglycaemia is maintained. Among persons with diabetes, the regulation of blood glucose concentration is impaired (Shamoon, 1992). The hallmark of diabetes is hyperglycaemia, abnormally high concentrations of blood glucose consistent with either an absolute or relative deficiency of insulin (Wu, 1993). A deficit in insulin action can be caused by either a failure in pancreatic insulin secretion or cellular resistance to the action of insulin. Classic symptoms of diabetes include frequent urination, weight loss, excessive thirst and hunger, blurred vision and recurring infections, but in its early stages the disease is often asymptomatic.

The term *diabetes mellitus* refers to a heterogeneous group of disease states with the common feature of hyperglycaemia due either to insulin deficiency or insulin resistance. Excess urine production resultant from hyperglycaemia is the origin of the word *diabetes*, which is Greek for "siphon," while *mellitus* is Latin for "honeyed," reflecting the high sugar content of urine in diabetes (glycosuria). Harris (1995b) classified four major types of diabetes defined by the U.S. National Diabetes Data Group (NDDG) (1979) and the World Health Organisation (1980, 1985): (a) insulin-dependent diabetes mellitus (IDDM), also known as Type I diabetes mellitus; (b) non-insulin-dependent diabetes mellitus (NIDDM), also known as Type II diabetes mellitus; (c) gestational diabetes mellitus (GDM); and (d) other types, including diabetes secondary to or associated with pancreatic disease, hormonal disease, drug or chemical exposure, insulin receptor abnormalities, and certain genetic syndromes.

IDDM usually, but not always, occurs before the age of 30 years. It presents with abrupt onset of classic diabetes symptoms and extreme hyperglycaemia associated with ketoacidosis that requires prompt medical treatment. Detectable concentrations of circulating endogenous insulin will be either low or absent. Approximately 10% of all people (adults and children) diagnosed with diabetes have this type. IDDM is thought to be caused by the autoimmune destruction of the pancreatic islet β -cells as a result of the combined effect of both genetic and environmental factors (Shamoon, 1992). Persons with IDDM require insulin replacement therapy to prevent diabetic ketoacidosis, coma, and death from insulin deficiency.

NIDDM is usually found in adults older than 30 years, and it accounts for close to 90% of all diagnosed cases of diabetes. The incidence of the disease increases with age, but in high-risk

populations susceptible persons develop NIDDM at earlier ages. The prevalence of diabetes in Pima Indians aged 25-29 years (13%) is, for example, as high as that for non-Hispanic Caucasians aged 60-64 years in the U.S. (Rewers & Hamman, 1995). Individuals with NIDDM may be symptom free for many years, as the onset and progression of symptoms occur slowly, and for this reason most unidentified cases of diabetes are NIDDM (American Diabetes Association, 1989). Diet and exercise are the mainstays of treatment for people with NIDDM, but oral hypoglycaemic agents (drugs that increase insulin release from the pancreas and utilisation of insulin by peripheral tissues) and insulin replacement therapy are also used to manage the disease (Shamoon, 1992). Insulin is usually not needed to prevent ketoacidosis in NIDDM, however, since some insulin continues to be produced by the pancreas (Rewers & Hamman, 1995).

GDM is a disorder with onset of symptoms of glucose intolerance during pregnancy. It occurs in 2-5% of pregnancies and usually disappears after delivery (Coustan, 1995). Women with GDM may have an elevated risk for perinatal mortality and morbidity, and they are at greater risk for developing diabetes and coronary heart disease later (Benjamin *et al.*, 1993). Pregnancy induces insulin resistance, which may precipitate overt hyperglycaemia among women with subclinical IDDM or NIDDM. The proportion of cases of GDM in which the disease is acquired during pregnancy rather than uncovered by testing, however, is unclear (Rewers & Hamman, 1995). GDM could either arise from the stresses of pregnancy or reflect pre-existing abnormal glucose tolerance. An often studied "adverse" outcome is macrosomia, variously defined as birth weight more than 4,000 g or 4,500 g (Coustan, 1995). In Pima Indian women submitting to oral glucose tolerance tests, maternal glucose concentrations were directly related to the likelihood of macrosomia and the relative weight of the off-spring up to 14 years of age (Pettitt *et al.*, 1991).*

Other types of diabetes associated with diseases, medications, chemicals, or genetic syndromes, account for approximately 1% to 2% of all disorders comprising the syndrome of diabetes (Ganda, 1995). Diabetes associated with other conditions may be secondary to the pathogenesis of these conditions, classified as: (a) pancreatic disorders (e.g., pancreatitis, pancreatic malignancy, haemochromatosis, etc.); (b) endocrinopathies (e.g., acromegaly, Cushing's syndrome, pheochromocytoma, hyperthyroidism, etc.); (c) drugs, chemicals and

*A tendency among the Pima toward obesity with increasing age seemed to obscure any effect of maternal glycaemia beyond age 14 years.

toxins (e.g., diuretics and antihypertensive agents, psychoactive agents, antiprotozoals, anti-convulsants, rodenticides, etc.); and (d) genetic syndromes (e.g., pancreatic deficiencies, mutant insulin syndromes, glucokinase gene mutations, chromosomal defects, etc.) (Coustan, 1995).*

Standardised criteria for diabetes defined by the NDDG and WHO permit discrimination among types of diabetes by different clinical presentations and genetic and environmental aetiologic factors (Harris, 1995b). It can be difficult to distinguish between types of diabetes, however, and classifying the disease involves both a clinical workup and an adequate medical history. Diagnosis of the disease among persons with classic diabetic symptoms is based on either random plasma glucose ≥ 11.1 mmol/L or fasting plasma glucose ≥ 7.8 mmol/L (Harris, 1995b). For individuals with equivocal symptoms or lower values for fasting plasma glucose concentrations, a diagnosis requires measurement of fasting plasma glucose concentrations as well as plasma glucose concentrations two hours following a 75-g oral glucose challenge (i.e., a two-hour oral glucose tolerance test (OGTT) with 75-g carbohydrate load). Criteria are then applied to classify individuals according to their OGTT as either: (a) normoglycemic (fasting and two hour plasma glucose < 7.8 mmol/L); (b) having impaired glucose tolerance (IGT) (fasting plasma glucose < 7.8 mmol/L and two hour plasma glucose 7.8-11.1 mmol/L); or (c) diabetic (fasting plasma glucose ≥ 7.8 mmol/L and/or two hour plasma glucose ≥ 11.1 mmol/L).

The NDDG and WHO criteria were selected because studies in populations with a high prevalence of diabetes showed that two-hour post-load plasma glucose concentrations had a bimodal distribution, with the antimode at ~ 11.1 mmol/L (Knowler *et al.*, 1990). A further factor in decisions about criteria was the frequency of microvascular complications of diabetes in the same populations. For example, individuals with fasting plasma glucose ≥ 7.8 mmol/L and/or two hour plasma glucose ≥ 11.1 mmol/L were at high risk for retinopathy and nephropathy, whereas microvascular complications were rare among individuals with fasting plasma glucose < 7.8 mmol/L and two hour plasma glucose < 11.1 mmol/L. The classification IGT is defined by plasma glucose criteria, not by microvascular complications. IGT is a deviation of the normal metabolic state, but not a disease *per se*; it describes people with hyperglycaemia at a lower level than that qualifying as diabetes. Many people with IGT have risk factors that increase their risk of developing coronary

*See Coustan (1995) for a comprehensive classification of secondary forms of diabetes or impaired glucose tolerance.

heart disease, and some of these people will progress to diabetes (Rewers & Hamman, 1995). Approximately 11% of asymptomatic adults have IGT when tested by OGTT.

Relative Severity

Prevalence and Incidence

Morbidity trends reveal parallels in the epidemiologic transition faced by Native Americans in Canada and the United States. Diabetes prevalence has until recently tended to be much lower in Canada, but prevalence rates among Aboriginal Canadians have risen over time and now approximate the lower range of typical prevalence rates observed among American Indians.* Incidence rates are not available for Aboriginal populations in either country. In the United States general population, the incidence of all forms of diabetes is approximately 2.42 per 1,000 people per year (Kenny *et al.*, 1995). Given the high prevalence of diabetes among Native American populations, the incidence of the disease among this segment of the general population is undoubtedly much greater than the average incidence rate for the general population.

Whereas approximately 2-3% of the non-Aboriginal population in Canada (Statistics Canada, 1987) and the United States (Kenny *et al.*, 1995) has diabetes, the prevalence of diabetes in many Native American populations is substantially greater. IDDM is relatively rare among Native Americans. NIDDM is the prevailing form of the disease (West, 1974, 1978). Virtually an unknown condition in any form before 1940, diabetes has become so increasingly prevalent since 1950 in Native Americans, that it has assumed "epidemic" status (Gohdes, 1995; Sievers & Fisher, 1985). Prevalence rates for Aboriginal populations in Canada and the United States are usually estimated from case registries maintained at health facilities, glucose testing at a community level, and surveys of self-reported diabetes. These estimates are thought to underestimate the true prevalence of diabetes as would be obtained from systematic, population-based screening (Young & Krahn, 1988).

In the United States, diabetes prevalence rates range from less than 3% in Alaska Natives (Middaugh *et al.*, 1991; Mouratoff *et al.*, 1969; Schraer *et al.*, 1988) to more than 50% in Pima Indians older than 35 years in Arizona (Knowler *et al.*, 1990). Rates of between 10% and 30% are

*Unless otherwise noted, prevalence reports are population-based (for adults and children together), though the majority of diabetes cases occur in middle-aged and older individuals.

most common (Carter *et al.*, 1989; Stahn *et al.*, 1993; Sugarman & Percy, 1989; Sugarman *et al.*, 1992). Few published data exist on the extent of diabetes in Canadian Aboriginal populations (Young, 1987), but the available literature indicates widely variable prevalence rates (Delisle & Ekoé, 1993; Evers *et al.*, 1987; Montour & Macaulay, 1985; Schaefer, 1968; Szathmary & Holt, 1983; Young *et al.*, 1985; Young & Shaw, 1987; Young *et al.*, 1990). Only the national survey of Medical Services Branch units by Young *et al.* (1990) permits the direct comparison of diabetes prevalence rates across Canada. Based on known diabetic cases at year end 1987, age-adjusted rates for Canadian Indians (using age and gender specific totals by province or region as the population denominator, standardised directly against the national population) ranged from 0.8% in the Northwest Territories to 8.7% in the Atlantic region. Prevalence rates for Canadian Indians in the Northwest Territories, the Yukon Territory and British Columbia were, respectively (%), 0.8, 1.2 and 1.6. In all regions, both the crude and age-adjusted rates were slightly greater for females than for males. For the remainder of the country, diabetes prevalence rates for Canadian Indians were between 5.1% and 8.7%, two to four times greater than for all other Canadians, for whom the self-reported rate of diabetes is approximately 2.5% (Statistics Canada, 1987).

Data indicating time trends in diabetes prevalence for Aboriginal Canadians are not available. Prevalence studies indicate, however, that the majority of Aboriginal Canadians developed their disease relatively recently, mainly within the last 20 to 30 years, suggesting that the incidence of diabetes is increasing in Canada's Aboriginal communities. Glycosuria was unknown among Athapaskan Indians in the Northwest Territories in the 1930s, despite "thousands" of urine glucose tests (Urquhart, 1935), and diabetes was not detected among more than 1,500 Aboriginal Canadians examined in the 1930s in Saskatchewan as part of a tuberculosis survey (Chase, 1937). The national survey by Young *et al.* (1990) found that the most important predictor of variation in diabetes prevalence rates was latitude; prevalence rates decreased as northern latitude increased, and were greatest in southern latitudes ecologically corresponding to areas of greatest urban development. These data support the notion that diabetes among Aboriginal Canadians is related to environmental changes associated with acculturation. Recent reports from Québec (Delisle & Ekoé, 1993) and Saskatchewan (Dyck *et al.*, 1995) indicate that

the prevalence of diabetes is greater among Aboriginal communities with easier access to urban areas than among those communities with limited access to urban areas.

In British Columbia, further analysis of the provincial survey carried out as part of the national effort by Young *et al.* (1990) showed that the prevalence of diabetes was 4.5% for registered Indians aged 35 years and older (Martin & Bell, 1990). Of the four Medical Services Branch regional zones in the province, diabetes prevalence was greatest in coastal and southern communities (Table 1). Again, the pattern of prevalence suggests a link between diabetes and acculturation related to urbanisation. The prevalence rate for registered Indians age 35 years and older in the Vancouver Island Zone was 6.3%, followed by the South Mainland Zone (5.2%), North West Zone (4.6%) and North East Zone (1.9%) (Martin & Bell, 1990). Of the total number of registered Indians in British Columbia, 25.5% were treated by diet alone, 35% were treated by diet plus oral hypoglycaemics, and 39.5% were treated by diet plus insulin (Table 2).

The British Columbia Medical Services Branch prevalence survey was repeated in 1995. A preliminary analysis found that the total number of cases had increased from 348 to 833, corresponding to an overall increase among registered Indians aged 35 years and older of 2.0% for males and 2.6% for females (Medical Services Branch, Pacific Region, 1995).

Table 1. Diabetes Prevalence Rates Among Registered Indians in British Columbia at Year-End 1987, by Medical Services Branch (MSB) Geographic Area, Age and Gender (n = 348)*

Geographic Area	Rate (%), all ages	Rate (%), age 35+
South Mainland Zone	1.5	5.2
Vancouver Island Zone	1.5	6.3
North West Zone	1.2	4.6
North East Zone	0.5	1.9
British Columbia (all MSB zones)		
males	1.1	4.1
females	1.7	5.0
both	1.2	4.5

*Adapted from Martin, J.D., & Bell, P. (1990). *Diabetes Mellitus in the Native Population of British Columbia, Canada* (report). Medical Services Branch, Pacific Region, Vancouver: Health Canada.

Table 2. Diabetes Therapy Among Registered Indians in British Columbia at Year-End 1987 (n = 326)* †

Type of Therapy	Number of Cases (n)	Percent of Cases (%)
Diet alone	83	25.5
Diet plus oral hypoglycaemics	114	35.0
Diet plus insulin	129	39.6

*Adapted from Martin, J.D., & Bell, P. (1990). *Diabetes Mellitus in the Native Population of British Columbia, Canada* (report). Medical Services Branch, Pacific Region, Vancouver: Health Canada.
 †n = 326 of 348 cases, due to missing data

Mortality

The risk of death from diabetes in Canadian Indians is greater by a factor of two for men, and greater by a factor of four for women, than the risk for Canadian men and women in general (Mao *et al.*, 1986). These data approximate those reported for American Indians. Over the last decade, the age-adjusted mortality rate from diabetes for American Indians has increased from approximately double the U.S. rate to more than four times that of the general United States population (Gohdes, 1986; Newman *et al.*, 1993; Sievers *et al.*, 1990; Sugarman *et al.*, 1990).

Death rates from diabetes among Aboriginal people in Canada and the United States are similar to those in the United States for African American men and women aged 45-74 years relative to Caucasian men and women in the same age group: the rate for African American men is 2.2 times the rate for Caucasian men, while the rate for African American women is 2.7 times the rate for Caucasian women (Centres for Disease Control and Prevention, 1994). Thus, there are similarities in mortality among other marginalised populations in Canada and the U.S.

Relation to Other Chronic Diseases in Aboriginal Populations

Muir (1991) compiled a monograph that synthesized the available data on the health of Aboriginal Canadians. This report was not complete in representing all provinces and territories on every conceivable health issue, but it brought together the best available data gathered through local Medical Services Branch units. In British Columbia in 1990, diabetes was the chronic condition

most frequently responsible for follow-up among registered Indians, accounting for 36.5% of all cases (Table 3). The only other province for which comparable data were available was Saskatchewan, though the data dated from 1986. At that time in Saskatchewan, diabetes was the most frequently reported chronic condition among the on-reserve Indian population, accounting for 46.6% of all cases (Table 4). In each province the proportion of cases accounted for by diabetes was more than 15% greater than for any other chronic condition.

Table 3. Most Frequent Chronic Conditions Responsible for Follow-Up Among Registered Indians in British Columbia as of February, 1990*

Condition	Number of Cases (n)	Percent of Cases (%)
Diabetes mellitus	343	36.5
Rheumatoid arthritis	187	19.9
Epilepsy	158	16.8
Osteoarthritis and allied conditions	136	14.5
Hypertension	116	12.3

*Adapted from Muir, B.L. (1991). *Health Status of Canadian Indians and Inuit — 1990* (report). Ottawa: Health Canada. As compiled by Medical Services Branch, Pacific Region.

Table 4. Most Frequently Reported Chronic Conditions for On-Reserve Indian Population in Saskatchewan, 1986*

Condition	Number of Cases (n)	Percent of Cases (%)
Diabetes mellitus	521	46.6
Essential hypertension	240	21.5
Rheumatoid arthritis	158	14.1
Hypertensive heart disease	105	9.4
Alcohol dependency	94	8.4

*Adapted from Muir, B.L. (1991). *Health Status of Canadian Indians and Inuit — 1990* (report). Ottawa: Health Canada. As compiled by Medical Services Branch, Saskatchewan Region.

Data from the 1991 Canada Census show for the adult population (15 years of age and older) reporting Aboriginal identity that diabetes ranks fifth nationally, and sixth in British Columbia, of nine specific chronic health problems reported by individuals who indicated at least one chronic health problem (the other eight categories were high blood pressure, arthritis or rheumatism, heart problems, bronchitis, emphysema, asthma, tuberculosis, and epilepsy or other seizures) (Statistics Canada, 1993b). These data are not directly comparable with those compiled by local Medical Services Branch units, as the Census data concern self-reports of Aboriginal identity (Indian, Inuit, and Métis) and Medical Services Branch data concern registered Indians and Inuit.

Weighing the Evidence on Importance

Diabetes is one of the most critical health issues facing Aboriginal Canadians. As such it justifies being ranked as a national and provincial health priority. Though its incidence has not been directly determined, prevalence rates have increased rapidly over the last 30 years, suggesting that the incidence of the disease is increasing among the Aboriginal population. The growing prevalence might be related to increased screening and detection efforts. Such initiatives are far from systematic, however, and are unlikely to account for the majority of the increase in cases. It is far more likely that the available data underestimate the prevalence of diabetes among Aboriginal Canadians.

Assessing the frequency of diabetes against that of other chronic diseases requires a careful weighting of its significant morbidity and mortality. Data are not available to estimate the dysfunction, disability and dissatisfaction associated with diabetes among Aboriginal Canadians, but the debilitating effects of the disease are very well known (World Health Organisation, 1990). Some of the chronic health problems ranked along with diabetes can be either associated with or are independent risk factors for the disease (Centres for Disease Control and Prevention, 1995). Actions against diabetes have the potential to attenuate the impact of other chronic diseases also influenced by lifestyle.

Aetiological Factors

The aetiology of diabetes is multi-factorial. Empirical data implicate individual-level, non-modifiable attributes of risk, including age, gender and genetic composition, as related to the occurrence of diabetes. These risk markers interact with potentially modifiable individual-level risk factors such as obesity, physical inactivity and inappropriate diet in determining whether a predisposition to developing diabetes is realised. In contrast to risk factors are risk conditions: the underlying causes or influences of behaviour and conditions of living that influence the expression of individual-level risk factors, be they behavioural, genetic or physiological. Risk conditions relate to and reflect lifestyle, which represents enduring patterns of socially influenced behaviour (Green & Kreuter, 1991).

The following sections assess individual-level factors associated with the development of NIDDM in Aboriginal populations.* Genetic influences are reviewed, but the strongest and most widely accepted risk factors for diabetes are those described as "... the inter-related triad of obesity, reduced physical activity and inappropriate diet ..." (King & Dowd, 1990, p. 4). It is currently unclear how these factors cause NIDDM, if they do at all. Also unclear is whether their influence is the same in different populations. It is clear only that they are strongly associated with the occurrence of NIDDM. This review considers the extent to which risk factors are related to the occurrence of NIDDM and the prevalence of risk factors among Canadian Aboriginal and other indigenous populations.

Human Biology — Genetic Risk

Among indigenous populations around the world, the history of diabetes is similar (Prior & Tasman-Jones, 1981; West, 1974; Zimmet *et al.*, 1990). Rapid environmental changes associated with cultural transitions from traditional to modern ways of living superimposed on a genetic susceptibility to the disease, are thought to have contributed to the increased prevalence of diabetes among indigenous peoples (Knowler *et al.*, 1990; Weiss *et al.*, 1989; Zimmet *et al.*,

*The emphasis on NIDDM reflects the fact that virtually all cases of diabetes in indigenous populations are of this type. The term *NIDDM* is used to refer specifically to this type of the disease when use of the more general term *diabetes* may be inappropriate or confusing in terms of specific relationships being discussed.

1990). Rates of diabetes and other chronic diseases associated with obesity are greater than those that could be attributed solely to lifestyle. The “New World Syndrome” hypothesis (Weiss *et al.*, 1984) and related theories (Ritenbaugh & Goodby, 1989) implicate genetically controlled metabolic adaptations no longer beneficial in a modern, “western” environment.

Consistent with the “thrifty” genotype hypothesis originally proposed by Neel (1962), recent archaeological evidence supports the notion that a “thrifty” genotype developed in Paleo-Indians who migrated to North America more than 11,000 years ago. This genotype allowed a selective advantage during prolonged periods of fasting that occurred between big game kills. The adaptation of Paleo-Indians to the resources of lower latitudes as far south as Arizona was such that their “thrifty” genes would not have been as advantageous (Wendorf, 1989; Wendorf & Goldfine, 1991). In Native Americans of Paleo-Indian ancestry, this “thrifty” genotype may contribute to NIDDM when a sedentary lifestyle is adopted and food sources are more constant (Wendorf & Goldfine, 1991).

Most agree that NIDDM has a genetic basis or component (Knowler *et al.*, 1983; Knowler *et al.*, 1988; Pierce *et al.*, 1995; Polonsky *et al.*, 1996). Diabetes prevalence rates are highest in full-blooded American Indians (Brousseau *et al.*, 1979; Knowler *et al.*, 1988) and among the offspring of American Indian parents who developed diabetes at a young age (Knowler *et al.*, 1990; Lee *et al.*, 1985). Still, increases in the frequency of diabetes among indigenous populations that have undergone socio-economic changes accompanied by increasing obesity implicate environmental determinants of the disease (Knowler *et al.*, 1990; West, 1974; Zimmet *et al.*, 1990). Changes in gene frequencies within these populations cannot be large enough to account entirely for rapid changes in the prevalence of diabetes (Knowler *et al.*, 1990). It seems that a genetic predisposition to developing diabetes is being unmasked by environmental changes associated with cultural transitions. Noting that Aboriginal Canadians are genetically heterogeneous and the great degree of variation in the extent of Euro-Canadian influence on Canadian Aboriginal lifestyles, Young *et al.* (1990) have suggested that the “... frequencies of genes involved in predisposition to diabetes may vary not just within, but also between Aboriginal populations ...” (p. 129), concluding that differences in diabetes morbidity are probably a function of variation in these genetic and environmental factors.

The importance of environmental factors in the development of NIDDM is unmistakable. NIDDM is not the sum but the product of a complex interaction between genetic factors and the environment (Granner & O'Brien, 1992). Disease phenotypes appear to become manifest only as the result of a highly variant series of complex interactions with environmental challenges to metabolism (Sing *et al.*, 1994; Wolf, 1995). Disease may be caused by an undue discrepancy between what an organism can tolerate as a function of genetic endowment and the burden of the environment at a given point in time (Weder & Schork, 1994). Therefore, a strong rationale exists for focusing on the primary prevention of NIDDM. The classic epidemiological conception of "environment" as all that which is external to the individual (Last, 1983) is somewhat crude, however, since labelling all non-biological factors "environmental" obfuscates the impact of behaviour and the role of lifestyle as the interface of behaviour and environment. The direct and indirect effects of the social environment are discussed in the next chapter, in relation to theories that can account for an apparent relationship between acculturation and diabetes among Aboriginal populations.

Obesity

As shown in the Pima Indians of Arizona (Knowler *et al.*, 1981; Saad *et al.*, 1988) and in the Nauruans of Micronesia (Sicree *et al.*, 1987), obesity (as inferred from body mass index) and fasting glucose and insulin concentrations are all important risk factors for the development of diabetes. The Nutrition Canada Anthropometry Survey of the 1970's showed that Canadian Indians generally weighed more for their age than did either Inuit or Canadians nationally (Health & Welfare Canada, 1980). In the Cree and Ojibwa Indians of northeastern Manitoba and northwestern Ontario, multivariate analyses showed that diabetic status and concentrations of fasting plasma glucose and glycosylated haemoglobin (a stable indicator of long-term glucose concentration) were predicted by age, triglycerides and body mass index (Young *et al.*, 1990). Abnormalities in glucose-stimulated insulin secretion and insulin resistance in the pathogenesis of NIDDM are thought to be mediated by weight gain causing insulin resistance (Hamman, 1992). There may be other mechanisms, however, whereby insulin secretion, weight gain, and insulin resistance are related (DeFronzo *et al.*, 1992; Leahy *et al.*, 1992).

The 1980 WHO Expert Committee on Diabetes Mellitus concluded that obesity was the most powerful risk factor for NIDDM (World Health Organisation, 1980), and prospective studies have established obesity's role in diabetes (Barrett-Connor, 1989). The influence of obesity, however, is less clear than previously thought. Both NIDDM and obesity are multi-dimensional entities, and the impact of obesity on NIDDM might also be multi-dimensional (Zimmet *et al.*, 1990). For example, the high concordance of NIDDM in twin studies together with a link to obesity may indicate that risk for NIDDM and obesity is inherited together (Pierce *et al.*, 1995). Duration of obesity is strongly related to the development of NIDDM (Everhart *et al.*, 1992; Golay & Felber, 1996), and other data suggest that the combined risks of family history of NIDDM and obesity may be additive or multiplicative (Morris *et al.*, 1989). Data from the Pima Indians indicate little effect of obesity without family history of the disease (Knowler *et al.*, 1981), and identical twin studies indicate that the genetic component of NIDDM may act independently of obesity (Barnett *et al.*, 1981). The manner in which obesity influences the incidence of NIDDM thus remains unclear.

Some authors have suggested that obesity could be subject to a genetic determination that may itself be linked to glucose intolerance, hypothesizing that if obesity and glucose intolerance are both manifestations of a disorder characterised by insulin resistance, for which hyperinsulinaemia is the underlying mechanism, then obesity may be the effect, rather than a cause, of the metabolic defect (King & Dowd, 1990). Cohort studies have shown that body mass index, plasma glucose and insulin concentrations are all predictors of diabetes (Haffner *et al.*, 1990; Kadowaki *et al.*, 1984; Sicree *et al.*, 1987). The temporal relationship among diabetes predictors, however, is only beginning to emerge. There is increasing evidence that insulin resistance associated with compensatory hyperinsulinaemia may be a fundamental biological mechanism of IGT and NIDDM, as well as obesity, hypertension, dyslipidaemia and cardiovascular disease associated with hyperglycaemia (DeFronzo & Ferrannini, 1991; Reaven, 1993).

The pattern of adiposity, more than the amount of adiposity, is especially predictive of NIDDM. Several prospective studies have demonstrated that a predominantly abdominal (or central) distribution of adipose tissue is a potent risk factor in both men and women, stronger than and independent of level of obesity, for diabetes and cardiovascular disease (Bergstrom *et al.*, 1990; Donahue *et al.*, 1987; Ducimetière *et al.*, 1986; Lapidus *et al.*, 1984; Larsson *et al.*, 1984;

Stokes *et al.*, 1985). Numerous cross-sectional studies support associations between abdominal adiposity and glucose intolerance, hyperinsulinaemia, hyperlipidaemia (Craig *et al.*, 1968; Després *et al.*, 1988; Evans *et al.*, 1984; Feldman *et al.*, 1969; Kalkhoff *et al.*, 1983; Krotkiewski *et al.*, 1983) and hypertension (Blair *et al.*, 1984; Hartz *et al.*, 1984). Central adiposity is evident in diabetic Oklahoma Indians (West, 1978) and among Dogrib Indians of the Northwest Territories, in whom it was associated with diabetes, glucose intolerance, and acculturation (Szathmary & Holt, 1983). Central adiposity is associated with diabetes in male Oneida and Ojibwa in southwestern Ontario (Evers *et al.*, 1989). In the Cree and Ojibwa Indians of northeastern Manitoba and northwestern Ontario, a prevalent pattern of central fat distribution (Young & Sevenhuysen, 1989) is associated with elevated glycosylated haemoglobin concentrations (Young *et al.*, 1990).

An appraisal of relationships among metabolic factors, obesity and body fat distribution, and the interaction of obesity, physical activity and dietary behaviour in future studies will better clarify the manner in which adipose tissue influences the incidence of NIDDM. Body fat distribution may explain, in part, why many non-obese persons develop NIDDM, and why many obese persons never develop NIDDM. Genetic determinants regulating adipose tissue distribution (Bouchard, 1988; Selby *et al.*, 1990) may reflect different pathways by which genotype are related to NIDDM and metabolic abnormalities.

The prevalence of obesity and abdominal adiposity in Aboriginal populations appears to be high. Comparisons between peoples and geographic regions are complicated by different indices for assessing obesity and body fat distribution, and differences in age and gender distributions. Taking a body mass index of at least 27 kg/m² as indicative of obesity, the prevalence of obesity in Aboriginal Canadians is approximately 40-60% for men and 60-85% for women (Brassard *et al.*, 1993; Daniel *et al.*, 1995; Dyck *et al.*, 1995; Fox *et al.*, 1994; Young *et al.*, 1985).

There are relatively few estimates of the prevalence of abdominal obesity. In a British Columbia Aboriginal population the proportion of adult men and women with waist-to-hip ratio values beyond the 75th percentile norms from the Canada Fitness Survey (1981) for their age and gender was 73% (Daniel *et al.*, 1995). A study of the James Bay Cree in which abdominal obesity was defined as waist-to-hip ratio greater than 0.99 without regard for age or gender found

that 47% of men and 23% of women were above this cut-point (Brassard *et al.*, 1993). A cut-point of 0.99 for men is highly conservative, however, and corresponds to the 75th percentile for males age 65 years and older in the general Canadian population. The same cut-point for women ignores sexual dimorphism in pelvic structure and is exceptionally conservative; it indicates a high level of obesity, since a waist-to-hip ratio value of 0.89 corresponds to the 75 percentile for females age 65 years and older in the general Canadian population. As the mean age for both men and women in this study was 49 years, it is likely that the true prevalence of abdominal obesity was substantially underestimated, especially among women.

Physical Activity and Sedentary Lifestyle

The role of physical activity in preventing NIDDM has not been widely considered (Briazgounov, 1988). Epidemiological data suggest that a relationship between physical inactivity and the development of NIDDM is highly probable, though some authors argue for a randomised controlled trial to confirm epidemiological and metabolic research (Kriska & Bennett, 1992). A linear dose-response relationship clearly exists between physical activity and health and functional effects, for low to moderate levels of activity (Blair *et al.*, 1992). Thus, the beneficial effects of activity need not require as much time and effort as previously thought (Harris *et al.*, 1989). The health benefits may be greater among older populations than middle-aged ones, since older individuals have a higher prevalence of chronic disease and lower levels of physical activity (Pescatello & DiPetro, 1993).

Reviewing several cross-sectional studies of Aboriginal peoples in the South Pacific, Zimmet *et al.* (1990) noted an apparently independent protective effect of physical activity against the development of NIDDM. Cross-sectional data from the Pima Indians in Arizona indicate greater glycaemic control and lower weight among active individuals in contrast to more sedentary individuals (Kriska *et al.*, 1993). A retrospective longitudinal study suggested that former female college athletes had reduced risks of subsequent diabetes (Frisch *et al.*, 1986), and prospective studies of both men (Helmrich *et al.*, 1991; Manson *et al.*, 1992) and women (Manson *et al.*, 1991) also suggest a protective effect of exercise against NIDDM.

The benefit of physical activity in reducing the risk of NIDDM is likely due to several biological effects of exercise. Exercise lowers blood glucose concentrations in persons with NIDDM (Joslin, 1985), an effect that can persist for several hours to days (Holloszy *et al.*, 1987). This short-term decrease in blood glucose is likely the result of several effects that occur during and following exercise: (a) an insulin-dependent increase in glucose uptake by muscle; (b) an increase in insulin sensitivity; and (c) in persons with NIDDM, the restriction of hepatic glucose production, due to high insulin concentrations (Ruderman *et al.*, 1990). That regular exercise may improve long-term glucose control, as indicated by glycosylated haemoglobin concentrations, is a consistent finding. A large body of literature also associates physical training with greater insulin sensitivity in skeletal muscle and adipose tissue (Ruderman *et al.*, 1990). Exercise also promotes weight loss and "metabolic fitness" (Blair *et al.*, 1992), and contributes to stress reduction and a sense of well-being through endorphinergic mechanisms (Daniel *et al.*, 1992).

Zimmet *et al.* (1990) reported a greater degree of habitual physical activity related to food gathering and agricultural practice in cultures maintaining a traditional lifestyle. These authors postulated that the adoption of sedentary lifestyles is an integral aspect of the acculturation of indigenous peoples, from which arises hyperinsulinaemia, insulin resistance and ultimately glucose intolerance, particularly in those who are obese. Australian Aborigines who reverted to a traditional way of life (involving changes in diet and level of physical activity), underwent weight reduction and a reversal of the metabolic abnormalities of diabetes (O'Dea, 1984). Longitudinal data on the beneficial effects of regular exercise in Native Americans are limited to those collected from the Zuni Indians and Ramah Navajos of western New Mexico. Two reports demonstrated that participation in Zuni fitness promotion programmes was associated with reductions in weight and improvements in glycaemic control (Heath *et al.*, 1991; Leonard *et al.*, 1986); another report documented weight loss alone (Wilson *et al.*, 1989).

Direct estimates of the prevalence of physical inactivity are not available for Aboriginal Canadians. The 1991 Canada Census allows a crude estimate, however, of the proportion of Aboriginal persons who participate in recreational activities that involve physical activity. For British Columbia and Canada overall, 54% of the total number of adults (15 years of age and older) claiming Aboriginal identity reported engaging in sports, dance or recreation that involved physical

activity during the year preceding the survey (Statistics Canada, 1993b). This proportion was the same as that for Aboriginal adults who reported the more sedentary recreational pursuit of having bought or rented a video-cassette movie during the same period (Statistics Canada, 1993c). The moderate proportion of adults who participate in some form of physical activity requires cautious interpretation, as the frequency, intensity and duration of activities are unknown. Still, an estimate of 46% for Aboriginal adults who do not engage in physical activity is not discordant with estimates of 40% and 52% for adults with activity levels insufficient for health benefits in the general U.S. (Harris *et al.*, 1989) and Canadian populations (Stephens, 1993), respectively.

Diet

Dietary behaviours are not conclusively established as risk factors for NIDDM, although several behaviours associated with a “western” lifestyle are believed to be related to the development of diabetes and other chronic degenerative diseases. These behaviours include: high consumption of total calories, high consumption of fat, high consumption of refined sugars, low consumption of total and complex carbohydrates and low consumption of fiber (Stern, 1991; World Health Organisation, 1994). Among Tarahumara Indians in Mexico who substituted a typical “western” diet for their usual low fat, high fibre diet of corn and beans, weight gain and increases in cholesterol concentrations occurred within five weeks (McMurry *et al.*, 1991). The restriction of dietary fat, especially saturated fat, seems to be the most important measure for preventing NIDDM (Feskens, 1992; Vessby, 1995). There is a strong relationship between NIDDM, obesity and alcohol consumption among Native Americans, but contributions to risk are inter-related and difficult to disentangle (Mohs *et al.*, 1988).

Young (1988) reviewed evidence documenting profound changes in the food habits of Aboriginal Canadians over several decades of cultural transition. An irony was apparent in the fact that “despite their nutritional superiority and lower costs, ‘country foods’ are decreasing in importance in the diet of many Indian groups” (p. 667). It is unclear, however, whether an increasing dependence among Aboriginal peoples on “western” store bought foods has an aetiological role in the development of NIDDM. Among Dogrib Indians, dietary differences are related to relative acculturation, but have little correlation with plasma glucose concentrations

(Szathmary *et al.*, 1987). Diabetic Cree-Ojibwa have a greater intake than non-diabetic Indians of proteins, and a lower intake of carbohydrates (Young *et al.*, 1990). In studies involving female Pima Indians, the development of diabetes was best predicted by carbohydrate intake, which was strongly related to total caloric intake and fat consumption (Knowler *et al.*, 1990). Diabetes incidence was not related to sucrose intake (Knowler *et al.*, 1990). The inability to differentiate the effect of specific dietary components on the development of NIDDM probably reflects the imprecision of available measurement techniques of diet or of early onset of NIDDM.

Despite the widespread consumption of almost exclusively high calorie, refined imported foods and high caloric intake in Aboriginal peoples of the South Pacific (Lee *et al.*, 1994), many studies have failed to demonstrate a connection between the prevalence of NIDDM and any particular dietary component; only the overall nature of dietary changes has emerged as a possible (and indirect) aetiological factor (Zimmet *et al.*, 1990). A trial of the traditional Hawaiian diet fed *ad libitum* to Native Hawaiians with multiple risk factors for cardiovascular disease demonstrated significant reductions in energy intake, serum cholesterol, body weight, and systolic and diastolic blood pressure (Shintani *et al.*, 1991). Reductions in dietary intake of sugar and saturated fat corresponding to decreases in serum cholesterol, body weight and systolic and diastolic blood pressure were observed in a remote Aboriginal community in Australia in response to community-based interventions (Lee *et al.*, 1994; Lee *et al.*, 1995). Such studies suggest that improvements can be achieved in diet and in levels of physiological variables implicated in the development and control of NIDDM, even though the precise aetiological role of specific nutrients is unclear.

Data from the 1991 Canada Census indicate that for British Columbia and Canada overall, the proportion of adult Aboriginal persons buying food from take-out restaurants at any point during the year preceding the survey was 74% (Statistics Canada, 1993c). About 40% of adults bought take-out food daily or almost daily. Meat, fish, or poultry were eaten daily by about 54% of adults, and several times a week by about 27% of adults (Statistics Canada, 1993b). These data suggest a high consumption among Aboriginal Canadians of saturated fat associated with take-out foods and meat and poultry, and that the consumption of total and complex carbohydrates, and dietary fibre, is low. For the year preceding the Census, 67% of adults reported the

consumption of alcohol, but only 3% reported consuming alcohol at least 4-6 times per week. Nevertheless, 62% of adults report that alcohol abuse is a problem (whether for the community or for one's self is unclear) (Statistics Canada, 1993b). Overall, the Census data suggest a relatively high consumption of total calories, probably accounted for mainly by saturated fats and simple carbohydrates. This conclusion is supported by ethnographic evidence from studies of food consumption, meal patterns and food preparation among Aboriginal populations in coastal British Columbia (Hopkinson *et al.*, 1995) and northwestern Ontario (Gittelsohn *et al.*, 1996).

Stress

There are varying approaches to an understanding of stress and its consequences. In all approaches there is agreement on the central role of discomforting life situations, socio-cultural background and rapid modernisation in the occurrence of stress-related outcomes (Henry & Stephens, 1977; Moss, 1973; Pestonjee, 1992). Early reports suggested that acculturation was responsible for the increase in diabetes among American Indian populations (Knowler *et al.*, 1981; West, 1978). A Canadian report (Szathmary & Holt, 1983) hypothesized that acculturative stress was responsible for greater two-hour post-load glucose concentrations and higher levels of central adiposity among Dogrib Indians who migrated to urbanised southern locations, in contrast to kin who remained in isolated northern settlements. Diabetes prevalence is greatest in southern latitudes and where there is easy access to urban areas (Dyck *et al.*, 1995; Young *et al.*, 1990).

It is possible that acculturation contributes to NIDDM and obesity not only through alteration of diet and activity patterns, but also through neuroendocrine reactions to psychogenic stress (Landsberg, 1986; Saad *et al.*, 1991). Thus, changes in behaviour and lifestyle may interact with specific reactions associated with social, cultural and economic stress (World Health Organisation, 1994). The pathways by which these events might be explained are discussed in Chapter 3 along with theories accounting for the direct and indirect effects of social environmental conditions on health. This section presages that discussion by reviewing evidence in support of the notion that stress at the level of the individual is a cause of, or at least a risk factor for, NIDDM.

The biopsychosocial pathways by which psychogenic stress might result in sickness are not clear, but a broad body of literature dating back almost 70 years links stress with sympathetic

(Cannon, 1929) and pituitary adrenocortical stimulation (Selye, 1956). Consistent, if circumstantial, evidence supports the role of stress in NIDDM. Stressful life events are related to an increased risk of cardiovascular disease (Haney, 1980; Theorell, 1982), for which NIDDM is a strong predictor (Hoy *et al.*, 1995; West *et al.*, 1983). Hypertension is strongly linked both to stress (Linden, 1988) and NIDDM (Helmrich *et al.*, 1991; U.S. Department of Health and Human Services, 1994). Moreover, stress reduction for individuals with NIDDM reduces anxiety scores and systolic and diastolic blood pressures, and these reductions co-vary (Okada *et al.*, 1995a).

In persons with NIDDM, hyperglycaemic effects are produced by acute psychological stress (Goetsch *et al.*, 1993) and sympathetic nervous system stimulation (Bruce *et al.*, 1992). Perceptions of daily stress are associated with high blood glucose concentrations and limited coping ability (Goetsch *et al.*, 1994; Konen *et al.*, 1993). Stress reduction in persons with NIDDM reduces glycosylated haemoglobin concentrations (Lane *et al.*, 1993; Okada *et al.*, 1995b). A large body of literature from animal studies supports the notion that stress reliably produces hyperglycaemia in NIDDM, and there is growing evidence of autonomic contributions to the pathophysiology of NIDDM in both animals and humans (Surwit *et al.*, 1992). Animal studies indicate that diets high in fat and simple carbohydrates can induce an exaggerated response to stress in certain genotypes (Surwit, 1993). Similarly, in a sample of Aboriginal Canadians with NIDDM, impaired glucose tolerance and normoglycaemic profiles, an inverse relationship was shown to exist between fasting glucose concentrations and mastery, the extent that people see themselves as being in control of the forces that affect their lives (Daniel *et al.*, 1995). The same study also demonstrated a positive linear trend in mastery across diabetic, impaired glucose tolerance and normoglycaemic groups.

There is biological plausibility in the notion that general neuroendocrine reactions to stress are associated with the development of NIDDM. It is unclear whether the effect of stress on diabetes is mediated through abdominal obesity (Björntorp, 1988a) or directly on glucose and insulin concentrations (Landsberg, 1986). Regardless, standardised stress is known to invoke neuroendocrine dysregulation at the hypothalamic level in mice, primates and humans (Jeanrenaud, 1994; Mårin & Björntorp, 1993). As postulated by Björntorp (1988b), it is possible that hypothalamic dysregulation in response to environmental stress could induce engagement

of: (a) the sympatho-adrenal axis (causing hypertension and increased concentrations of free fatty acids); (b) the pituitary-adrenal axis (causing increased secretion of adrenal steroids); and (c) the pituitary-ovarian or gonadal axis (causing altered sex steroid concentrations, anovulation in women, and abdominal obesity). Stress-induced engagement of these central nervous system and autonomic-neuroendocrine system axes could thereby contribute to the development of most risk factors for stroke, cardiovascular disease, NIDDM and some cancers. Recent data in support of this hypothesis come from the Whitehall II study. Eric Brunnee *et al.* (in press, 1997) have shown that employment grade is (a) inversely associated with concentrations of insulin and 2-hour glucose, and (b) positively associated with job control and effort-reward imbalance (as assessed by both self-reported and external determinations).

Difficulties in defining and measuring stress and the lesser importance traditionally accorded to psychosocial issues preclude an estimate of the prevalence of stress among Aboriginal populations. Further, it is difficult to disentangle an effect of psychogenic stress from behavioural changes in understanding the impact of acculturation on NIDDM (see Chapter 4). Nevertheless, in newly-industrialised and developing countries, a growing body of evidence suggests that increases of epidemic proportions in diabetes are closely related to unhealthy lifestyle changes (King & Rewers, 1993; World Health Organisation, 1994). These changes are the same as those faced by Aboriginal Canadians over the last 90 years if not more: increases in the consumption of saturated fats, reduced physical activity and increasing obesity, and increasing social, cultural and economic stress.

Summary

Gaps exist in the epidemiological and other scientific literature supporting causal relationships between risk factors and NIDDM in Aboriginal populations. Nevertheless, the risk factors reviewed are sufficiently associated with the development and control of NIDDM, and their prevalence has been sufficiently established, to allow their aetiological relevance to be assessed in terms of relative importance and changeability. Table 5 provides such a typology, which helps to identify and appraise targets for intervention (Daniel & Green, 1995). Though intervention is oriented towards factors that are changeable, consideration must also be given to unchangeable factors,

such as genetic predisposition, age and gender. These risk markers should be evaluated to keep a perspective on the multiple determinants of NIDDM and to identify high-risk sub-populations. As the presence of more than one risk factor in the same people further increases the risk of chronic disease such as diabetes (Rose, 1992), there is a rationale for multiple risk factor interventions.

Table 5. Risk Factors Associated with the Development and Control of Non-Insulin-Dependent Diabetes Mellitus Among Aboriginal Peoples and Ratings of Each on Importance and Changeability*

Associated Risk Factor	Type of Risk Factor	Importance		
		Causal Effect	Prevalence	Changeability
Age (35+ years)	chronological	moderate	moderate	none
Gender (female)	genetic	low	moderate	none
Family history	genetic	high	high	none
Obesity	anthropometric	high	high	moderate
Abdominal adiposity	anthropometric	high	high	moderate
Physical inactivity	behavioural	high	high	moderate
Dietary	behavioural			
High consumption of:				
total calories	behavioural	moderate	high	moderate
saturated fats	behavioural	moderate	high	high
refined sugar	behavioural	moderate	high	high
Low consumption of:				
total carbohydrates	behavioural	moderate	high	moderate
complex carbohydrates	behavioural	moderate	high	high
dietary fibre	behavioural	moderate	high	moderate
hyperinsulinaemia	physiological	high	moderate	moderate
hyperglycaemia	physiological	high	moderate	moderate
psychogenic stress	physiological	moderate	unknown	unknown

*From Daniel, M., & Green, L.W. (1995). Application of the Precede-Proceed planning model in diabetes prevention and control: a case illustration from a Canadian aboriginal community. *Diabetes Spectrum*, 8(2), 74-84.

It has been argued that there exists an urgent need to establish definitively the role of behavioural risk factors such as physical activity and dietary habits if community interventions involving a focus on behavioural and environmental change are to be viable and justifiable expenditures of resources (Manson & Spelsberg, 1994; Stern, 1991). Anthropometric and metabolic risk factors for NIDDM, which include obesity, adipose tissue distribution and circulating glucose, insulin, glycosylated haemoglobin and triglyceride concentrations, are becoming well established. Much research on NIDDM would appear to have been predicated, however, on the assumption that the generation of new data on the individual-level correlates of disease will somehow find appropriate application and lead naturally to an improved health status among the populations studied (Nutting, 1986). This assumption has been ill-founded, for observational and intervention studies have not generally directed attention to the inter-relationship between risk factors and risk conditions, especially behaviour as a function of lifestyle reflecting the direct and indirect effects of the prevailing social environment.

It is not an unreasonable conclusion that enough is known of the aetiology and natural history of diabetes, and its prevalence and impact in Canada's Aboriginal communities, to warrant the implementation and evaluation of interventions targeted at: (a) reducing the incidence of NIDDM by reducing the risk of its onset (primary prevention); and (b) improving individual and community level conditions influencing the early detection and management of established cases of NIDDM (secondary prevention). Uncertainties that exist regarding the precise role of risk factors such as obesity, physical activity and diet in the development of NIDDM lend support to multiple-risk-factor intervention approaches for prevention through a healthful lifestyle strategy (Barnard *et al.*, 1994; Zimmet *et al.*, 1986).^{*} This can be justified also on the grounds that these same lifestyle and community conditions can be associated with prevention and control of other chronic diseases. The following section reviews arguments for and against community-based approaches to the primary and secondary prevention of NIDDM. The rationale for intervention when the aetiology is unclear is two-fold: (a) urgent social need; and (b) sufficient knowledge of the correlates of diabetes in a broad variety of populations.

^{*}The methodological quality of the evidence for prevention is discussed in a subsequent section.

Support for Community Interventions

A combination of primary and secondary prevention strategies is necessary to achieve effective control of diabetes (Tuomilehto & Wolf, 1987; Zimmet *et al.*, 1986). Both forms of prevention are amenable to community-based control and direction (Office of Disease Prevention and Health Promotion, 1987), with non-Aboriginal health care providers serving in the short term to provide support and expertise as these strengths develop in the community (Gilmore, 1990). Full and meaningful community participation requires that the direction and nature of prevention strategies be determined and controlled by Aboriginal people (Postl, 1986).

There are two alternative approaches for the prevention of NIDDM in populations (King & Dowd, 1990). The population, or “community intervention,” approach seeks to remove the causes of disease in communities as a whole, whereas the high-risk, or “intervention in a community” approach aims to identify people at greatest risk, and to intervene selectively (Green & Kreuter, 1991). The high-risk approach is thought to offer greater efficiency and effectiveness than the population approach (Stern, 1991). A strong case exists for the efficacy of selective high-risk screening and intervention on the basis of family history (McCance, 1983). NIDDM is a disease that aggregates in families, and the literature suggests a strong genetic component to NIDDM. A number of additional considerations suggest, however, that the population approach in Aboriginal communities might actually prove more beneficial than the high-risk approach in the prevention and control of NIDDM.

If communities can achieve a normative effect in reducing behavioural and environmental risk factors for NIDDM, the cost-effectiveness and efficiency of the population approach may surpass the greater efficacy of the high-risk approach in the prevention of NIDDM. In support of this notion is (a) the high prevalence of risk factors for NIDDM and apparently growing incidence of NIDDM among Canadian Aboriginal peoples, and (b) the likelihood that interventions broadly targeting healthful behaviours and reduction of environmental risk factors for NIDDM will reduce morbidity and mortality from other chronic diseases also influenced by lifestyle (Zimmet *et al.*, 1986).

As the high-risk and population strategies are generally complementary (Rose, 1985), the high-risk approach can be invoked as necessary from the framework of a population approach to

prevention and health promotion. Both approaches typically compete for policy and fiscal support, but the high-risk approach ignores a moral imperative to provide to communities reasoned advice about maximising health for all (King & Dowd, 1990). Moreover, the incidence of morbidity and premature mortality can be reduced for an entire population only by changing risk factor distributions at the population level, not by concentrating on the upper percentages of the risk distribution (Rose, 1992). For indigenous populations in which the entire distribution of blood glucose is at concentrations higher than in non-indigenous populations, this position or displacement is invariably associated with recent and rapid environmental changes. Attempts to improve the situation through community-based interventions thus might hold promise.

The effectiveness of behavioural changes in preventing progression to NIDDM has been demonstrated by three studies, each involving high-risk individuals with impaired glucose tolerance at risk for progression to NIDDM. The first study was longitudinal, and focused on the effect of weight loss (Long *et al.*, 1994). The other two studies involved dietary change and increased physical activity; one was randomised (Pan *et al.*, 1994), and the other not (Eriksson & Lindgarde, 1991). Non-experimental trials in Aboriginal populations with individuals with and at risk for diabetes (cited above) have demonstrated reductions in weight (O'Dea, 1984; Wilson *et al.*, 1989), improvements in glycaemic control (Heath *et al.*, 1991; Leonard *et al.*, 1986), and more healthful dietary intakes corresponding to improvements in physiological and biochemical variables (Lee *et al.*, 1994; Lee *et al.*, 1995; Shintani *et al.*, 1991). A pilot study of the efficacy of a community-based education and support intervention for Mexican Americans with NIDDM reported improvements in diabetes knowledge, fasting glucose concentrations, and glycosylated haemoglobin concentrations (Brown & Hanis, 1995). Such studies suggest the efficacy, effectiveness and feasibility of interventions to prevent progression to diabetes and to reduce levels of risk factors for NIDDM. The results of observational studies do not, however, provide conclusive evidence of the effectiveness of behaviour modification for NIDDM prevention.

True primary prevention studies have not tested whether population-based initiatives can achieve reductions in the incidence of NIDDM, rather than in the prevalence of risk factors for NIDDM. Randomised trials have not assessed whether favourable modifications of weight, body fat distribution, physical activity and diet can reduce the risk of NIDDM among persons who do not

already have impaired glucose tolerance. In a comprehensive review of the epidemiological and biological evidence for primary prevention, Manson and Spelsberg (1994) estimated that the risk of NIDDM could be reduced 50-75% by control of obesity and 30-50% by increasing physical activity. Insufficient data and methodological differences among the studies reviewed precluded a meaningful estimate of the influence of diet in the prevention of NIDDM. Estimates for obesity and physical activity reflect expert opinion rather than determinations of the aetiologic fraction, as NIDDM incidence rates are not available for persons exposed and not exposed to interventions to reduce the occurrence of the disease. Further, the diversity of methodologies employed in the studies reviewed was insufficient to support a formal meta-analysis. The evidence in support of community-based intervention is hardly conclusive. It is important, therefore, to review other perspectives on the utility of the population-based approach to NIDDM prevention and control.

Advantages of the Population-Based Approach

The embedding of health-related behaviours in lifestyle suggests that social norms, cultural values, and economic factors can be targeted as environmental determinants of health and health-influencing behaviours. In a democratic society it is impossible for a central government to dictate uniform behaviour about lifestyle issues. Weight loss, physical activity and diet cannot be mandated. Effective, relevant and appropriate strategies for lifestyle change might best be debated and collectively decided upon close to the homes of those affected.

A community-based population intervention requires the co-operation of various community sectors (social, political, economic) influential regarding social policy and norms (Bunton, 1993). Given such co-operation, a population-based intervention clearly has an advantage over a high-risk intervention in that it combines community education with structural modifications of the environment (Frankish & Green, 1994). This increases the likelihood of successful behavioural change and reaches a larger number of people. As norms of behaviour change and as supply industries (e.g., food stores, restaurants) adapt to a new social pattern, the maintenance of behavioural changes no longer requires a high degree of individual effort or forethought.* The effectiveness of high-risk interventions is limited in that targeted education is

*For example, the popular emphasis on "Lite" foods and products low in dietary fat, promoted by television and other media, serves to encourage the maintenance of behavioural change.

seldom linked with structural modification of the environment. Consequently, people can find it difficult to maintain behavioural changes (Green *et al.*, 1996).

A high-risk approach does not offer the potential for normative change, because it targets only a small percentage of the population at risk, and because it deals with individuals, not entire communities. Furthermore, it is palliative and temporary. By dealing only with people who are susceptible to the particular causes of cases, it will always be necessary because the causes of cases are not necessarily the determinants of incidence among populations. The high-risk approach is useful only when uncertainty exists about the causal influence of risk factors, but if causes can be removed, susceptibility is no longer an issue (Rose, 1985).

A further consideration is the economic and political case for community-based action initiatives (Frankish & Green, 1994). This argument presupposes that prevention is an “investment” that (a) produces a dividend of reduced morbidity and mortality and (b) produces an informed electorate and a consumer demand through community education. Political change is influenced by an informed electorate and commercial change is influenced by consumer demand. In reaching a large percentage of the population, community-based action initiatives have much greater potential than high-risk approaches to achieve political and economic change. Policy paradigms (Doern & Phidd, 1986) inhibiting social and normative change can become entrenched and may change very slowly because they are tied to the education and socialisation of “experts” who control social processes. The collective action of individuals can serve to force policy change through political and economic action. In this way can be achieved the creation of more healthful political and economic climates that serve to support and reinforce behavioural change.

Limitations of the Population-Based Approach

Goodman and Goodman (1986) presented several criticisms of prevention programmes: (a) the benefits of prevention have been oversold and the secondary effects underestimated; (b) non-medical concerns have been forced into the medical model; (c) distinctions between prevention and other measures such as screening or therapy have been compromised; (d) programmes have transferred responsibility for disease to the victim; and (e) prevention has been promulgated as a

panacea. These criticisms do not reflect problems inherent in the concept of population-based prevention *per se*, they reflect problems that arise in the application of the concept.

One frequent criticism refers to the benefit of prevention at the level of the individual, and in this respect the population-based approach does not offer as much benefit as the high-risk approach (Rose, 1985). The majority of people in a population will not succumb to NIDDM. Rose (1985) has christened this phenomenon the *prevention paradox*: “a preventive measure which brings much benefit to the population offers little to each participating individual” (p. 38). As a consequence of the prevention paradox, it is postulated that motivation on the basis of health rewards is likely to be weak, but much more powerful motivators for individuals are the social rewards of enhanced self-esteem and social approval (Lock & Wister, 1992).

Another criticism relates to low-order risks inherent in any mass prevention project. Given small benefits at the level of the individual, a small benefit can be outweighed by a small risk. On this point Rose (1985) cited the World Health Organisation clofibrate trial, where a cholesterol-lowering drug killed more than it saved, even given that the fatality rate was only 1/1000/year. Arguing that low-order risks may be difficult to estimate in population-based prevention initiatives, Rose (1985) stressed the need to define two approaches: (a) those involving the restoration of biological normality by the removal of an abnormal exposure (e.g., reduction of dietary fat), where there can be the presumption of safety; and (b) those that leave intact the underlying causes of incidence, and impose some new, ostensibly preventive intervention (e.g., jogging), where adequate evidence of safety must be demonstrated. Physical activity among people who have been sedentary for a prolonged period is a biologically stressful intervention, and it is necessary to appraise, where possible, the risks associated with activity in people at risk for NIDDM.

Applied Prevention and Control Programmes in Canada

Relatively few community-based NIDDM prevention and control programmes have been mounted in Canadian Aboriginal populations as applied research projects for which effectiveness can be assessed empirically. This may reflect largely theoretical support for such initiatives. The Kahnawake Schools Diabetes Prevention Project (Macaulay *et al.*, 1995), near Montréal, Québec, and the Sioux Valley Diabetes Prevention Project (Mustard *et al.*, 1995) in southwestern

Manitoba, are population-based primary and secondary prevention studies that sought to reduce the prevalence of risk factors for NIDDM, rather than reducing the incidence of NIDDM. Neither study, however, has yet been evaluated. The Sandy Lake Health and Diabetes Project (Hanley *et al.*, 1995), in the Sioux Lookout Zone in Ontario, is a community-based project geared towards gathering epidemiological data and planning interventions suitable for implementation (Gittelsohn *et al.*, 1995), but it is not a primary prevention programme *per se*. Thus, there exist only a few diabetes projects engaging Aboriginal Canadians in prevention efforts at the population level.

A number of secondary prevention projects exist across Canada. Of those concerned with the early detection of diabetes and attempts to control the disease among existing cases, notable examples include those involving the James Bay Cree in northern Québec (Robinson *et al.*, 1995), the Haida Gwaii in British Columbia's Queen Charlotte Islands (Heffeman *et al.*, 1996) and urban Aboriginal people in Saskatoon (Dyck & Cassidy, 1995) and Toronto (through the Anishnawbe Health Toronto community health centre) (McClure *et al.*, 1992). Evaluation data are available only for two of these projects. The James Bay Cree study reported a significant reduction in fasting glucose among a group of individuals ($n = 25$) who spent three months in the wilderness in contrast to a comparison group ($n = 26$). Of a battery of measures, fasting glucose was the only variable for which change was observed (Robinson *et al.*, 1995). The Haida Gwaii study reported statistically significant reductions in serum cholesterol and high-density lipoprotein concentrations over a three year period among persons with established NIDDM for whom paired data were available (18 of 52 participants) (Heffeman *et al.*, 1996). For the same group of individuals, there were no significant changes in body weight, body mass index, glycosylated haemoglobin (A_{1c}), fasting glucose or triglyceride concentrations.

Other prevention programmes for Aboriginal people exist across the nation. These are primarily educational, targeting improvements in knowledge or in attendance or participation in clinic-based settings for persons with established diabetes (Blais *et al.*, 1991; Litwin, 1987). As these programmes target individuals with established disease, they qualify as tertiary rather than secondary prevention strategies. Few such initiatives have been evaluated systematically on the basis of quantitative outcomes, and where evaluation data are available, results are not generally encouraging (McClure *et al.*, 1992). A unique community-based education programme involving

diabetic individuals ($n = 15$) and non-diabetic family members ($n = 44$) in the Nuu-chah-nulth community on the west coast of Vancouver Island in British Columbia did not observe any statistically significant changes in either group in weight, body mass index, body shape, or in cholesterol, triglyceride, or fasting glucose concentrations (King-Hooper *et al.*, 1995). Given the low numbers of individuals involved in most secondary and tertiary prevention programmes, it is scarcely surprising that few positive effects have been demonstrated.

The effectiveness of most prevention programmes is hindered by a lack of resources, inadequate or non-existent follow-up and, often, an apparent lack of interest in diabetes from Aboriginal people (Young & Smith, 1992). For Aboriginal people with access to hospital dietitians or outpatient education units, low or inconsistent usage of these resources is common (Shah & Farkas, 1985). There appears to be more interest among Aboriginal people in community-based "understanding-oriented" activities not generally conceived and implemented as prevention programmes suitable for evaluation as applied, field-based research (Boston *et al.*, 1997; Grams *et al.*, 1996; Macdonald *et al.*, 1995; Travers, 1995). This interest probably reflects a need to grieve major personal and cultural losses by making conscious and processing the sources of trauma as part of a healing and general habilitative process (Mussell, 1992). Diabetes is just one symptom of ill health. Though the design of many such projects precludes causal inference, these projects may ultimately have some effect in increasing awareness and levels of knowledge and in modifying community norms to support healthful lifestyles. Such changes may be achieved directly or indirectly through the generation and implementation of community-directed intervention strategies (Gittelsohn *et al.*, 1996; Hagey, 1997; Herbert, 1996).

Whether existing diabetes prevention and control efforts have been or can be judged successful on the basis of systematic evaluations, there is a clear distinction in the extent of Aboriginal support between those initiatives imposed upon communities or individuals and those that involve Aboriginal people in all aspects of planning, design and implementation (Kewayosh, 1991). There has been and continues to be resistance and resentment towards service programmes developed and implemented for Aboriginal communities by non-Aboriginal health professionals (Mardiros, 1987). The imposition of service programmes reflects a failure to recognise that the eventual effectiveness of strategies for lifestyle change is dependent on

perceptions of relevance and appropriateness among those who are the intended recipients of such services (Webster & Nabigon, 1993).

Non-Aboriginal health professionals have not always accepted that conflicts in cultural values, attitudes and beliefs can render ineffective most attempts at disease prevention and health promotion. Diabetes education programmes have been shown generally to have at least a moderate effect on participant knowledge and on metabolic and dietary variables associated with glycaemic control (Brown, 1990; Brown, 1992; Laitinen *et al.*, 1994). Such programmes, however, may be ineffectual for Aboriginal people. Failures in Aboriginal diabetes education are thought to reflect unrealistic expectations for behavioural change, perhaps by the abstraction of behaviour from its social context, as well as some degree of paternalism and discrimination within the health care system (O'Neil *et al.*, 1986). Also, the reality that most educational programmes are not intended for Aboriginal people specifically, suggests a lack of socio-cultural relevance in accounting for their limited use and impact in Aboriginal populations (Litwin, 1987).

Socio-cultural factors require consideration when adapting treatment regimen and education programmes to the needs of Aboriginal peoples, and in planning, implementing and evaluating intervention programmes (Blais *et al.*, 1991; Garro, 1987; MacDonald *et al.*, 1990; Mail *et al.*, 1989). Recognition of this need has spread beyond the health education sector to reach segments of the public health research community that in the past have been less likely to acknowledge the need to match research objectives, questions, design and methodology to the values and culture of the population under study (American College of Epidemiology, 1994).

Socio-Cultural Considerations

The participation of the individual in the maintenance of his or her health is a tenet of health promotion, from which community responsibility evolves (Postl, 1986). This participation and responsibility is not likely to evolve when health care professionals — whose role is to facilitate the development of interventions — fail to consider broader aspects of health and quality-of-life issues (Boston *et al.*, 1997; Huttlinger *et al.*, 1992; Huttlinger & Wiebe, 1989). The concept of health is meaningful only when situated within a particular socio-cultural context, and appropriate interventions must be designed with sensitivity to such contexts (DeMars, 1992; May, 1986).

This section considers social, cultural, political and economic issues related to the quality of life of Aboriginal people, relevant to planning community interventions.

Cultural Characteristics

Acknowledging heterogeneity among Native Americans, some general characteristics of contemporary Aboriginal people that distinguish them in their outlook from the non-Aboriginal population include: (a) a spiritual attachment to the land; (b) sharing with others; (c) a lack of materialism; (d) a belief that a supernatural power exists in all objects, animate and inanimate; (e) strong ties to the family; (f) a desire to remain Aboriginal; and (g) a determination to retain culture and language (Jackson & Broussard, 1987).

Illness Interpretation and Health Belief Systems

Medical anthropology defines several “explanatory models” (Kleinman, 1980), “semantic illness networks” (Good, 1977), or other forms of health belief systems (Young, 1982) that Aboriginal peoples use to understand illness and make decisions related to illness. Notwithstanding individual and cultural variability among peoples in how illness aetiology or process is interpreted, shared cultural knowledge about diabetes is of importance in health education, treatment and intervention settings (MacDonald *et al.*, 1990; Moody & Laurent, 1984). An understanding of how Aboriginal people interpret their illness experience is of theoretical and practical importance in considering the development, implementation and evaluation of community interventions (Boston *et al.*, 1997). Kleinman’s (1989) notion of “cultural salience” is pertinent in this regard, as the response of Aboriginal individuals and their families to diabetes is dictated more by cultural convictions regarding the nature of the illness experience than by beliefs about *diabetes*.

Studying an Ojibwa reserve community in Manitoba, Garro (1987) used open-ended questions based on Kleinman’s (1980) explanatory model interview format, and a true-false series of questions presented using a tape recording in Ojibwa. The focus of this work was to investigate cultural knowledge and treatment choices relating to chronic diseases in several Manitoba reserves. Pioneering the use of empirical data in this area, Garro (1987) described three socio-cultural concepts of understanding about diabetes: (a) diabetes arises from a state of

imbalance, typically diet-related imbalances, and that steps taken to correct this balance may result in an improvement of the condition or elimination of symptoms; (b) diabetes is a reflection of a drastic and uncontrollable change in diet, from a traditional Indian diet based on wild foods to one that relies almost exclusively on store-bought foods; and (c) when someone has diabetes, their blood sugar is not always high, but it varies. The Ojibwa concept of imbalance has also been reported to be a central socio-cultural concept of diabetes in an urban Ojibwa setting (Hagey, 1984) and in a Sioux community (Lang, 1985). Among non-Aboriginal persons with diabetes, the importance of balance for biological, psychological and social coping strategies has only recently become viewed as important to health and well-being (Wikblad & Montin, 1992).

Hagey (1987) reported two Ojibwa cultural influences on a framework for interpreting illness: (a) the principle of balance; and (b) the principle of holism. Critical of Garro's (1987) empirical employment of the cultural competence model, Hagey (1987), a structural anthropologist, argued that "... while attempting to uncover underlying first principles of [Aboriginal] logic and articulating these in Western philosophical terms, one can lose the many subtleties and innuendoes of intent and emphasis under this method" (p. 111). Nevertheless, Hagey's (1987) qualitative conclusions about cultural influences on diabetes are similar to Garro's (1987) quantitative conclusions.

Culturally specific illness explanatory models offer a prevention framework that is (a) grounded in an understanding of how illness is interpreted and managed among Aboriginal peoples, and (b) oriented towards a mutually negotiated understanding of illness process and control between different explanations and belief systems (Garro, 1987). Conflicts can arise when health care professionals and community members differ on several key issues: (a) social and cultural backgrounds; (b) beliefs about the origin or cause of a particular sickness; (c) explanations for the meaning of illness; and (d) interpretations of a common symptom (Eni, 1989). There exists considerable potential for conflict between non-Aboriginal researchers and Aboriginal people over how best to counter diabetes and other chronic diseases.

The effectiveness of cross-cultural projects could be improved if certain issues were considered before attempting to develop and implement interventions. The following questions,

modifications of those contained in Brownlee's (1978) manual for health workers, can guide planning efforts with the input of Aboriginal people:

- (a) What beliefs and practices in the health care area are beneficial to health? What beliefs and practices are harmful to health? Should harmful beliefs and practices be changed?
- (b) What are the functions of various health beliefs and practices? How are various beliefs and practices linked to one another? What meaning do they have to those that practice them? Do individual beliefs and practices link to form a meaningful whole?
- (c) Are potential suggestions for change in certain health beliefs and practices realistic, considering the total situation? Are such suggestions realistic considering the place of certain beliefs or practices within the culture? What effects or repercussions may certain changes in health beliefs and practices have in other areas of life?
- (d) When posing changes in health beliefs and practices, is it possible to develop innovations that are consistent with the existing culture? Can innovations be developed that emphasise continuity with old traditions?

Consideration of the above questions could help to orient non-Aboriginal health care professionals and Aboriginal people in a way that accounts for differing explanations and belief systems (Boston *et al.*, 1997; Garro, 1987). An understanding of contemporary Aboriginal socio-cultural issues, including theories of disease causality and therapy (Gregory, 1988; O'Neil, 1988), the role of traditional medicine (Camazine, 1980; Mala, 1988; McClure *et al.*, 1992), social organisation mechanisms and the relationship of the community to health promotion initiatives (Blais *et al.*, 1991; Jackson *et al.*, 1982; Nichter, 1984), are important in conducting research that is relevant to prevailing value systems.

Value Systems

There are fundamental differences in value systems between Aboriginal and Euro-Canadian cultures (Brant, 1990; Katz, 1981). Aboriginal values ("ethics") emphasise principles of sharing, non-interference, hospitality, use of time in a flexible manner and emotional restraint. The Euro-Canadian culture values competitiveness, material success, commitment to employment and a clear distinction between work and leisure time. The discordance between value systems can

affect interactions between Aboriginal people, non-Aboriginal health care providers, and the health care system (McClure *et al.*, 1992).

Differences in social structure, values and communication patterns are potential barriers to the effective acquisition and integration of health knowledge (Shah & Farkas, 1985). Among the Cree-Ojibwa, a sense of powerlessness in health care has been attributed to a lack of mutual understanding and shared values with health care providers (Wieringa & McColl, 1987). Masi (1989) stressed the importance of health care approaches that are culturally appropriate, noting that *degrees* of acculturation must be considered regarding health care approaches. Values and cultural health belief systems thus might vary with acculturation, but deep-rooted differences in values and attitudes distinguish Aboriginal from non-Aboriginal Canadians in general.

Farkas (1987) reported that Aboriginal people with diabetes experience considerable difficulty in their interactions with non-Aboriginal physicians and health educators. Noting that many clinical interventions are perceived by Aboriginal people as interference, interruption of their lifestyle and invasions of their privacy, Farkas (1987) argued that the value placed on respect for personal autonomy in Aboriginal culture contra-indicates attempts to control or interfere with another person's autonomy.

Socio-Political Considerations

The present health status of Aboriginal peoples is a function of their history of social and political oppression (Bennett, 1988; Cornell, 1988; York, 1990). In Canada, legislation has suppressed Aboriginal rights (Mathias & Yabsley, 1991). The health problems affecting urban, rural and remote Aboriginal communities reflect political, economic and social conditions of living.

The 1991 Canada Census collected data on a variety of social issues from the adult population indicating Aboriginal identity. A legacy of social and political oppression is indicated by the large proportions of individuals, for Canada overall and by province, who report social problems concerning suicide, unemployment, family violence, sexual abuse, drug abuse, alcohol abuse, rape and other health and social issues (Statistics Canada, 1993b). Social pathologies are a function of the processes associated with inequalities in social class and status (De Vos & Suárez-Orozco, 1990; Runciman, 1972) and relative and absolute poverty (Carney, 1992;

Moynihan, 1968). There is little doubt about the low socio-economic status of the Canadian Aboriginal population (Statistics Canada, 1993c). Low socio-economic status is associated with feelings of powerlessness and low degrees of health knowledge (Foets *et al.*, 1985; Padgett & Brodsky, 1992; Wierenga & Wuethrich, 1995).

A western biomedical and individualistic approach to health clearly is not appropriate to meet Aboriginal health needs. As stated by Postl (1986), "the linkage between traditional healing practices and western medicine must be negotiated with the recognition that the dominant system is far from having all the answers and has not been entirely relevant to the needs of Native people" (p. 254). Recognition of the need for socio-cultural relevance has stimulated the creation of interdisciplinary training programmes for Canadian medical residents in community medicine, epidemiology, public health and health policy (Square, 1996; Thorne, 1993). Another example is the recommendation made in the clinical practice guidelines of the Canadian Diabetes Advisory Board for the creation of Aboriginal community diabetes educators to provide the foundation for community care (Expert Committee of the Canadian Diabetes Advisory Board, 1992). Health care professionals are increasingly recognising a need for culturally relevant health promotion strategies to contribute to the control of NIDDM (Brassard *et al.*, 1993; Grams *et al.*, 1996; Macdonald *et al.*, 1995; Sarsfield, 1988; Tookenay, 1996).

Granting the importance of greater cultural sensitivity among non-Aboriginal health care professionals, community-driven health promotion initiatives may offer the greatest potential to impact on the health and quality of life of Aboriginal peoples. There is a strong desire among Aboriginal Canadians to take charge of their own health by decreasing their dependence on non-Aboriginal health professionals and the technology of western medicine (Boston *et al.*, 1997). It has been proposed that in a new role, non-Aboriginal health professionals will serve not as figures of authority, but as advocates "empowering individuals and communities so they can understand the causes of illness, make informed decisions, and promote their own well-being ..." (Mardiros, 1987, p. 23). This position reflects the desire of Aboriginal people for control over their lives.

McClure *et al.* (1992) undertook a review of policy issues relating to the health of Aboriginal people. Changes taking place in the areas of health, community development and community control were clearly related to a new sense of empowerment among Aboriginal

Canadians. The demand that Aboriginal people regain complete control over their lives, including those dimensions that influence their health status and access to health care, reflects this rapidly evolving sense of empowerment. This growing sense of empowerment is not always encouraged, however. O'Neil *et al.* (1993) reported that the resistance of the medical establishment and government funding agencies to research that addresses socio-cultural health issues with political implications is in itself a political act, and that "research questions are favoured which limit the responsibility of political and economic structures in the production of health problems" (p. 229). Scientifically sound lifestyle-oriented prevention and health promotion initiatives are indeed difficult to design. Nevertheless, the methodological challenges of such work should not preclude the need for research addressing social needs (Hagey, 1997).

Quality of Life

The literature reviewed thus far has focused on a broad variety of cultural, social, economic and political issues related to the health of Aboriginal peoples. Social indicators of health, a function of social and political oppression, have been discussed. Arguably important to community interventions are cultural relevance and logic, a holistic balance framework, a need to negotiate consensus over differences in health belief and value systems and, overall, the strong desire of Aboriginal Canadians to take control of the determinants of their health. Thus has surfaced the subjective quality-of-life issue perhaps most important to Aboriginal peoples: the desire to regain control over their lives, including those dimensions that influence their health status and access to health care. Framing the issues in terms of quality of life is important as it allows dimensional processes and concepts related to the health of Aboriginal peoples to be bound together and placed back into the whole from which they were abstracted (Wolf, 1982).

In the context of a community-based diabetes prevention and control initiative, the development of a sense of empowerment is likely to be predicated on the extent to which the community takes control of, and responsibility for, the intervention process. This control and responsibility is likely to depend on whether strategies are (a) grounded in an understanding of how illness is interpreted and managed within the community and (b) consonant with a mutually negotiated understanding of illness process and control (Garro, 1987). Thus, specific cultural

values, beliefs and attitudes are provided opportunity for positive effect as factors predisposing and reinforcing lifestyle changes independently and interactively with enabling social and economic resources (Arnold *et al.*, 1995; Gottlieb & Green, 1987).

Aboriginal understandings about the causes of diabetes clearly do not simply reflect health education messages and the teachings of biomedical practitioners, which are primarily ahistorical, oriented at the level of the individual, and fail to account for the emergence of diabetes among Aboriginal populations (Garro, 1995). Empowerment through responsibility for the intervention process allows for Aboriginal constructions of diabetes as an environmental and social phenomenon (Boston *et al.*, 1997). The contextualisation of diabetes as a product of acculturation provides a basis for improvements in quality of life, as a totality of inter-connected processes with a social and historical basis. The biomedical abstraction of diabetes as primarily an individual responsibility framed in narrow clinical terms denies any relationship between clinical status, health and quality of life, if the broader social and historical context of the disease is ignored in prevention and control.

Summary

This chapter appraised the extent and impact of diabetes in the Canadian Aboriginal population, its importance as a health issue, and those risk factors implicated in its aetiology. A rationale was provided for community-based, integrated approaches to the prevention and control of diabetes, focusing on changing behaviours in combination with changing environments. The population-based approach to prevention and control was contrasted with the high-risk approach targeting only individuals at elevated levels of risk, and intervention programmes involving Aboriginal Canadians were reviewed in terms of their effectiveness and limitations. Few programmes have been developed as applied research projects enabling empirical appraisals of effectiveness. A general lack of socio-cultural relevance was implicated as potentially hindering the acceptance and viability of many interventions directed at Aboriginal populations.

Socio-cultural and related political and economic considerations were also reviewed, focusing on general cultural characteristics, value systems, illness interpretation and health belief systems. It was concluded that broader health and quality-of-life issues can be addressed by

contextualising and responding to diabetes as a product of acculturation, and that this requires community control and responsibility for the intervention process. Aboriginal constructions of diabetes as an environmental and social phenomenon could provide the basis for new models of health care delivery relevant to community needs. Thus, personal and collective efficacy can serve to empower communities to initiate and maintain behavioural and environmental change.

CHAPTER 3

THEORETICAL FOUNDATIONS

Even when research activity is not founded on explicit theory, neither theory nor research activity can be judged independently of the other. Formal theory can be helpful for conceptualising and explaining the dimensions of a problem, its antecedents and ramifications. Theory can also be used as a tool for predicting and guiding, where appropriate and justifiable, the development and implementation of particular intervention strategies (Ottoson & Green, 1987). This chapter reviews social determinants of lifestyle and behaviour and theories accounting for a relationship between acculturation and diabetes in Aboriginal populations. Theories for explaining and predicting behavioural and environmental change are then examined in relation to their potential utility for population-based interventions.

Accounting for a Relationship Between Acculturation and Diabetes

This section provides a conceptual perspective on the relationship between risk factors and risk conditions regarding the role of acculturation in the development of diabetes among indigenous populations. Central to this discussion is the notion that acculturation, as a social process, is inherently stressful at the level of individuals. Such stress may account for the relationship between environmental change and the development of diabetes among Aboriginal peoples.

Evidence on stress as a cause of, or a risk factor for, NIDDM was reviewed in Chapter 2, though the term "stress" was not defined explicitly. As given by Young (1980), stress is considered here to refer to an input-output process consisting of observable stressful events, observable symptomatic outcomes (or the potential for such outcomes) and processes, internal to the individual and generally observed only indirectly, which connect stressful events to symptoms, where stressful events are exogenous inputs which at an organismal level are noxious or threatening and predispose a complex series of neuroendocrine responses that may ultimately manifest as observable symptomatic outcomes.

Stress may be acute or chronic. A widely-accepted stress framework by Elliot and Eisdorfer (1982) divides the stress process into four explicit components consistent with Young's (1980) definition: (a) *stressors* (events), occurrences that may produce physical and psychosocial reactions; (b) *reactions* (responses), individual responses to the stressor (biological or psychological) that depending on their intensity and duration may result in physical or psychological effects; (c) *consequences* (outcomes), the long-term effects of reactions; and (d) *mediators* (processes), filters and modifiers (genetic, psychological, social and physical) that can influence the effect of stressors, reactions, and consequences in individuals and groups.

Social Determinants of Lifestyle and Behaviour

First, a general framework for the relationship between risk factors and risk conditions will be described to account for the role of acculturative stress in health. The work of René Dubos on the tubercle bacilli in the 1940s and 1950s led him to reformulate the prevailing theory of disease causation as the deterministic result of the presence of pathological organisms. His approach was to view the disease process as an ecosystem encompassing multiple events. "Its solution," he predicted, "transcends treatment of symptoms in the individual patient and might require social reforms reaching even into the field of ethics" (Cohn & Moberg, 1991, p. 72). Dubos maintained that the important element in disease was not infection or any deterministic cause. He viewed any stress — external or internal — that alters resistance, as provoking the onset of illness and then determining the outcome of the disease.

Environmental and behavioural or lifestyle factors are reciprocal in their relations to each other. As a consequence of this reciprocal relationship, if the social environment is distinguished from the physical environment, then health may be considered to be influenced directly and indirectly by the social environment, and directly and indirectly by behavioural and lifestyle factors (Green & Kreuter, 1991). The same relations apply for quality of life, noting that health status mediates quality of life only in part (Figure 1).

There are two basic pathways by which social factors can influence health: (a) the effect of positive and negative emotions (stress reactions) and the central nervous system; and (b) through patterns of lifestyle and behaviours that are either detrimental or beneficial to health (Badura &

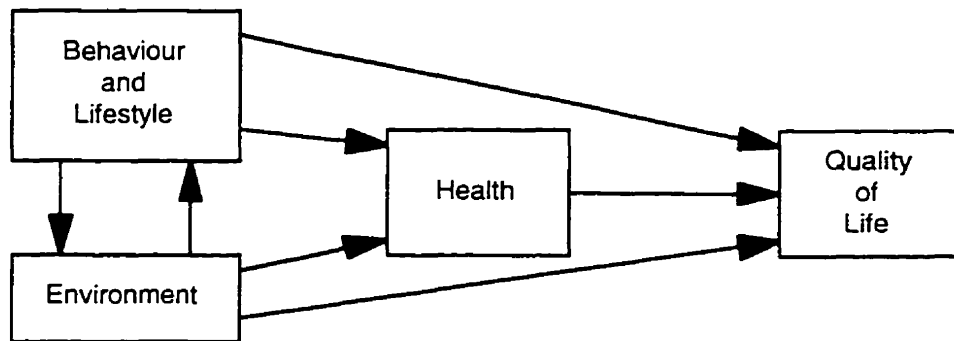


Figure 1. Direct and Indirect Effects of Environmental and Behavioural and Lifestyle Factors on Health and Quality of Life. Adapted from Green & Kreuter, 1991. *Health Promotion Planning: An Educational and Environmental Approach*. Mountain View: Mayfield Publishing Co.

Kickbusch, 1991). As mediated by the stress process, the former pathway is direct and the latter pathway is indirect. Social determinants of health are conceptualised as risk conditions (Graham, 1974). Deleterious aspects of lifestyle and behaviour are conceptualised as risk factors (Graham & Graham-Tomasi, 1985). The relationship between risk factors, risk conditions and health is confounded. The implication for practice is that multiple interventions targeting risk factors and risk conditions together, are necessary to address sickness associated with stress. Targeting improvements in risk factors alone can improve absolute health status for both high and low socio-economic groups (Bennett, 1995). Differentials in health will remain unchanged, however, unless risk conditions are also addressed.

Two conclusions may be derived when the complexity of the inter-relationship between health, risk factors and risk conditions is made explicit. The first conclusion is that health and illness are social as well as biological facts, for “there is no way to define a biological ‘norm’ or ‘deviations’ without reference to specific populations and their socio-cultural characteristics” (Mishler, 1981, p. 4). The tenet of the biomedical model that all disease can be fully explained by deviation from biological norms is, therefore, false.

René Dubos’s work with potentially pathogenic microbes established that their presence was necessary but not sufficient to cause disease. The total environment mediated the effect of pathogenic organisms, which could persist in a dormant state in the body for long periods, or rapidly cause disease. Dubos also established that under suitable conditions, even ubiquitous

nonpathogenic microbes can cause diseases (Dubos, 1959). By analogy, at the level of the individual, any abstraction of risk factors from their relation to risk conditions limits our capacity to understand health and sickness. Risk factors are necessary but not sufficient prerequisites for illness and disease. Risk conditions moderate the effect of risk factors on health and may under certain conditions influence health directly. This reasoning is aligned with the two pathways by which social factors can influence health: (a) the indirect effect on health of environmental conditions of living (risk conditions) through deleterious lifestyles and behaviours (risk factors); and (b) the direct effect of social environmental stressors (risk conditions) on individuals through stress reactions and stress consequences.

The second conclusion to follow from the complex confounding between health, risk factors and risk conditions is as follows. Implicit in most "objective" psychosociological attempts to account for and describe the influence of social environmental conditions in terms of their direct and indirect effects on health, is the abstraction of the individual from his or her place in society to a desocialised and amorphous environment (Young, 1980). The growing literature on the inverse relationship between socio-economic status and morbidity and mortality (Marmot *et al.*, 1991; Shekelle *et al.*, 1969) usually falls short of explaining the causal pathways by which the social processes of deprivation and inequalities influence health (Carney, 1992; Krieger & Fee, 1994; Moynihan, 1968; Runciman, 1972). Stressors and the risk conditions that influence people's vulnerability to sickness can be conceptualised as products of the conflicting social and group interests that characterise an individual's place in society (Corin, 1994). These are replaced by the professional by what Young (1980) calls "... a *zone of anxiety* within which the power to affect people's well-being is diffuse and subjective (hence the emphasis on 'psychological supports', 'coping mechanisms', [and] 'stressful life events'), and 'change' is constituted as a pathogenic environment-out-of-control" (p. 133, original emphasis).

Although the codification and measurement of notions such as stressful life events, social support, control and coping mechanisms explain the epidemiology of stress (Williams & House, 1991) and are helpful in considering its aetiology (Israel & Schurman, 1990), such phenomena are influenced essentially by how people perceive and appraise them. Perceptions are influenced by social and cultural concepts of meaning (Corin, 1994). Much of the literature on stress, including

models that might account for a relationship between stressful conditions of living, lifestyle, behaviour, and disease, is predicated on attempts to connect pathogenic events to pathological consequences (Elliot, 1995; Folkman & Lazarus, 1980; Pearlin *et al.*, 1981; Pearlin & Schooler, 1978; Veit & Ware, 1983). The way people perceive pathogenic events and pathological consequences distinguishes most stress research from other approaches to disease aetiology and epidemiology. This is because of the presumed role of cognitive appraisal in the identification of potential stressors and individual coping mechanisms in adaptational consequences.

Cognition precludes the prediction or appraisal of stress reactions and stress consequences without reference to the properties of the person concerned (Dooley & Catalano, 1991; Israel & Schurman, 1990; Lazarus & Folkman, 1984). Such reasoning is unnecessary in accounting for direct environmental effects on health, but most environmental effects are mediated by cognitive appraisal of the environmental stressor.

Determinants of stress (stressors) mediate emotional arousal, which occurs, according to Lazarus (1966, 1968), because an individual is *aware* of stressful stimuli. The individual *appraises* them as either (a) threatening, meaning that the individual *anticipates* harm, or (b) challenging, meaning that the individual *perceives* that his or her usual mode of being may be insufficient and the consequences of not adapting are serious. Lazarus (1968) cautions that cognitive appraisal is not necessarily synonymous with full awareness. It may be important, therefore, to distinguish stress from situations *involving* emotional arousal and those that *elicit* emotional arousal (Cassel, 1974). Selye (1975) believed that the term “psychogenic stress” should apply to instances involving emotional arousal. The literature on psychogenic stress supports the notion that stressors (exogenous inputs that predispose neuroendocrine reactions) are associated with conditions that elicit emotional arousal (Mason, 1975a; Mason, 1975b; Ursin, 1991).

The nature of a person’s emotional arousal (anxiety, fear, anger, depression, guilt, or shame) to a given situation is a function of how he or she appraises that situation. This appraisal includes the complex ways in which he or she perceives the locus of control of the events being experienced, the meaning of relevant past life events, and the consequences of adaptive reactions. These are in addition to “special personality attributes” that are distinct from cognitive processes (Lazarus, 1968). Reactions could be pre-cognitive but developmental in origin. In

some instances the individual will not be fully aware of actual or potential stressors, yet will nevertheless enter into a state of emotional arousal. This explains why cognitive appraisal cannot completely account for all instances of emotional arousal. Risk conditions inherent in the social environment may predispose or cause stress reactions and consequences without cognitive perception. These reactions and consequences, therefore, will be independent of consciously chosen lifestyle and behaviour.

Characteristics and forces of the social environment that cause or predispose emotional arousal without cognitive perception need to be distinguished from personal characteristics that influence cognitive appraisal. This is difficult when research abstracts the individual from his or her place in society. These abstractions are often transformed into what are uncritically considered to be "properties of the individual" insofar as they are measurable and relate to emotional arousal and the stress process. Such properties are, in terms of the framework in which they were measured, artefacts of the social environment as it relates directly to stress and health. The abstraction yields a further level of confounding between properties of the individual and social environmental factors in relation to the health consequences of stress (Figure 1). Why not acknowledge and attempt to assess directly the nature and impact on the stress process of social effects?

Psychosocial strategies aim to account for the social factors influencing people's health and their vulnerability to sickness. By extracting "personal" properties from social phenomena, however, non-ecological sociological analyses of stress (Lazarus & Folkman, 1984; Williams & House, 1991) are no more specific than purely biomedical analyses in accounting for the influence of social factors on stress and health. This frame of reference leads to conclusions such as "social support is distributed unequally," "people with lower incomes are vulnerable to psychological and physical damage," and "positive social bonds within the family and community and at the workplace are fundamental to high self-esteem and psychological well-being." Such generalisations are often juxtaposed with assertions that "prospects for the health of societies are determined by social, political and economic forces that shape this environment" and that "we need to understand these trends and their implications for health and well-being more thoroughly" (Badura & Kickbusch, 1991, p. 4).

The point is that a non-ecological frame of reference is inherently limited in connecting causes in the environment with effects in the individual. A greater understanding of the social, political and economic forces that influence stress and health cannot be achieved by treating social factors as the independent exposure variable that explains variation in people's vulnerability to sickness solely in terms of the properties or characteristics of the people concerned (Delzell, 1996). It is increasingly recognised that the confounded nature of the relationships among risk conditions, risk factors and health requires that risk factors be addressed in combination with risk conditions, and that integrated, ecologically-based practice strategies are necessary (Green *et al.*, 1996; Heller, 1990). Yet the causal pathways by which social environmental processes influence health through the stress process, remain to be given adequate attention.

In considering the broader issue of relations between risk factors and risk conditions in regard to the role of stress in health, the following assertions have been made:

- The relationship between risk factors, risk conditions and health is confounded;
- Health and illness are social as well as biological facts;
- Social factors (risk conditions) influence health indirectly by predisposing positive or negative patterns of lifestyle and behaviour (risk factors) that bear on health;
- Social factors influence health directly as environmental stressors (risk conditions) that cause stress reactions resulting in biological or psychological consequences;
- It is a false assumption that cognitive perception of stressors is a necessary prerequisite for emotional arousal and the manifestation of stress reactions;
- The abstraction of the individual from the context of society, and the transformation of all factors influencing emotional arousal and stress responses into personal attributes, causes personal and social environmental factors to be confounded in relation to the health consequences of stress; and
- The true impact of the social environment in relation to the stress process and its effects on health has not been widely considered.

These issues are addressed in the next section as they relate to theories explaining the relationships between diabetes, stress, behaviour and lifestyle, and social conditions.

Acculturative Stress and Diabetes — a Theoretical Basis

It is insufficient simply to assert that the social environment and lifestyle and behavioural factors are reciprocal in their relations with each other. It is also insufficient to say that both the social environment and lifestyle or behavioural factors each independently influence health. The two pathways that can be explained most easily lead (a) from the social environment to lifestyle and behaviour and then to health and (b) from lifestyle and behaviour to health. The direct pathway from the social environment to health must be explained.

Theories that adequately account for the effects of risk conditions together with risk factors in effects on health should do more than describe the causes as constructs such as “social support,” “coping mechanisms,” and “control.” These indirect influences of the social environment on health through lifestyle and behaviour must bring to bear theories to explain the direct effect of conditions of living that, though perhaps accepted as legitimate and *not* consciously appraised as threatening, nevertheless result in emotional arousal and stress reactions related to NIDDM (and other consequences of neuroendocrine stimulation). In recognising the shared importance of individual and environmental factors in relation to stress and NIDDM, relevant theories should by definition be “ecological” in their breadth (Saegert & Winkel, 1990).

The above statement on the value of ecological theories does not negate the importance of specific theories constrained to explaining more limited relationships between lifestyle or behavioural factors and health. By definition, however, a theory “is a set of interrelated constructs (variables), definitions, and propositions that presents a systematic view of phenomena by specifying relations among variables, with the purpose of explaining natural phenomena” (Kerlinger, 1979, p. 64). In contrast, a model is a systematically organised and tested collection of existing theories and constructs that explains relations among existing theories and variables as they relate to some application. Israel & Schurman (1990), for example, have modelled the stress process in relation to health education, but their model does not explain phenomena, and it is not considered here. Many theories purporting to explain the phenomenon of social environmental

stress in effects on health are specifications of an incomplete pathway defined by only by cognitive perception.

Grand Theories

The federal report “A New Perspective on the Health of Canadians” examined the interaction of each of four determinants with health: human biology, the environment, lifestyle and behavioural factors, and the health care system (Lalonde, 1974). None of these determinants are empirical entities, they are all theoretical constructs, or *systems*. Constructs or systems consist of series of related definitions and are the major units of theory; they form an inter-related body of propositions. The social environment can be conceptualised as separate from the physical environment and the health care system as a component of the social environment. This fits the hierarchical ordering posited by *Systems Theory* of biological, psychological and socio-cultural systems, each with its own resources, needs and limitations (Katz & Kahn, 1978). This hierarchy or set of overlapping concentric circles can be applied to clarify the nature of the interaction between these determinants of health (Green & Ottoson, 1994; Green *et al.*, 1996).

The relationships among biological, psychological and socio-cultural systems are dynamic and reciprocal, such that change at one level inevitably affects other levels. The limitation of *Systems Theory* in accounting for NIDDM as a function of acculturative stress is its emphasis on concepts such as status quo, homeostasis and equilibrium. The theory is adequate insofar as an individual’s *perception* of stress may be the result of — and a contributor to — stressors and changes within the family, community, or society as a whole (Israel & Schurman, 1990). It does not explain reactions that occur without the perception of stress, such as when people accept as “legitimate,” social arrangements they perceive at some level to be undesirable. In such instances people may not adjust their perceptions to reduce the tension or “dissonance” of inconsistent beliefs, because they are below the level of consciousness (Wicklund & Brehm, 1976). *Systems Theory* assumes that all systems are open and that change at one level is recognised and accounted for at other levels (Berrien, 1976). The presence of *systemic* stressors tied to social locations and social group experiences, distinct from *random* stressors that operate with equal

probability across all social groups (Aneshensel, 1992), suggests that limiting social arrangements yield stress not attenuated by re-adjustments at other levels of the system.

Though not theories *per se*, frameworks that embody an *ecological perspective* allow for the role of conditions of living in health and sickness through their interaction with lifestyle and behaviour. McLeroy *et al.* (1988) describe an ecological public health perspective conceptually similar to René Dubos's notion of a host-agent-environment complex as a complete ecosystem. This perspective relates a hierarchy of factors ranging from individual characteristics, primary social groups, and social institutions to local and national public policy, and incorporates these into a reciprocal ("transactional") causative relationship between individuals and their environment. Similarly, Germain (1991) emphasises continuous reciprocal exchanges (transactions) between people and their environments. Stressors are a function of adaptive exchanges. Through adaptation, social environmental stressors such as power, oppression and pollution threaten health and social well-being. Functional abilities and perceptions of being able to influence one's environment depend on concepts of self, self-esteem, self-direction, human relatedness and competence, as well as attachments and social affiliations.

In the context of an ecological perspective, Bronfenbrenner's (1979) *Theory of the Ecology of Human Development* (from developmental psychology) is not inconsistent with the notion of direct and indirect environmental stressors in effects on health. This theory posits that human development is a function of an expanding series of contexts that surround the individual in his or her immediate setting, and that relationships among the environment, social processes and behaviour determine development. Health and sickness may also be conceptualised as a function of the complexity of relationships among the environment, social processes, and behaviour, in which stress is an inherent element.

NIDDM as a function of the effect of stressors can be considered to be a consequence of complex, dynamic environmental conditions. The impact of social phenomena can be appraised not only in terms of the properties of individuals as such properties relate through cognition to behaviour and lifestyle, but also in terms of concepts of social norms, culture and lifestyle as such concepts relate to the interface of behaviour and environment (Toffler, 1980). Determinants of stress, then, may reflect not a "pathogenic environment-out-of-control," but a natural state of

constantly changing internal imbalances within the social system. This conception is aligned with homeostasis and equilibrium theories insofar as imbalances and re-adjustments between social groups do not necessitate a major shift in the status quo. Differences in health status, however, reflect systematic differences in the nature of stress experienced by individuals differentially situated within the social system (Turner *et al.*, 1995). Such stress, as a function of ongoing and difficult conditions of daily life in a constrained sub-system, suggests a tension inherent in the structure of society. NIDDM as a function of acculturation can be explored, therefore, through the contrast of two theories of social change: *Conflict Theory*, and *Functionalist Theory*.

Conflict Theory is predicated on Marxist and Weberian analyses (Parkin, 1979; Weber, 1947). These analyses share an emphasis on the competition of social groups to achieve their own interests. *Conflict Theory* emphasises fundamental inequalities, competition and imbalance as constant aspects of any system, resulting in continual adjustments (Dahrendorf, 1959). Impetus for change is usually attributed to internal explanations, with social change occurring when one of several interests in a system gains ascendancy over others. In contrast, *Functionalist Theory* is predicated on Durkheim's (1938) perspective on social organisation. It emphasises patterns and systems that maintain a system (Cancian, 1960; Parsons, 1951), but "... in a coercive, rather than consensual, sense ... [in that] ... those who control important parts of a system, especially the economic and political sectors, establish the social norms, and attempts to change norms are likely to be met by resistance to them" (Thompson & Kinne, 1990, p. 51). Impetus for change is usually attributed to extrasystemic factors. Talcott Parsons (1951), for example, applied functionalist perspectives to health and illness as primary factors in the maintenance of social equilibrium in his conceptualisation of the "sick role," which locates illness between the extremes of dysfunction and deviance (and therefore subject to societal sanctions).

Relating *Functionalist Theory* to NIDDM, the conceptualisation of social phenomena in terms of people's explicit perceptions of such phenomena as stressors, that is, as extrasystemic factors, accounts for the effect of environmental factors on lifestyle and behaviour, and the consequent effects of lifestyle and behaviour on health and sickness. Relating *Conflict Theory* to NIDDM, the conceptualisation of social phenomena as stressors implicit in the nature of social and cultural norms, that is, as intrasystemic factors, accounts for the direct effect of environmental

factors on people's health without the explicit perception of such phenomena as stressors.

Conflict Theory does not lead to the constitution of a "pathogenic environment-out-of-control." It acknowledges, in agreement with current perspectives on chaos theory and science (Reeves, 1993), that "... change is ubiquitous not only in time but also in space, that is to say, every part of societies [sic] is constantly changing ..." (Dahrendorf, 1968, p. 197).

That *Functionalist Theory* leads to the constitution of a "pathogenic environment-out-of-control" is not as contradictory as it might appear. The extrapolation enables the aetiology and epidemiology of stress reactions and consequences to be understood through exploration of lifestyle patterns and behaviours as they are consciously influenced by environmental stressors. An understanding of the stress process, however, requires the acknowledgement and exploration of existing, ostensibly accepted, social arrangements of living in relation to their effect on health through a stress pathway involving non-perceived emotional arousal.

The explication of stress in relation to NIDDM through theories of social change accounts for NIDDM as a direct and indirect function of stress reactions caused by social living conditions. The conceptualisation of the social system as an ecosystem encompassing multiple events and possibilities is analogous to René Dubos's concept of microbial ecosystems, in which stress either internal or external to a host determines the expression of disease. NIDDM among Aboriginal populations reflects the additive and multiplicative effects of random and systemic stressors. Random stressors are those that are not embedded in social situations or experiences over the life course. They are discriminated using epidemiological methods predicated on Functionalist Theory. Perceptions of extrasystemic factors as stressors are related indirectly through the properties of individuals to stress outcomes. Abstracting individuals from the social system, while useful, precludes consideration of the systemic stressors that accompany basic inequalities and imbalance in society. Conflict Theory enables consideration of the inherent stress experience of groups in a particular part of the social system. Systemic stressors are relevant to understanding the direct link between social conditions of living and NIDDM. Acknowledging systemic stress as contributing to NIDDM suggests that modification of the social environment in combination with individual-level interventions is required to reduce the direct and indirect effects of stress.

Having considered grand theories, the following section examines “process” or “middle-range” theories that specify processes of change in relation to stress and NIDDM. Such theories, however, explain only one causal pathway: from the environment to cognitive appraisal to lifestyle and behaviour, and then to health. Process theories do not account for a direct effect of environmental stressors on health. Given their reciprocal relationship, lifestyle and behavioural factors can influence the environment, which in turn may influence lifestyle and behaviour, with further, perhaps synergistic effects on health. Thus, in this case, the pathway leads from the environment to health by way of behaviour and lifestyle, granting a series of reciprocal exchanges between behaviour, lifestyle and the environment. Such theories are important tools for guiding the development of interventions targeting changes among individuals.

Process Theories

Albert Bandura’s concept of *Social Learning Theory* (Bandura, 1969, 1977, 1986) (also known as Social Cognitive Theory) provides three distinct pathways that can account for a relationship between cognitively-appraised environmental stressors, behaviour, and the manifestation of stress as NIDDM (Evans, 1989). All three pathways relate to the construct of *self-efficacy*, defined as a sense of self-belief in existing competencies and skills, the ability to put those skills to effective use and to develop further competencies and skills, in relation to perseverance, accomplishment, motivation and personal well-being (Bandura, 1977).

The first pathway involves perceived coping inefficacy, which increases vulnerability to stress and depression. Subjective stress is created through emotional reactions concerning perceptions of limited personal coping capabilities and perceptions of little ability to exercise control over one’s environment. Emotional arousal involves neuroendocrine responses resulting in NIDDM. Choice behaviour is affected, as thinking processes hinder instead of aid the ability to persevere in the face of obstacles, potentialities are not developed, and motivation is inhibited. In short, a reciprocal relation between cognition, behaviour and environment produces further behaviours and cognitive patterns that reinforce perceptions of coping inefficacy and patterns of physiological response such as NIDDM.

The second pathway is mediated by depression. A low sense of efficacy for developing and maintaining social relationships (control) that provide support systems and buffers (social support) against stressors results in greater vulnerability to depression. Stressors therefore are less likely to be buffered and more likely to provoke reactions involving emotional arousal and neuroendocrine responses leading to NIDDM. Perceptions of an inability to achieve levels of performance regarded as indices of self-worth are related to depression.

The last pathway involves central nervous system modulation of expectancy learning. In certain (potentially stressful) situations, self-expectations of coping efficacy can cause anticipatory neuroendocrine reactions. Over time, the specific situational context can start to effect emotional arousal and stress reactions, independent of stress caused by self-expectation. This pathway might appear to be independent of cognition and a thus direct function of the environment, but the impetus resides with the individual's self-expectation of coping efficacy, requiring cognition of stressors. Reciprocal exchanges between the individual and the environment produce stress reactions associated with but not caused by behaviour as expectancy learning occurs. According to this theory, NIDDM may develop as a consequence of expectancy learning.

Attribution Theory may also account for a relationship between cognitively-appraised environmental stressors, behaviour and the manifestation of stress as NIDDM (Michaela & Wood, 1986). In application it is similar to the concept of coping inefficacy. *Attribution Theory* posits that people are motivated to explain, interpret, and understand their personal environments (Perlman & Cozby, 1983). A search for causal attributions or reasons is thought to be motivated by an inherent desire to decrease ambiguity by rendering the social world predictable and controllable, and is related to the broader concept of personal or cognitive control (Pittman & D'Agostino, 1985). Thus when faced with stressful environmental circumstances people ask the question "Why me?" and then can attempt to explain or make a causal attribution with regard to such circumstances. Attribution processes may occur at conscious or unconscious levels (Weiner, 1985). The cognitive appraisal of a stressor, however, appears to be a necessary prerequisite for an attribution process, even if attributions occur below the level of consciousness.

Attributions are related to self-esteem, anxiety levels, hopelessness, depression, motivation and cognitive deficits (Abramson *et al.*, 1978; Weiner, 1985). Dimensions of

attributions include locus of causation (source of cause either within or external to a person), controllability (whether cause is controllable), stability (relative stability of cause) and globality (specificity of outcomes) (Lewis & Daltroy, 1990). As the theory applies to stress and NIDDM, any attributions involving some combination of external locus of causation, low degree of controllability, lack of stability and global outcomes, are likely to produce stress. These will be manifested as negative expectancies, lowered self-esteem, and either specific or global performance deficits, both motivational and cognitive. Subjective stress is created through emotional reactions to these attributions. Behaviour and lifestyle may change to conform to negative attributions, causing environmental feedback, reinforcing the stress process, and possibly predisposing the development of NIDDM.

Explicit in *Social Learning Theory* and implicit in *Attribution Theory* is the concept of *reciprocal determinism*, which posits that human behaviour can be explained in terms of a reciprocal interaction between cognitive, behavioural, and environmental determinants. Reciprocal determinism neither conceptualises people as powerless objects controlled by external environmental forces nor as free agents who may achieve and become whatever they wish. As people and their environments are reciprocal determinants of each other, the limits of self-direction co-exist with opportunities for influencing destiny.

The concept of reciprocal determinism has made important contributions to practice and theory. A limitation of the concept, however, in terms of NIDDM as a function of environmental stress at the level of the individual, is the presumed role of perception. The predication of stress reactions on cognitive appraisal suggests that individuals might be responsible for the stress or stressors they perceive, at least to the extent that they can act to influence their personal environments and thus improve their health. Yet the likelihood is low that such behaviour at the level of the individual can influence the social environment. Individuals have little control over the effects of social norms, cultural values, and economic factors as environmental determinants on health and health-influencing behaviours and lifestyles. There is also the fact that awareness is necessary for action at any level.

Given that not all stress reactions may be mediated by cognitive appraisal it is important, therefore, that stress and its consequences be considered in the context of the attributes of individuals *and* the society in which they live. This interpretation supports the idea of “collective efficacy,” by which people high in individual self-efficacy work together as a group to effect change at the level of the group, organisations, community and society. Targeting collective efficacy allows for blending individual and community-oriented practices. Community-based actions can provide options for consciously-chosen behaviour change, and environmental support for change mechanisms operating at or below the level of consciousness. Such actions may attenuate the impact of acculturation on health, by buffering stress and strengthening individual and collective capacities to modify and shape external environmental forces.

Theories to Explain and Predict Behavioural Change

This section reviews several social psychological theories relevant to interventions involving behavioural change. The emphasis is on evaluating the practicability of initiating and maintaining positive preventive and health promotive behaviours, such as physical activity and healthful dietary practices, to prevent and control diabetes. Social psychological explanations of behaviour covered here include the *Health Belief Model* (Becker, 1974; Rosenstock, 1974), the *Theory of Reasoned Action* (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975), and *Social Learning Theory* (Bandura, 1977, 1986).

The Health Belief Model

The Health Belief Model was developed to predict preventive behaviours at the level of the individual. As applied to changing or managing physical activity and dietary practices, the Health Belief Model posits that readiness to take action on a positive behavioural change stems in large part from the perceived threat of obesity, diabetes or other complications. This reflects a combination of beliefs about perceptions of susceptibility (familial and cultural risk, and of personal lifestyle factors) to diabetes and beliefs about its potential severity (morbidity and mortality or social and economic or emotional consequences). Any cue for action then forces the individual to consider behavioural changes, potential benefits in reducing susceptibility or severity of diabetes.

Such perceived benefits are then weighed against perceptions of any barriers or costs associated with the behaviour; these barriers might be physical, psychological, or financial.

People are more likely to engage in or increase their practice of a positive behaviour if they are aware of the health consequences of failing to engage in that behaviour and if they believe they are vulnerable to diabetes. In weighing potential benefits against the estimated difficulties of change, an individual might decide that the payoff is not worth the effort. This is where the need for reinforcing social cues to action becomes clear, if the model is to predict preventive behaviours in a population-based initiative. For example, diabetes patients' compliance with prescribed medications is positively associated with perceived benefit, internal and external motivations, emotional stability and supportive structure, and negatively associated with perceived barriers and negative social environment (Nagasawa *et al.*, 1990).

The Health Belief Model is most applicable to persons either at risk for or with established disease (Norman, 1986). This reflects its assumption that health is important to all when in fact health value orientation differs among individuals (Walsh & McPhee, 1992). Insofar as the Health Belief Model suggests behavioural change is unlikely unless individuals are convinced they are at risk, it supports a high-risk, rather than population-wide, approach to prevention.

The Theory of Reasoned Action

The Theory of Reasoned Action aims to make explicit the rational and social links between attitudes and behaviour, by describing the formulation of a behavioural intention as a crucial step toward action. It proposes that volitional behaviour derives from intention to engage in the behaviour. This intention, in turn, is a function of attitude towards the performance of a behaviour and subjective norms regarding the behaviour (Ajzen, 1988). The model assumes that behavioural intention is the intermediate determinant of an individual's behaviour (Carter, 1990). Attitude towards physical activity or healthful diet is a function of beliefs about the efficacy of physical activity and diet in preventing consequences such as diabetes, tempered by an evaluation of the importance of the perceived consequences of physical activity and particular dietary behaviour. Subjective norms are a function of expectation by significant others such as family, peers and health care professionals, weighted by motivations to conform to norms and the

expectations of others. These mediating links help to explain why people do not always behave in accordance with their expressed attitudes.

Though often people with positive attitudes engage in negative behaviours, sometimes people with negative attitudes can be manoeuvred into engaging in positive behaviours (Madden *et al.*, 1992). Thus the Theory of Reasoned Action supports a population-based initiative to the extent that negative attitudes towards physical activity and healthful diets can be exploited, insofar as social norms favourable to such behaviours can be created within a population. The Theory of Reasoned Action supports neither a population-based approach nor a high-risk approach to diabetes prevention and control unless one of two conditions exist: (a) social norms favouring physical activity and healthful diets prevail; or (b) such norms can be created in at least the immediate social environment (e.g., family or workplace). A major distinction between the Health Belief Model and the Theory of Reasoned Action is that the latter is almost entirely rational; the Theory of Reasoned Action does not account for emotional fear-arousal elements such as those associated with perceptions of susceptibility to NIDDM.

Social Learning Theory

Social Learning Theory can be applied to explain and predict behaviour with a greater emphasis on environmental and behavioural factors. Whereas the Health Belief Model and the Theory of Reasoned Action assume that a healthful lifestyle is essentially persons deciding on their behaviour, Social Learning Theory posits the concept of reciprocal determinism, whereby the behaviour of an individual is dynamic in relationships between environmental and personal constructs that influence each other simultaneously (Perry *et al.*, 1990). By conceptualising behaviour not as a one-way product of environment, Social Learning Theory thus is distinguished from operant conditioning theory. Behaviour can therefore be linked to lifestyle and contextualised within the social environment, providing a valuable theoretical basis for a programme designed to facilitate the cognitive, or self-regulatory, act of taking control of behaviour and environment. In this regard the concept of *self-efficacy* can be applied in three fundamental ways to the adoption of health promotive behaviours and prevention-oriented self-care activities such as physical activity and healthful diet (Evans, 1989).

First, perceived self-efficacy affects whether people in a population-based prevention initiative will even consider adopting healthful behaviours. People with a low sense of self-efficacy will either (a) not try at all to change or (b) try but quickly abandon their efforts if rapid successes are not forthcoming. The extent to which people will persevere in maintaining a preventive behaviour is predicated more on their level of perceived self-efficacy than on any degree of fear arousal. The second efficacy effect relates to the level of the benefits people perceive they derive from a "treatment," in this case, physical activity or healthful diet. Bandura (1986) provides evidence that perceived self-efficacy enhances change in adherence to exercise programmes. The third way in which self-efficacy affects health is in the maintenance of changed behaviours; it strengthens the durability of changes and reduces vulnerability to relapse.

The implication is that a population-based approach to the prevention of NIDDM through physical activity and healthful diet may be successful to the extent that a high emphasis is placed on promoting the belief that people have the capability to influence their lifestyle, rather than on trying to motivate by fear. It has long been suspected that the "tombstone" approach to health education is ineffective (Larimore, 1953). This viability of a population-based approach is undoubtedly influenced also by the initial level of perceived self-efficacy in a population; however, low perceived self-efficacy may be overcome by engaging the population in a "grass-roots up" approach emphasising participation (Green, 1986) and empowerment (Rappaport, 1984). Intervention strategies should therefore seek to promote and build on baseline self-efficacy, effectively by application of principles of participatory research, defined as "systematic enquiry, with the collaboration of those affected by the issue being studied, for the purposes of education and taking action or effecting social change" (Green L.W. *et al.*, 1995, p. 43).

Given that Social Learning Theory acknowledges reciprocal relationships among the environment, behaviour and cognition, it is the most holistic and perhaps the most realistic of the theories reviewed here. An analysis of its implications suggests that a population-based approach to the prevention of NIDDM is supported to the extent that intervention processes promote self-efficacy rather than fear as a means of facilitating positive behavioural changes (Bandura, 1982; Bandura & Schrenk, 1981). Social persuasion and other forms of influence have an important impact on personal efficacy (Allegrante *et al.*, 1993), and behavioural interaction between social,

personal and environmental factors among persons with insulin-dependent diabetes supports health belief and illness behaviour models of diabetic adjustment and control (Peyrot & McMurry, 1985). Given exposure to interventions developed collaboratively in a way that promotes capabilities and positive self-perception, Social Learning Theory predicts that positive behaviours will be learned through symbolic (verbal) and vicarious reinforcement, and that these will be executed when people believe that actions will be reinforced. The theory can be construed to predict that increased self-efficacy through involvement in a collaborative initiative will account for increases in healthful eating and in physical activity among those who participate actively.

Strategies for Environmental Change

The development of culturally relevant self-care, educational and control programmes for NIDDM requires that the community be enabled to change behaviours and the environment. The likelihood that a community will be able to approach and undergo beneficial environmental change has been reported to be dependent on the presence of three related factors: (a) a sense of community; (b) a shared vision; and (c) a positive culture (Allen & Allen, 1987). These elements are based on the study of factors most important in blocking solutions to problems prior to the introduction of a change initiative, and factors that contributed most to the solutions achieved where change initiatives were successful.

A sense of community is considered present when people feel as if they belong together and trust one another. Trust and mutual respect within a community has been hypothesized to increase the likelihood of goal realisation in health promotion programmes (Allen & Bellingham, 1994). *A shared vision* leads people to be enthusiastic about the goals of their community and about the general mechanisms used to achieve those goals. A shared vision is necessary to avoid having people working at cross-purposes, where there is little common agreement about what the community is trying to achieve. Perhaps more importantly, a shared vision can bring together people with divergent views in a commonly agreed upon and sustained effort; it gives people a chance to integrate their own personal goals and approaches with those of the community through participation in a programme or project. *A positive culture* is founded on the

belief that goals can be accomplished when people work together and creatively towards a common form of achievement.

Community Organisation

Towards enabling a community to initiate and maintain behavioural and environmental change, the concept of *community organisation* applies as the process by which community groups are helped to identify common problems and goals, to mobilise resources, and in other ways to develop and implement strategies for reaching the goals they have determined (Minkler, 1990). Implicit in this definition is the concept of *empowerment*. In essence, empowerment constitutes an enabling process by which people and communities take control of their lives and environment (Rappaport, 1984). Murray Ross (1955), one of the “fathers” of community organising, argued that community organisation could not be considered to have taken place unless competence or problem-solving ability was increased by the process.

Community competence refers to the ability of a community to engage in effective problem solving (Iscore, 1980). A competent community has been defined as “one in which the various component parts of the community are able to collaborate effectively on identifying the problems and needs of the community; can achieve a working consensus on goals and priorities; can agree on ways and means to implement the agreed upon goals; [and] can collaborate effectively in the required actions” (Cottrell, 1983, p. 403). All these abilities require that the community be organised. How a community becomes organised can be approached from different theoretical perspectives.

Earlier models of community considered them to be relatively complete, self-contained, and autonomous in terms of their connections to larger units of the social structure (Efrat, 1974). Although superseded by a contemporary social ecological perspective (Green *et al.*, 1996), the older human ecological system perspective (Choldin, 1985) is still useful for planning involving distinct communities, particularly those in rural areas. Attention is focused on population characteristics such as size, density, heterogeneity, the physical environment, the social organisation or structure of the community, and the technological forces impacting on it. The community's age structure, the degree of integration of subsets of the population, and the means

of communications are also appraised (Fellin, 1987). This approach provides a basis for blending with social systems perspectives that contextualise communities as reflecting the social problems and processes of the greater urban society (Reitzes, 1980).

The notion that communities change their structure and function as a result of social, political and economic developments is relevant to Canadian Aboriginal communities, surrounded by and interacting with Canadian society, and evidencing the impact of acculturation. A contemporary social ecological perspective integrates earlier concepts of community, and presents health as “a product of the interdependence between the individual and sub-systems of the ecosystem (e.g., family, community, culture, physical and social environment)” (Green *et al.*, 1996, pp. 271-272).

Models of Community Change

The perspective adopted on community influences what becomes viewed as the appropriate domains and functions of community organisation. Community organisation has been conceptualised and treated as a singular model of practice, but there is not any single unified model of community organisation. The best known of several classifications of alternative community change models is the typology of Rothman and Tropman (1987), which consists of three models of practice: locality development, social planning, and social action. Rothman and Tropman (1987) maintained that whichever the model applied, the organisational process can only be considered as such if (a) it is of a continuing nature and (b) the process includes staff (professionally trained or not) who are responsible for sustained action processes. This definition applies to participatory procedures relevant to planning and implementing community-based diabetes prevention and control initiatives.

Locality Development

Locality development presupposes that community change is best pursued through the broad participation of a wide spectrum of people at the community level, in goal determination and action (Rothman & Tropman, 1987). Its derivative is found in the literature as “community development.” The United Nations defines community development as “a process designed to create conditions

of economic and social progress for the whole community with its active participation and the fullest possible reliance on the community's initiative" (United Nations, 1955, p. 6). Themes emphasised in locality development include democratic procedures, voluntary co-operation, self-help, development of indigenous leadership, and educational objectives. It is a *process-oriented* model in that goals are oriented to system maintenance and enhancement. It targets the establishment of co-operative working relationships among groups in the community, creating self-maintaining community problem solving structures, stimulating wide interest and participation in community affairs, fostering collaborative attitudes and practices, and increasing indigenous leadership. These types of goals were characterised by Murray Ross as "community integration" and "community capacity" (Ross, 1955).

Social Planning

Social planning emphasises a technical process of problem-solving with regard to substantive social problems, such as mental and physical health, housing and recreation (Rothman & Tropman, 1987). Rational, deliberately planned, and controlled change has a central role in this model. Community change can vary from much to little, depending on how the problem presents and what organisational variables are present. The approach presupposes that change in a complex industrial environment requires expert planners, who use their technical abilities to skillfully guide complex change processes. Of central importance is the design of social plans and policies, and their implementation in effective and cost efficient ways. The concern is with establishing, arranging and delivering goods to people who need them. Building community capacity or fostering radical or fundamental change does not necessarily play a major part. Social planning is both a task-oriented and goal-oriented model, rather than a process or human development oriented model, in that the emphasis is on tasks and goals targeting the solution of substantive social problems.

Social Action

Social action presupposes a disadvantaged segment of a population that needs to be organised, perhaps in alliance with others, in order to make successful demands on the larger community for

increased resources or treatment more in accordance with social justice or democracy (Rothman & Tropman, 1987). It sometimes targets basic changes in major institutions or community practices. Social action often seeks redistribution of power, resources, or decision making in the community and in the basic policies of formal organisations (Alinsky, 1946). The social action approach can target both *process* and *task* goals. Task goals might require that the policies of formal organisations be modified to some extent; process goals might include building a constituency with the ability to acquire and exercise locally-based power and decision-making abilities.

Creating power can translate into the empowerment of individuals and communities, and improvements in self-esteem (Alinsky, 1969). For example, the involvement of a person in a community organising effort can translate into an improved sense of control (Cohen & Syme, 1985) as a result of increases in tangible and intangible resources available to them through their social network (Antonovsky, 1979). This increased sense of support and control can have positive health benefits. As a psychosocial factor, community involvement can improve personal confidence, individual coping capacity and life satisfaction (Leighton & Stone, 1974). Social participation has also been demonstrated to augment the immune function of an individual and decrease his or her likelihood of illness (Thomas *et al.*, 1985).

While the three models of community organisation are not mutually exclusive, organisational efforts generally exhibit a degree of central tendency that locates them within one of the categories. Given the need for autonomy and local control in relation to facilitating meaningful improvements in quality of life, a community-based intervention to counter diabetes in an Aboriginal population might most reasonably be aligned with the locality development model, at least in the context of a public health initiative.* Such an initiative might be aligned secondarily with the social planning model, to the degree that external facilitators could make use of technical abilities in pursuing research or other sources of funding enabling the development and evaluation of a public health intervention. At a fundamental level, however, the social planning model is not entirely consistent with Aboriginal concepts of autonomy and self-determination.

*It is quite conceivable that the social action model could provide an alternate basis for community action on specific or general health concerns, particularly when these concerns are identified and acted upon by the community, not external health professionals or researchers.

Implications for Prevention and Control

The foregoing has reviewed theories useful in conceptualising and explaining, essentially from a western perspective, the dimensions of diabetes in the Canadian Aboriginal population and the antecedents and ramifications of the problem. The inherent stress of acculturation, mediated through cognitive pathways at and below the level of consciousness by conditions that elicit emotional arousal, can be seen to have both direct and indirect effects on health and quality of life. The relegation of Aboriginal peoples to dependency on social, political and economic arrangements inconsistent with their traditional cultural values is posited here as the basis of acculturative stress, and is a fundamental antecedent, at least theoretically, of diabetes and other chronic diseases as well as a variety of social pathologies. This notion is aligned with René Dubos' theory of disease as a function of stress reactions in an ecosystem encompassing multiple events. The increase in diabetes among Aboriginal populations is not simply the deterministic result of inappropriate diet, physical inactivity or obesity at the level of individuals, for these may be stress reactions in an ecosystem defined by undesirable social, cultural, political and economic events, for which realistic alternatives are limited.

The implications for prevention and control are that attempts to change behaviour and lifestyle require concomitant efforts to modify the social environment in support of behavioural and lifestyle-related change at the level of populations. Furthermore, if oppressive circumstances and cultural alienation contribute to the development of disease, then attempts to prevent and control disease must involve an ecological frame of reference that draws on culture *per se* as a powerful factor for reducing dependency on external arrangements that legitimise and maintain the existing social order. Grand theories of social change suggest that opportunity for change can attenuate the direct and indirect effects of acculturative stress. Social Learning Theory and perspectives and models of community organisation support the empowering and immediate benefits of collaborative and participatory actions at the local level to achieve structural modification of the social environment. The concept of reciprocal determinism suggests that the cognitive, self-regulatory act of taking control of environment will promote healthful behaviour through positive changes in lifestyle and in self-perception. Consequent increases in individual

and collective efficacy can support the adoption and maintenance of further health promotive behaviours and self-care activities as well as environmental changes.

Attributions about the cultural and community-based foundations of healthful changes, and about the external, environmental causes of diabetes, can be channelled to support further actions reinforcing behavioural and environmental change. Attributions can therefore stimulate reinforcing cues to action necessary for promoting preventive behaviours in a population-based setting, assuming that there exists or can be created among the population an explicit awareness of risk for disease. Negative attitudes and attributions can be exploited to shift community norms to buffer, through culturally meaningful strategies, the external forces predisposing disease.

For all their relevance, western theoretical perspectives must nevertheless be linked to Aboriginal conceptions of health, illness and the disease *diabetes*, if they are to have utility in community-based diabetes prevention and control initiatives. Having applied theories to explain the relations among factors and groups of variables, the operations in the application of theory to diabetes prevention and control in an Aboriginal population remain to be identified. Aboriginal conceptions can provide the basis by which to translate and merge, in ways that are meaningful and relevant, the abstract, generalised elements framed by western theory and prior research on the real world nature of the problem. Theory and prior research cannot contribute to operationalising and specifying the means by which a programme is intended to produce its effects if attention is not directed towards understanding how Aboriginal people perceive chronic diseases associated with an increasing interaction with the larger Canadian culture. Attention must be directed, therefore, to the relationship between culture, health and sickness.

Linking Western Theory and Aboriginal Logic

Determinants of health include human biology, the environment, lifestyle and behavioural factors, and the health care system (Lalonde, 1974). Conceived this way, the health care system is in essence the institutionalised medical care system of the *professional* sector, distinct from the *folk* and *popular* sectors of health care (Kleinman, 1980). Most health maintenance and care is delivered, however, in the popular sector by sick individuals, their families, social networks and communities, and some health care is delivered in the folk sector by specialist, non-professional,

non-bureaucratic, quasi-legal and sometimes illegal modes of care (Chrisman & Kleinman, 1983). Individuals are free to pass through the three sectors, although as described in Chapter 2, the interaction of Aboriginal people with the professional sector can be less than effective due to differing cultural backgrounds, values and belief systems.

The holistic conceptualisation of health care as a cultural system encompassing all a society does to address its health care needs through the popular, folk and professional sectors, is predicated upon a distinction between *illness* and *disease* (Eisenberg, 1977). Whereas social, economic and environmental origins of health, illness, and illness behaviour are inextricably linked to culture, the concept of disease is linked to the paradigm of biomedical science, which is a component of western culture (Kleinman *et al.*, 1978). Based on the tenet that disease can be fully explained by deviation from biological norms, the biomedical model abstracts illness from social, cultural and institutional contexts, reducing illness to an independent entity (Mishler, 1981). Thus, in the context of Canadian culture and Aboriginal perspectives that do not fully accept the modern or “western” view of the world, *sickness* is a function of both illness and disease. As discussed in Chapter 2, it is clear that Aboriginal constructions of diabetes as an environmental and social phenomenon (Garro, 1995) are at odds with clinical perspectives concerned primarily with malfunctioning or maladaptive biological processes in an individual.

An attempt to link western theory and Aboriginal conceptions about diabetes requires understanding cultural notions of illness associated with the disease *diabetes*. Culture can be conceived in this regard as primarily an environmental, as opposed to behavioural, influence. This approach may be relevant even where the interface between Aboriginal culture and Canadian culture is difficult to define, since it is widely accepted that Aboriginal culture remains a significant part of the personal identity of Aboriginal people, even among those who would appear to have moved apart from their cultural traditions (May, 1986). The unit of analysis is not so much the individual and his or her behaviour or even the social environment, but the culture that guides behaviour and determines aspects of or reactions to the social environment. Recognising Aboriginal culture as an environmental influence allows for the development of a link between western explanatory and predictive theory, and Aboriginal logic influencing constructions of

diabetes. Towards developing this link, the following sections apply the concept of “Medical Rationality” to elucidate “equilibrium models” of cultural logic compatible with western theory.

Medical Rationality

Medical Rationality was described by Young (1979) as a socio-ecological framework concerned with how people evaluate, compare and choose practices intended to identify, ameliorate, cure, prevent, or cause sickness. Medical Rationality has similarities to the Theory of Reasoned Action and all value expectancy theories, including the Health Belief Model. Whereas these theories explain and predict at the level of the individual, Medical Rationality is a social-epidemiological framework upon which a broad assessment of culture in relation to health can be based. Medical Rationality draws attention to: (a) the social arrangements and forces that determine or predispose the use of different kinds of health practices; (b) the ecological, nutritional, and socio-economic factors that determine people's exposure to and vulnerability to sickness-inducing circumstances; and (c) the demographic patterns that are associated with the distribution of at-risk populations (Lieban, 1973; Wellin, 1977). By locating beliefs and practices within this framework, the following questions can be asked (Young, 1979): Why do people believe that particular behaviours or health practices produce their reputed effects? Given a range of possibilities, why do people engage in particular behaviours or practices rather than others?

The framework of Medical Rationality is shaped by a set of premises that derive from the philosophy of utilitarianism and is reflected by discourse on the nature of rational humankind and the universality of rationally-determined behaviour (Sahlins, 1976). As articulated by Young (1979), there are four premises. The first of these is that in every society each individual is capable of calculating his or her interests. That is, the individual is inclined to choose rationally from among what he or she perceives as alternatives, and to set priorities on different wants, for example, by placing self-preservation over physical pleasure. Second, although rational choice presupposes coherent beliefs about the world, there are notable differences among populations in the way objects and events are perceived and appraised, and these differences are determined by the particular cultures and experiences of populations. Third, material and environmental circumstances limit the kinds of alternatives from which people are able to choose. The fourth

premise is that even after a population's unique perceptions and circumstances are taken into account, there often remain some behaviours that do not appear to be the product of calculation.

As means to understanding how people evaluate and compare what they believe are their alternative courses of action, Medical Rationality can be applied to sort a population's medical or health beliefs into notions about: (a) pathogenic agents, whether purposive or nonpurposive; (b) internal or external events triggering onset of sickness, whether inside or outside a person's body; and (c) linkages between and among agents and events, whether related through narrative, image, or analogy (Young, 1979). It is then possible to explain the persistence of particular systems of belief by the way they are seen to explain events and by the way they take credit for observable outcomes. A notable example of this approach involved Ojibwa leaders and nurse educators in Ontario in an initiative to adjust the local cultural system of belief regarding diabetes in order to induce health and quality-of-life responses considered more beneficial to diabetics and their families (Hagey, 1984). The main vehicle for this undertaking was a narrative entitled *Nanabush and the Pale Stranger* (McLeod, 1982). As given by Hagey (1984, p. 265), the story tells of Nanabush, a legendary figure who represents the teacher in Ojibwa culture, and his first encounter with the personified character of Diabetes, the Pale Stranger. No one can lie to Nanabush, so what Diabetes tells Nanabush is taken to be the truth about himself:

I can't be passed around like a cold, measles, the pox or mumps. People, as I have said, invite me in. Some people belong to families who are vulnerable to my visits, though a good many people are not. But anyone who does not eat properly, who does not watch their health, is inviting me in to stay. But anyone who does have to put up with me can do so simply by taking the right medicine at the right time and eating and living in a good, healthy way. There are ways to learn how to handle me and people teach these ways. So you see I can be kept in place. McLeod (1982), cited in Hagey (1984)

Applying the framework of Medical Rationality, the narrative approach can be seen to embody the perspective that perceptions of daily life, including illness events, are constructed metaphorically. The Nanabush story was used to provide cultural solutions to problems identified by the Ojibwa regarding the development and control of diabetes, through the use of metaphoric relationships that provide an underlying rationality to the narrative in terms of Aboriginal logic (Hagey, 1984). That is, metaphors were used to illuminate beliefs relating to diabetes and to resolve conflicts between Ojibwa beliefs and those of western biomedicine for the regulation of

blood glucose and the prevention of complications due to hyperglycaemia. Positive reactions to the education programme suggest the utility of cultural logic as a basis for integrating western perspectives to resolve conflicting belief systems. Culturally rational metaphors can make health information understandable and useful, as well as meaningful and tolerable that which is normally feared and avoided (Hagey, 1984).

From an environmental perspective, the framework of Medical Rationality can be used to interpret the cultural determinants of health and reciprocal determinants of change in behaviour and environment. In the narrative-as-metaphor example, the rationality underlying reciprocal determinants of change in behaviour and environment derives from and appeals to the Aboriginal conception of sickness as a consequence of disharmony, lack of holism, or imbalance (Garro, 1987; Hagey, 1987; Isaacs, 1978; Lang, 1985). Health is perceived in many Native American cultures as a state in which the entire being — spirit, mind and body — is in balance (Jackson & Broussard, 1987). This conception of health applies not only to individuals, but to entire populations, where Aboriginal logic recognises a reciprocal relationship between the health of individuals and communities.

Hagey (1984) documented the perspective held by the Ojibwa that "... in the final analysis Indian people must assume responsibility for the imbalances that have upset their community, and this includes responsibility for imbalances in one's body ... [because] ... blaming ancestors, or white man or blaming at all has the effect of decreasing self control or your responsibility for yourself or your freedom to act on your own decision" (p. 269). Thus, the Nanabush story is culturally rational because it promotes internal control to buffer the potentially overpowering external force of diabetes and its predisposing conditions. Insofar as self-belief is the basis of individual and collective efficacy, Aboriginal beliefs about inner strength and its spiritual and cultural basis can be drawn upon and integrated with western theory involving self-efficacy and reciprocal determinism to promote positive behaviours and supportive environmental changes. The utility of western theory is likely to depend on the degree to which it is transparent through rational alignment with cultural logic.

Equilibrium Models

Among the world's cultures, the most widely used image or analogy of sickness is a disturbed equilibrium (Chrisman & Kleinman, 1983; Kleinman *et al.*, 1978; Young, 1979). Specific frameworks, or models, are often aligned with some form of religious system (Camazine, 1980). The state of equilibrium is modelled by some cultures in terms of static proportions (e.g., hot-cold balance in Hispanic-American folk medicine), dynamic relations between parts (e.g., Chinese medicine), exclusively internal relations (e.g., western biomedicine) and by others as internal equilibria reflecting cosmic relations (e.g., South Asian Ayurvedic medicine) (Chrisman & Kleinman, 1983). These explanatory systems are often contrasted on a polar continuum between "externalising" and "internalising" beliefs (Young, 1976). For example, sickness explanations involving witchcraft or ancestral spirits represent a highly externalising system, whereas western biomedicine represents a highly internalising system. Most equilibrium models are a combination of externalising and internalising explanations for sickness.

Among the Ojibwa, the understanding of being out of balance in terms of having or being susceptible to diabetes is illustrated metaphorically through contrast of Nanabush, representing internal control, with his opposite, the mythical Windigo, a less-than-human entity representing disharmony, greed, instinct without reason, and lack of spiritual strength. Diabetes is considered to be a Windigo disease, a potentially overpowering, external force (Hagey, 1984). Thus, an equilibrium model is implicit in the general balance framework of Ojibwa folk theory. Hagey (1984) noted that balance frameworks are compatible with the equilibrium emphasis of the scientific literature on the management of diabetes, where western perspectives embody mechanistic metaphors for restoring homeostasis through regulation of carbohydrate metabolism by adjusting insulin levels and restricting sugar intake. Thus, equilibrium models can be used as a basis for diabetes prevention and control among Aboriginal individuals and populations, through culturally rational and relevant exchanges integrating western perspectives.

Equilibrium models are useful for understanding and resolving situations where cultural conflicts occur in the prevention and management of diabetes (Kleinman *et al.*, 1978; Mail *et al.*, 1989). For example, non-Aboriginal health care providers may not understand a common cultural logic associated with folk therapies operating under balance frameworks. According to Hagey

(1987), this logic is virtually universal in human cognition and is the algebraic operation “two negatives resolve to a positive,” translated as a proposition for therapy into the form “a negative stimulus must be counteracted with an equally negative force in order to resolve to a positive situation.” Among almost every culture on earth, a prominent example of this kind of logic is the use of negative power to cancel a negative spell cast through evil witchcraft or sorcery.

Hagey (1987) provided a specific example of cultural conflict involving such a logic: the situation where an Aboriginal person is informed by a health care provider that “too much sugar is bad when your blood sugar is high.” In the dualistic western tradition, “too much sugar is bad” means “avoid taking too much sugar.” It has been shown among the Ojibwa (Hagey, 1984) and other Aboriginal groups (Jackson & Broussard, 1987), however, that a frequent response when blood sugar is high is to ingest a quantity of sugar, insofar as “two negatives make a positive.” Culturally, this is a logical, rational interpretation and response (Hagey, 1987). The result may be positive for some people, insofar as it is biologically plausible that glucose can stimulate the central nervous system, increase blood pressure, decrease fatigue, stimulate physical activity and thereby effect the uptake of glucose. The basis of such a response needs to be understood, however, in presenting alternative strategies for normalising blood glucose concentrations.

Beyond the clinical level, equilibrium models can be used to integrate and communicate to individuals and entire communities explanations accounting for a relationship between stress, acculturation and diabetes. Western theories of diabetes as a consequence of stress associated with inexorable external political, social, and economic forces, are not inconsistent with Aboriginal explanations of being out of balance with nature and having to live in an environment incompatible with cultural values. Aboriginal concepts of illness as a result of personal or collective disharmony related to cultural breakdown are not incompatible with western explanations of stress-related illness through exposure to adverse environmental stimuli and limited opportunity or resources for corrective adaptations to environmental changes. A balance framework might even make relevant and meaningful the western conception of stress reactions as ostensibly corrective sympathetic nervous system and pituitary adrenocortical responses to adverse external environmental stimuli. For example, physiological reactions could be framed in terms of the body’s attempt to move through a process from homeostasis to disruption to re-equilibrium.

To summarise, Aboriginal culture can be understood to influence health as the outcome of an interaction with the surrounding Canadian culture. The application of western theories and perspectives to diabetes prevention and control in Aboriginal populations requires some conception of how Aboriginal people perceive diabetes as a product of acculturation. Medical Rationality provides a broad socio-ecological framework by which culture can be assessed in relation to health and sickness, enabling particular systems of belief to be understood by the way they explain events. Drawing on beliefs about internal strength and its spiritual and cultural basis, and equilibrium models as explanatory platforms for integrating western theories of behavioural and environmental change, culturally rational and acceptable intervention strategies can be developed that incorporate scientific knowledge and state-of-the-art, evidence-based practices. This is important not only to resolve conflicts about the nature of the problem and appropriate intervention strategies, but to promote cultural integrity through a negotiated understanding of illness process and control. Cultural integrity is represented by Nanabush, the embodiment of internal strength, stable equilibrium, responsibility and the order and power of Aboriginal people. To ignore culture would, in effect, perpetuate the alternative Windigo extreme: external control, imbalance, lack of basis for unity and support, further subjugation and, of course, diabetes.

CHAPTER 4

METHODOLOGICAL ISSUES IN COMMUNITY-BASED RESEARCH

This chapter reviews methodological issues affecting the design, implementation and evaluation of community-based intervention studies. The issues reviewed are not necessarily inclusive of all that might arise in community-based research. Emphasis is placed on considerations relevant to the community-based diabetes prevention and control project that is the focus of this dissertation. The issues reviewed apply generally, however, to health promotion and disease prevention programmes targeted at entire populations with the aim of changing health outcomes and disease risk through behavioural and environmental intervention. The methodological paradigm adopted is that of applied research; it is concerned with the experimental evaluation of social interventions. Methodological rigour, especially internal validity, is held to be important for inferring causality.

The material compiled in this chapter is relevant because an exploration of the merits and limitations of procedures not common in epidemiology provides a context and justification for methodological and analytic decisions made in the design and analysis of the diabetes project reported here. The review builds on what is known and accepted in other disciplines through integration and synthesis, to derive a framework suitable for evaluating diabetes prevention and control in an applied field setting. It also provides a basis for the position taken here that the results of small community trials need to be framed in terms of methodological challenges and creative if unorthodox strategies to attenuate the impact of such challenges. A thorough review serves an important purpose as there is no single "best" way of designing, conducting and analysing a community trial. Rather, the pathway chosen should balance contextual realities with the need for scientifically sound information and appropriate techniques for obtaining such information. The position taken is that it is less informative to cite or describe in passing the use of particular strategies, particularly when they are obscure or derive from other disciplines, than to provide details on their background in relation to other options.

The material reviewed here draws on experimental and statistical theory, and spans the disciplines of epidemiology, psychology, education and sociology. The scope of the review is broad. Some topics are considered at a level of detail greater than might be typical for a dissertation. This reflects the need to bring together and integrate diverse perspectives and strategies for coping with the multiple threats to validity, messy data, limited control and other methodological challenges of community research. This sort of integration does not exist in textbook form. Texts serve a pedagogic purpose where knowledge is codified into discrete packages that can be summarised, taught, and appraised. In this process a canon of acceptable academic knowledge is assembled, legitimated and reproduced. The state of knowledge on evaluating community interventions has not reached this level. What is known is incomplete and provisional, and will be subject to continued challenges and reformulations.

Community-Based Intervention Studies

Community-based disease prevention studies can be described in terms of the following features (Salonen *et al.*, 1986): (a) the target populations are usually few in number and are geographically or administratively defined; (b) the intervention is directed at entire populations rather than solely at selected groups or individuals; (c) the intervention activities are carried out in the people's usual physical and social environment instead of special clinics; (d) the intervention is incorporated into the existing health services system and economic structure of the community; and (e) the intervention is based on community involvement and makes use of existing social networks. Specific strategies used often include community-wide organisation and activation (Bracht & Kingsbury, 1990; Rothman & Tropman, 1987), media campaigns (Flora & Cassady, 1990) and social marketing (Lefebvre, 1992). Such studies are distinct from clinic-based prevention efforts directed at high-risk individuals, even when such efforts take place in a community or other social setting (Graham-Clarke & Oldenburg, 1994; Hjermann *et al.*, 1981; Multiple Risk Factor Intervention Trial Research Group, 1982; Rose *et al.*, 1983).

Founded on the principles of participation (Green, 1986) and empowerment (Rappaport, 1984), many community-level initiatives employ a "grass-roots" or "bottom-up" approach to social change. There is a trend towards the application of participatory and collaborative approaches that

link researchers with community participants in planning, implementing and evaluating community-based research initiatives (Elden, 1983; Fetterman *et al.*, 1996; Green L.W. *et al.*, 1995). In this way existing community leadership and social networks are used to facilitate the transmission and uptake of extensive direct education for the general population. Simultaneously, social environmental changes (e.g., policy) are implemented to support behavioural interventions (Green & Kreuter, 1991).

Several large community-based cardiovascular disease prevention programmes have been undertaken in industrialised countries (Gyarfas, 1992; Nissinen & Puska, 1991). These initiatives include the North Karelia Project (Puska *et al.*, 1985), the National Research Programme "1A" Primary Prevention of Cardiovascular Disease in Switzerland (Gutzwiller *et al.*, 1985), the Stanford Three-Community Study (Farquhar *et al.*, 1977), the Stanford Five-City Project (Farquhar *et al.*, 1990; Fortman *et al.*, 1986), the Minnesota Heart Health Programme (Jacobs *et al.*, 1986; Luepker *et al.*, 1994) and the Pawtucket Heart Health Programme (Carleton *et al.*, 1995; Lefebvre *et al.*, 1987). Community-based approaches in family planning and immunisation campaigns predated the cardiovascular studies (Green & McAlister, 1984). They have also been applied to the prevention and control of a variety of other diseases and health problems (Bang *et al.*, 1990; COMMIT Research Group, 1995a; COMMIT Research Group, 1995b; Pentz *et al.*, 1989; Wagner *et al.*, 1991; Worden *et al.*, 1987). As discussed in the previous chapter, there are relatively few published reports on community-based diabetes prevention and control programmes; such projects have been smaller than the well-known cardiovascular disease prevention initiatives.

Overall, the results from large-scale intervention efforts have indicated only minor or modest gains attributable to the intervention programme. Though further progress in theoretical strategies and specific evaluation methodologies is required, the conduct of population-based interventions is nevertheless of considerable public health importance. Compelling reasons exist for undertaking community-based studies, even given their methodological limitations and difficulties (Farquhar, 1978). Carefully evaluated community intervention programmes form a link between basic laboratory and clinical research and the large scale application of public health programmes in society. Only by changing risk factor distributions at the population level, *not* by

concentrating on the upper percentages of the risk distribution, can morbidity and mortality be reduced for an entire population (Blackburn, 1983; Kottke *et al.*, 1985; Rose, 1982).

In a review of community intervention studies on cardiovascular risk factors, Gyarfás (1992) noted the important consequence of such studies in reducing uncertainty about the effectiveness of such actions, and in answering questions about the meaningful use of existing resources and other possible outcomes associated with these activities. Insofar as the experiences and results of community intervention studies have supported the notion that well conceived, comprehensive programmes can positively influence lifestyles and the risk factors and disease and mortality rates of entire populations, Gyarfás (1992) argued that major practical demonstration projects can be a powerful tool for encouraging collective social development.

Intervention Programmes As Social Experiments

Community-level interventions can be structured as experiments designed to test specific hypotheses. In this sense the term *experiment* pertains to some sort of direct manipulation of the situation by researchers who wish to infer causality about the effect of intervention components on a disease or health issue of concern. Experiments enable the presumed consequences of an intervention programme (i.e., a “treatment”) to be empirically assessed in terms of causality. A diabetes prevention programme, for example, could be evaluated in terms of the degree to which it could be considered to have caused, in a defined population, a reduction in the incidence of diabetes or in the prevalence of risk factors for diabetes. Experimental evaluation has been and still is considered to be the “gold standard” of evaluation research efforts (Boruch, 1996; Shortell & Richardson, 1978). In a text on programme evaluation strategies, Veney and Kaluzny (1984) state that “[u]nder the proper circumstances, an experimental study can provide an unequivocal answer to the ultimate evaluation question: [d]id the program make any difference?” (p. 175).

In its intent an experimental evaluation is similar to the goal of the randomised controlled trial first used in agriculture (Fisher, 1925, 1935) and education (McCall, 1923; Thorndike *et al.*, 1916), and later in the 1940s by Sir Austin Bradford Hill in the health field to provide quantitative information to evaluate the treatment of tuberculosis (Daniels & Hill, 1952). Emphasis is shifted in evaluation research from concern with efficacy under highly controlled and narrow conditions, to

effectiveness under real-world (and less controlled) field conditions. As is the case for many diagnostic and therapeutic technologies, health promotion and preventive activities do not always establish their efficacy before becoming operational. That the randomised controlled trial is the “gold standard” for evaluating clinical prevention activities is unequivocal. Nonetheless, the utility of the randomised controlled trial begins to break down as the level of analysis progresses from the individual to the population, and as the object of analysis shifts from biomedical conditions and clinical responses to epidemiological factors and health systems “treatments” or arrangements (Frenk, 1993). True experimental trials require random allocation to experimental and control groups, systematic manipulation of the experimental group, control over extraneous factors affecting both groups, and measurement of a specific outcome variable by which to compare groups. These conditions can be difficult or impossible to meet in field-based research.

Social experiments can be dichotomised on the basis of whether treatment groups were created by assigning participants to treatments in a random or nonrandom fashion. In a seminal paper on experiments in social settings, Campbell (1957) noted this distinction but did not at that time define alternative nomenclature for such designs. Later work by Campbell characterises *quasi-experiments* as involving non-random allocation of participants to treatment groups, and “*true*” *experiments* as involving random allocation of participants to treatment groups (Campbell & Stanley, 1963, 1966). Because community-based research involves entire communities as “treatment” and “control” groups, the “participants” are aggregates of nonrandomly assigned residents. Communities, not individuals, are the units assigned to treatment conditions.

Community-level intervention trials of a “true” experimental nature are sometimes undertaken, where entire communities are assigned randomly to treatment conditions (Freedman *et al.*, 1990; Green S.B. *et al.*, 1995; Simpson *et al.*, 1995; Wagner *et al.*, 1991). Known generally as cluster randomised trials, such projects are administratively and logistically complex, and require enormous commitments for funding, personnel and time (Peto *et al.*, 1993). In an era of fiscal restraint they are the exception, rather than the rule.

Many community-level interventions are quasi-experimental and involve only a small number of communities, for reasons that may have nothing to do with sampling or statistical theory. Political issues or social needs may provide the impetus for intervention, and financial

constraints may limit the number of communities that can be studied. A commitment to cluster randomised trials (e.g., Klar, 1995) tends to disregard these realities. Nevertheless, there is an on-going debate in the policy evaluation literature about the usefulness of evaluation designs involving small numbers of non-randomly assigned clusters. Lalonde and Maynard (1987), for example, argued that sampling and econometric techniques (Achen, 1986; Heckman & Robb, 1986; Muthén & Jöreskog, 1983) cannot adequately control for the effects of sample selection associated with using a non-randomly formed comparison group, and that all evaluations not based on random assignment must be viewed skeptically. This position reflects the potential for bias when the effect of a quasi-experimental intervention is confounded with differences between intact clusters of individuals; it also ignores the role that theory and logic may play when methodological purity is not feasible. Furthermore, the results of any one quasi-experiment may well be tenuous, yet consistent results across inherently similar studies will provide evidence of relative effectiveness (Cronbach *et al.*, 1980; Ziman, 1978).

Perhaps the most common design in evaluation research is a pre-test–post-test design, or some variation thereof, in which subjects are not randomly assigned to treatment and control groups (Weiss, 1972). Campbell and Stanley (1966) refer to this as the *nonequivalent control group design*, noting that "... the groups constitute naturally assembled collectives ... as similar as availability permits but not yet so similar that one can dispense with the pre-test ... [wherein] the assignment of [the intervention] is assumed to be random and under the experimenter's control" (p. 47). Taking this design as a prototype, Kenny (1975) defined quasi-experiments in terms of the following characteristics:

(a) An untreated group and a treated group; (b) pre-treatment and post-treatment measures; and (c) an explicit model that projects over time the difference between the untreated and treatment groups, given no treatment effect. The third requirement is a synthesis of the other two and is at the heart of quasi-experimentation. It is the concern with plausible, rival explanations of any hypothesized treatment effect In true experiments, where by definition assignment into treatment conditions is random, the rival explanation of the treatment causing a mean difference between the treatment and control group is sampling error, and a significance test is used to rule out that explanation. For most quasi-experiments both sampling error and biased selection into groups loom as plausible rival hypotheses. Given nonrandom assignment, the treated and untreated groups may differ even in the absence of any treatment effect. Time is brought into the design to *project* the amount of this difference between the treated and untreated groups. (p. 345, original emphasis)

It has long been known that causal inference about the effect of a treatment is more tenuous for quasi than for “true” experiments (Blalock, 1964). Selection bias is possible when subjects are non-randomly selected from the population of which they are intended to be representative, and the threat of allocation bias exists whenever individuals are assigned non-randomly to treatment conditions (Sheps & Birnbaum, 1992). Moreover, because quasi-experiments involve aggregates of individuals, both group-level and individual-level biases can influence estimates of treatment effects (Greenland, 1992). As bias is difficult to assess and may be impossible to control during analysis, its potential impact should be prevented wherever possible at the design stage, and appraised in relation to all inferences drawn.

Formal rules of evidence can be applied for inference about the effect of a social experiment. Discussed below are three conditions necessary for causal inference in field-based research. An appraisal of these three requirements leads to the specification of four distinct types of validity that apply to the evaluation of relationships in any experiment, whether quasi or “true.” Distinctions between quasi-experiments and “true” experiments are considered in relation to these four kinds of validity. Though accepted in the social sciences, these components of validity have not been codified in the same way in the health sciences, though similar concepts exist under different labels not directly concerned with social experiments.

Validity in Social Experiments

Experiments are a means to test causal hypotheses, and an understanding of the conditions required for causal inference is of fundamental importance in evaluation research. Cook and Campbell (1976) describe three such conditions. The first is *temporal antecedence*, which requires that a cause must precede an effect in time. Randomisation in a “true” experiment increases the probability that the treatment groups will be equivalent at the pre-test, in proportion to the number of units allocated, to the extent that post-test differences related to the treatment carry a high likelihood of having occurred after the introduction of the treatment. In a quasi-experiment, knowledge of pre- and post-test scores in groups exposed and not exposed to a treatment enables some measure of change in an outcome variable to be associated with the introduction of the treatment. Any differences between the groups at baseline can be controlled

statistically in the analysis of pre-to-post differences, but only if they have been explicitly measured.

The second condition required for causal inference is that the treatment must co-vary with the effect, as a treatment cannot be causal if it has no effect. Statistical criteria are applied to ascertain the degree to which any co-variation apparent between a presumed cause and effect might reflect sheer chance (random) variation. Convention dictates that the null hypothesis be rejected when the possibility of such error (α) is 5% (or 0.05, expressed as a probability). The validity of statistical conclusions is also influenced by the probability (β) of an erroneous decision to accept (or, more specifically, to *not* reject) the null hypothesis, which is a function of statistical power ($1 - \beta$). A further factor influencing the validity of statistical conclusions is the inappropriate use or misuse of statistical techniques and procedures. False conclusions about co-variation between a treatment and a presumed effect comprise the first distinct threat to validity (assuming temporal antecedence), and are cumulatively referred to as threats to *statistical conclusion validity* (Cook & Campbell, 1979).

The third condition necessary for causal inference is a lack of viable interpretations that could account for an ostensibly causal relationship between a treatment and an effect; that is, *internal validity*, the second threat to conclusions drawn from social experiments. Campbell and Stanley (1966) distinguish internal validity as “the basic minimum without which any experiment is uninterpretable ... the *sine qua non* ...” (p. 5). It is considered to exist when the researcher has made accurate conclusions about co-variation between variables (Campbell, 1969). Cook and Campbell (1976, 1979) define two categories of internal validity: (a) the extent to which the apparent effect of a treatment can be disentangled from correlated extraneous variables that might have caused the effect to be observed (i.e., confounding), this being a problem mostly with quasi-experiments; and (b) the extent to which isomorphism exists between an operational indicator and the concept it ostensibly measures, components of which include psychometric concepts of construct, predictive, content and face validities, as elaborated by others (Nunnally, 1978; Shortell & Richardson, 1978). In this sense internal validity involves ruling out alternative explanations of a presumed causal relationship between the treatment and the effect measured. Threats to internal validity must be ruled out as a condition for inferring causality.

Closely related to internal validity, but not a necessary condition for inferring causality, is *construct validity*.^{*} The third threat to the validity of the conclusions drawn from social experiments, construct validity concerns the measurement process or operations and the theoretical variables or constructs; it involves ruling out alternative interpretations of how a treatment and its presumed effect are referred to in *hypothetical* terms. Threats to construct validity are threats to the correct labelling of the cause and effect operations in abstract terms that may come either from formal theory or common linguistic usage (Cook & Campbell, 1976). Cook and Campbell (1979) stress the importance of "... a precise explication of constructs ... since it permits tailoring the manipulations and measures to whichever definitions emerge from the explication" (p. 65). Construct validity thus concerns the issue of generalising to other non-identical treatments ("construct validity of causes"), and of generalising from the outcome measures employed to other effects ("construct validity of effects"). In general, doubts about internal validity pertain to whether a causal relationship can be reasonably inferred, whereas doubts about construct validity pertain to how the cause and effect should be labelled.

The fourth threat to the validity of the conclusions drawn from experiments is *external validity*. Like construct validity, it is not a necessary condition for inferring causality. External validity concerns the extent to which causal relationships are robust in terms of their generalisability to and across populations of persons, settings and times. The demonstration of a causal relationship at one point in time, in one particular setting and in one particular sample, does not necessarily enable any inference with regard to the robustness of that relationship. Cook and Campbell (1979) note that any such generalisations might and eventually should be made on the basis of theory, and therefore could be reconceptualised as relating to "construct validities." Thus the validity of generalisations to other persons, settings and times may be conceptualised as a function of the validity of the theory involved, and the accuracy of the theory-relevant knowledge of the persons, settings, and future periods to which a researcher wanted to generalise.

Applying the conditions and validities discussed above, Cook and Campbell (1976) define a useful social experiment in terms of the extent to which it: (a) makes temporal antecedence clear; (b) is sensitive and powerful enough to demonstrate that a potential cause

^{*}This incarnation of the term, as applied to conclusions drawn from social experiments, has a more subtle meaning than the psychometric conception of isomorphic relations (Nunnally, 1978).

and effect could have co-varied; (c) rules out all extraneous variables that might alternatively explain the relationship between the cause and effect; (d) eliminates alternative hypotheses about the constructs involved in the relationship; and (e) enables the observed causal relationship to be generalised to and across other settings, populations and times. Whereas temporal antecedence, co-variation between treatment and effect (statistical conclusion validity) and accurate conclusions about co-variation (internal validity) are necessary conditions for causal inference, correct labelling of cause and effect operations (construct validity) and generalisability (external validity) are not. These last two validities, however, are basic to the relevance of causal paths elucidated by social experiments. The following section considers theory-based and analytic issues in relation to conditions for causality and the validity criteria presented thus far.

The Theoretical Model

Evaluating any social intervention is a complex and multi-faceted task (Shadish *et al.*, 1991). As the design of an intervention is usually based on some theory of programme action, it is important to make explicit the theoretical model specifying the key intervention components and the causal mechanisms by which they are intended to accomplish the programme objectives (Bracht, 1990). The theoretical model can serve as the basis for design, measurement and evaluation decisions; it can help to identify the shortcomings of an ineffective programme, and aid the interpretation of an effective programme (Green & Lewis, 1986).

On the advantages of theory in evaluation research, Bickman (1987) defined ten functions of an explicit theoretical model: (a) to contribute to scientific knowledge; (b) to assist policy-makers; (c) to enable discrimination between theory failures and programme failures; (d) to identify the problem and the target group; (e) to provide a description of programme implementation; (f) to uncover unintended effects; (g) to specify intervening variables; (h) to improve formative use of evaluation; (i) to clarify measurement issues; and (j) to improve consensus formation. Chen and Rossi (1983, 1987) discussed some of these functions in relation to how a strong theoretical model may attenuate problems of internal validity when randomised experiments cannot be undertaken.

The explicit modelling of programme processes, particularly causal pathways by which a treatment produces an effect, provides a conceptual framework by which evaluation research can be planned, implemented and evaluated. Against a theory-driven approach to programme evaluation Lipsey and Pollard (1987) contrasted "... atheoretical or 'black-box' evaluations [that] rely on simple input-output formulations which, at best, are crude and undifferentiated and, at worst, limit the evaluation to the program and its goals 'as given,' that is, as stipulated and operationalized by program personnel, with the consequence that important features may be overlooked" (p. 317). There are two kinds of theory relevant to applied social research (Chen & Rossi, 1980): (a) *treatment theory*, the change mechanism through which a treatment can have effects on the problem; and (b) *problem theory*, the natural or social causes of the problem itself. Treatment theory is generally more pertinent for quasi and "true" experimentation than for observational or correlational designs, which are most often concerned with describing the aetiology of problem situations (Lipsey, 1990).

The role of treatment theory is especially important for non-randomised interventions, insofar as quasi-experimentation is more a system of logic than a set of techniques (Trochim, 1986, 1989). The terms and grounds of such a logic depend fundamentally on the articulation of appropriate treatment theory. Despite the inherent limitations of quasi-experiments in contrast to "true" experiments, treatment theory can strengthen causal inference in cases where method and circumstance result in an inadequate demonstration of causal cues or the implausibility of rival explanations. Lipsey (1990) reviewed a variety of ways in which treatment theory can augment cues to causality and eliminate rival explanations, some of which were framed by Koepsell *et al.* (1992) in terms of evaluative design, data analysis and advancement of treatment effectiveness. These considerations are reviewed and expanded upon, drawing from a variety of further works.

Evaluative Design and Process

For any community-based health promotion and disease prevention programme, a specific theory of action should be constructed prior to the collection of research data, since the ease with which causal links can be hypothesized may affect the choice of outcome variables. A theoretical model links the treatment at one end with the outcome at the other end. The model should be derived

from existing theory and prior research. Making the model explicit in terms of how a programme will produce its targeted effects requires specifying key inputs and outputs, and the sequence connecting them. This approach opens up the “black box” of process evaluation, such that implementation becomes critical in assessing the validity of programme interventions (Palumbo & Oliverio, 1989). The failure to address how a programme is to be implemented poses threats to the validity of social experiments, as previously discussed. On this matter Trochim (1986) wrote that “a theory-driven approach to quasi-experimentation will be futile unless we can demonstrate that the program was in fact carried out or implemented as the theory intended” (p. 4).

To enable the development and implementation of intervention components, a rational pathway should link the mobilisation of community structures to initiatives that serve to motivate and assist individuals in activities related to achieving targeted behavioural changes (Koepsell *et al.*, 1992). Nested within a “large” theory such as Social Learning Theory (Bandura, 1977), “small” treatment theories (Lipsey, 1990) explain how grant funds, programme specifications, technical assistance and other inputs translate into actions that can achieve and disseminate intervention components. Thus is specified the *treatment model*. An “activated” community reaches individuals through intervention components that change norms and encourage healthful lifestyles. Methods and measures, both quantitative and qualitative, are selected to correspond to components of the treatment theory; data are gathered from community organisations to assess the nature of their collaboration and activities in intervention; political and economic structures are surveyed to establish environmental change; and surveys of individuals provide data on exposure to interventions, norms, and behaviours (Cook & Reichardt, 1979; Jick, 1979).

Insofar as traditional quantitative approaches are not entirely suited to measuring key aspects of group interaction influencing implementation processes, qualitative methods may be highly appropriate for monitoring both the manner and the extent of programme implementation (Mullen *et al.*, 1986; Patton, 1990). Indeed, predicated on an explicit treatment model, there may be no recourse but to qualitative methods to answer questions concerning an apparent lack of quantifiable effect of a programme. In this instance, a qualitative process evaluation could answer crucial questions concerning, for example: (a) the effectiveness of implementation; (b) whether a programme could not be fully implemented for some individuals, where compliance was variable;

and (c) whether there was no effect because of barriers to programme access (McKinlay, 1996). Even where beneficial effects are observed, qualitative methods can assist in conjunction with quantitative techniques to answer questions about programme effects in relation to the receptivity of selected individuals or sub-groups, or other competing, uncontrolled interventions.

Treatment Theory and Data Analysis

As a specification of “small” treatment theories nested within “large” or “middle-range” process theories of social change, the treatment model is in essence an analytic model (Thompson & Kinne, 1990). An analytic model specifies independent, mediating, and dependent variables as well as causal pathways (Koepsell *et al.*, 1992). Assuming that a treatment can be considered to have affected the outcome, a quantitative process analysis based on an *a priori* specification of the treatment model allows researchers to examine the treatment effects as well as to build and test a theory regarding the more general causal mechanisms responsible for the outcome behaviour. Given a theoretical causal model for the outcome behaviour, the results of the research can be generalised more easily to other settings, populations and treatments. Further, if the process is known, then the variables are known that have a direct impact on the outcome of interest and, with such knowledge, more efficient treatments can be designed. Judd and Kenny (1981), for example, used multivariate statistical techniques to analyse a treatment model specifying the process mediating the effects of the Stanford Heart Disease Prevention Project. Such methods have been used primarily in the social sciences (Cole *et al.*, 1993; Kenny & Zautra, 1995; Wolinsky, 1978), and only infrequently in medical (Jeyaseelan & Rao, 1995; Karlin, 1987) and public health research (Cobas *et al.*, 1996).

Farquhar (1978) described several ways to strengthen causal inference for quasi-experiments through supplementary analyses including: (a) dose-response analysis (e.g., co-variation between educational input and knowledge gained); (b) network analysis (e.g., to trace the path of communications within a community); (c) path analysis (for causal modeling of complex systems involving two or more regression equations); (d) time series or trend analyses (for repeated measures over time); (e) ancillary event monitoring (using periodic small sample surveys and network analysis, to improve internal validity by incorporating inadvertent events into formal

path analyses); (f) tracing inputs through markers (e.g., to aid causal inference by tracing a marker in an educational message delivered via one medium to distinguish its effect from that of analogous content delivered through different media); (g) lagging of inputs (e.g., lagging intervention campaigns for a community to control secular trend effects); and (h) analysis of unobtrusive measures (at the level of either the community or the individual).

Lipsey (1990) suggested that the chronic problem of low levels of statistical power in community-based interventions might be attenuated if treatment theory were directed towards selecting valid, sensitive outcome measures that more precisely reflect the true effect size associated with effective treatments. Even sensitive outcome measures, however, may fail to demonstrate more than a small-sized treatment effect (Fishbein, 1996). If a small-sized effect is meaningful, and indeed it may be (Rose, 1992), then it is necessary that the measures reflect not only the treatment theory upon which a study is based, but that sufficient numbers of individuals required to detect a small effect are actually sampled.

Advancement of Treatment Effectiveness

Summative evaluations of the effects of community-based intervention programmes are often mixed (Nissinen & Puska, 1991), controversial (Salonen, 1987; Salonen *et al.*, 1986), or negative (Yeaton, 1990), and it may be the case that many indeterminate results are never reported in the literature. Just as a negative result from a well-designed experimental trial can generate important information, however, a well-specified treatment theory may enable the clarification of positive or negative results in a community-based intervention (Koepsell *et al.*, 1992). Treatment theory can also enable the differentiation of faulty treatment methods from faulty evaluation methods or the inadequate implementation of interventions (Lipsey, 1990).

Many community-based prevention programmes are similar, and evaluations based on a specific treatment theory should advance the field by applying details of effective concepts and by avoiding previous mistakes (Koepsell *et al.*, 1992). Campbell (1987) noted that from the perspective of abstract analytic-theoretical science a “treatment” is often a complex package reflecting expert clinical judgement, not the proven efficacy of its theoretically pure components (i.e., main effects plus interactions), and that an evaluation of a complex treatment as valid

provides the basis for further studies, both clinically and theoretically guided, which in turn use more complex treatment packages.

Maintaining that there exists a complex social system of diagnosis and delivery in the context of preventive interventions, Campbell (1987) argued against testing only “theoretically pure variables in isolation or in experimentally controlled higher-order interaction” (p. 416). Campbell (1987) noted further that “we applied social scientists need not only randomized experiments and quasi experiments, but also case studies, ethnography, participant observation, gossip collection from informants, hermeneutics, and so on ... ideally [to be] used as a supplement to experimentation, but if need be they may be used alone ... *not* because the social sciences seek a different kind of validity than do other sciences, but rather because *to stay with our problems*, we must use techniques which, while improving the validity of our research, nonetheless provide less clarity of causal inference than would a retreat to narrowly specified variables under laboratory control” (p. 417, original emphasis). Conceding the uncertainty of the context and the need for adaptability, Campbell (1987) reiterated that the critical tools of “threats to validity” and “plausible rival hypotheses” are still central to causal inference.

The literature reviewed thus far on validity in social experiments and the theoretical model guiding the design, analysis and impact of the results observed, is of primary relevance to planning a community-based diabetes prevention and control programme. It was asserted that methodological rigour is central to causal inference. When randomisation procedures are neither possible nor feasible, quasi-experiments based on strong, well-defined treatment theory may (a) identify and attenuate if not actually negate various threats to internal validity, (b) improve statistical conclusion validity by specifying statistical techniques and interpretations informed by theory, and (c) improve construct validity through the use of strong, sensitive and relevant measures. If such a logic supports with confidence the conclusion that a presumably causal treatment and its effect were properly measured and identified, and that extraneous influences were sufficiently controlled, then conclusions about the treatment and its effect may be generalised to other people, settings and times as a function of the theory involved.

Design Considerations

When designing a field experiment, one has some degree of control over the treatment structure and design structure. Consideration of these features of a design assists in selecting and carrying out appropriate analyses of effects. Milliken and Johnson (1992) define the *treatment structure* of an experimental design as the treatment, the treatment combinations, or populations that one has selected to study or compare by measuring their effect on given response variables. They define the *design structure* of an experimental design as the manner by which the experimental units are grouped into homogeneous groups or blocks to make as uniform as possible the conditions under which the treatments are observed. If the experimental units are very homogeneous, then there need be only one block of observations, in which case the design structure is equivalent to the treatment structure (e.g., a completely randomised experiment).

Having selected a treatment structure and a design structure, the preferred procedure, resulting in a “true” experiment, is to assign randomly (randomise) the treatments of the treatment structure to the experimental units in the design structure (Holland, 1986). This ensures independence among the units of analysis, which is required for valid results under most analytic procedures. Fisher (1935) put this concisely when he described randomisation as “the reasoned basis for inference.” As discussed, nonrandomised experiments do not preclude the possibility of inference, though controlled social experiments involving the assignment of treatments to entire communities should theoretically contrast a group of intervention communities with a group of comparison communities (Sherwin, 1978). The effect of a social intervention, however, is usually measured not at the level of the community, but in terms of individual-level behavioural or physical changes. Moreover, it is usually the case that only a small number of communities may be involved in a social experiment, thus limiting the efficiency of a community-level contrast.

Unit of Analysis — Group versus Individual

Statistical conclusion validity is compromised when the unit of analysis is taken to be the individual, rather than an aggregate of individuals exhibiting some degree of “relatedness” (Kenny & Judd, 1986; Scariano & Davenport, 1987). The criterion of independence dictates that the unit of analysis should correspond to the unit of assignment. If there are t treatments and t

experimental units, an experiment can be conducted and the mean of each treatment can be estimated from the data. Theoretically, an estimate of the error variance cannot be obtained, unless some or all of the treatments are replicated (Bretthorst, 1993). The replication of treatment combinations is necessary to be able to have an independent estimate of the error variance (Milliken & Johnson, 1989). Two independent measures of one person's fasting glucose concentration do not provide a measure of the true variation in the fasting glucose concentrations of different people, and measures of multiple individuals within a few discrete social units do not provide a measure of the true variation in the fasting glucose concentrations of the population of people. Therefore, a diabetes prevention project involving one intervention community and one comparison community is in essence a non-replicated experiment for which the variation measured by sub-samples of individuals is an index of within-community variation and not community-to-community variation (Milliken & Johnson, 1989).

The essential issue is that the observations from individuals within intact social groups cannot be considered independent; they will be "clustered" (positively correlated), reflecting common experiences or conditions, selection factors, or both. Kish (1965) introduced this concept as the "design effect" in the context of survey research. The design effect represents sources of non-independence as sources of variance. It is the ratio of the variance of the estimate under the actual design used to produce the estimate to the variance of the estimate assuming the same data to have come from a simple random sample. Insofar as members of a sample from the same cluster (e.g., community, classroom, etc.) tend to be more alike than the population as a whole, members of a sample from the same cluster tend to provide less information about the population than do members from different clusters. Thus, the design effect usually increases the variance of survey estimates of population parameters. For multi-stage cluster samples the design effect will usually exceed 1.0, sometimes substantially, while for simple or stratified random samples the design effect will be close to or slightly less than 1.0 (Kish, 1965).

Lindquist (1940) may have been the first to recognise the general problem of non-independence of error when cluster sampling is used with the unit of analysis taken to be the individual. He suggested using cluster means as the appropriate level of analysis, but met with resistance from McNemar (1940), who took exception to a significance test that did not involve the

variation of the units (individuals) on which the means were based. Notwithstanding an understanding of the issue among survey researchers, knowledge of non-independence associated with clustering in interventions remained confined primarily to educational and psychological research until Addleman (1970) published a report on clustering in experimental trials. Though slow to be recognised in the public health research community, within ten years of Addleman's report several authors had elaborated on the need for care in the analysis of clustered data in intervention research (Burstein *et al.*, 1980; Cornfield, 1978; Donner *et al.*, 1981).

The impact of failing to account in analyses for non-independence due to clustering is as follows. Given differentiated social units to which treatments are assigned, if the data are naively analysed as if individuals had been randomised at the design stage, then the standard error and confidence interval for the estimated intervention effect will be underestimated and the Type I error rate will be inflated. This occurs because the variance of the individuals observed does not include the extra variance attributable to the assignment units (Addleman, 1970). Inherent differences among social groups assigned to different treatment conditions will always add extra variation to the treatment means in tests of effects (Zucker, 1990). The proper analysis of a community-based trial must therefore include all sources of variance dictated by the design, including that from groups, in estimating variances of effect estimates.

Non-independence due to some specifiable source can often be evaluated by examining the "intra-class correlation" among measures within groups (Bland & Altman, 1990; Shrout & Fleiss, 1979). Intra-class correlation is a function of the similarity of individuals within groups, relative to the similarity between groups. Thus, the extra variation attributable to the assignment units in a community-based trial will be approximated by a positive intra-class correlation coefficient (ICC) indexing the clustering of the individuals within social units. Donner *et al.* (1981) described this phenomenon in terms of an inflation factor analogous to the design effect because it can be expressed as a multiplier of the usual variance estimate. In general, the effect of clustering depends on both the cluster size and the intra-class correlation (Wolter, 1985). For continuous variables the ICC (ρ) is the ratio of between cluster variability to total variability, given by

$$\rho = \frac{\sigma_c^2}{\sigma_c^2 + \sigma^2} ,$$

where σ_c^2 is the community-level or between-cluster variance component and σ^2 is the individual-level or within-cluster variance component (Winer, 1971, p. 244).

Strategies for Analysis of Clustered Data

A variety of techniques have evolved to take clustering into account in analyses, most of which assume the randomisation of more than a few clusters to each treatment condition (Donner & Klar, 1994). These techniques are not used widely in practice because of their greater expense and an apparent lack of understanding about the effects of clustering. A recent review of cluster randomised primary prevention trials between 1990 and 1993 found that less than 60% of studies took clustering into account in analyses (Simpson *et al.*, 1995). An earlier survey of cluster randomised non-therapeutic intervention trials between 1979 and 1989 found that 50% took account of the effect of clustering in analyses (Donner *et al.*, 1990). In addition, a review of eight school-based drug-use prevention trials found that only two (25%) used procedures enabling an adjustment for clustering in analyses (Ennett *et al.*, 1994). Simpson *et al.* (1995) suggested that among quasi-experiments, the proportion of studies that appropriately analyse clustered data is probably even lower than for cluster randomised trials. Systematic reviews of quasi-experimental trials have not been undertaken, however.

Of studies that adjust for clustering, three procedures are used most often. These involve using the cluster as the unit of analysis, nested mixed effects analyses, and the fixed effect statistical adjustment. Each of these approaches is reviewed below.

Cluster as unit of analysis. Using this strategy, the outcome variable is a summary statistic for all individuals in each cluster (Abdeljaber *et al.*, 1991; Williams *et al.*, 1981). This is a traditional approach with a long history of use, often in educational research in classroom settings (Lindquist, 1953). Tests based on clusters as the unit of assignment will yield Type I error rates at the nominal level because the variance of the assignment units includes the extra variation (Hopkins, 1982). Unfortunately, the variance of the assignment units carries few degrees of freedom for the error term because the estimation of the component of variance caused by the assignment units is based on the far fewer number of units assigned to each condition than on the individuals observed in each unit (Murray *et al.*, 1994b). For a small number of communities, analyses based

on the unit of assignment carry little likelihood of being able to reject the null hypothesis of no treatment effect. A further disadvantage of clusters as the unit of analysis is that under classical procedures direct adjustment for individual-level covariates is not possible, although two-stage analyses of least squares cluster means adjusted for individual-level covariates have been conducted to circumvent this problem (Dwyer *et al.*, 1989; Murray *et al.*, 1994a).

It has been estimated that if communities are to be randomly allocated and analysed as clusters, the number of communities needed in order to draw conclusions with a reasonable degree of statistical power is at least 16 (Sherwin, 1978). Although standard statistical methods are used most often to compare cluster responses between different interventions, controlling for community-level baseline risk factors such as size or location, other methods do exist. Most notable of these alternative methods are randomisation, or permutation tests (Dawid, 1988; Edgington, 1987; Noreen, 1989). The Community Intervention Trial for Smoking Cessation (Green S.B. *et al.*, 1995), for example, used non-parametric permutation tests for analyses of specific outcome variables for 11 matched pairs of communities. For a given outcome variable, the mean of the 11 pairwise differences between intervention and comparison communities was calculated for each of the 2^{11} (= 2048) equally likely ways that intervention assignments could have occurred during randomisation. The rank of the observed mean among all 2048 possible means provided the significance level. Although such tests provide a valid method to test for programme effects with a minimum of statistical assumptions, they also carry the disadvantage of never being able to reject the null hypothesis if the number of communities studied is small.

Nested mixed effects analysis. The second strategy to take account of clustering uses the individual as the unit of analysis, where each individual appears in only one community and each community appears in only one treatment condition (Gomel *et al.*, 1993; Koepsell *et al.*, 1991). Nested mixed effects analyses are part of a general class sometimes referred to as hierarchical (Bryk & Raudenbush, 1992), multi-level (Goldstein, 1995), or random coefficient (Longford, 1993) models. This classification applies to all experimental situations for which there exists a hierarchy consisting of units grouped (and sampled) at different levels. Given at least two community units per treatment condition, and provided that the community factor is specified as a random effect (with the treatment factor in which communities are nested specified as a fixed

effect), nested analyses offer a viable strategy to reconcile and generalise many “unit of analysis” issues that have become recognised in the literature on evaluations of social experiments (Salonen *et al.*, 1986; Whiting-O’Keefe & Simborg, 1984; Williams *et al.*, 1981).

Fixed Effect Statistical Adjustment. The third approach is to estimate the design effect and use it to adjust standard errors, summary statistics and significance values from standard analyses that treat all classification variables as fixed effects (Bell *et al.*, 1993; Lando *et al.*, 1990; Payment *et al.*, 1991). This technique is of the greatest utility for non-replicated experiments involving one cluster per treatment condition, where one cannot calculate an independent, internal estimate of the inflation of variance associated with the correlation of individuals within each community. If the analysis is based on any of the general linear model methods (e.g., a fixed effects analysis of treatment conditions in which communities are nested), then the treatment effect estimates themselves will be unbiased and will need no adjustment (Carroll, 1989). Assessing treatment effects against the individual-level error variance will cause the resulting test statistics to be biased, however, because the error variance should reflect both individual- and group-level variability. External estimates of the intra-class correlation can be used to calculate the design effect and to correct test statistics when a fixed effects analyses is the only analytic approach possible. Correcting fixed effects analyses for the design effect takes clustered samples into account whether nesting is specified or not. Nested models do not automatically account for the correlated error for which the design effects adjusts (Dielman, 1994).

A question that arises is whether the effect of clustering must always be accounted for, or if in some instances it can be safely disregarded by treating the sampled data as the population of interest. This is a controversial issue that needs to be framed in terms of a broader methodological and philosophical debate. A general sufficient condition for ignoring clustering in an analysis is when the distribution of the outcome variable for given levels of the independent variable and covariates does not depend on which cluster an individual is in (Korn & Graubard, 1991). It may not be obvious whether this condition is satisfied for cluster-type surveys involving simple random selection, and there is little chance it will be satisfied for social experiments with small numbers of communities, randomised or not, since there are likely to be a variety of cluster-by-intervention interactions. Further, many distinctions are likely to exist among individuals across communities

and, while some of these may be known and measurable, many others will be unknown and unmeasured (Judd & Kenny, 1981a). Even if the forces that predispose individuals to establish themselves in different communities could be considered to act effectively at random, once groupings are established they will tend to become differentiated, and this differentiation implies that the group and its members influence and are influenced by group membership (Goldstein, 1995). To ignore this relationship is to risk rendering invalid any analyses of treatment effects.

Analytic Efficiency and Studies Involving Few Social Units

Classical survey analysts recommend accounting for clustering in analyses of multi-level data (Hansen *et al.*, 1983; Kish & Frankel, 1974; Lee *et al.*, 1989). All such procedures are fundamentally conservative, however, and if performed unnecessarily will result in an inefficient analysis, and an excess of Type II errors (Korn & Graubard, 1991). The approximate inefficiency in doing an analysis that accounts for clustering when unnecessary, based on the cluster as the unit of analysis, is (Cornfield, 1978):

$$\text{Inefficiency} = 1 - \left\{ \frac{z^{1-\alpha/2}}{t_d^{1-\alpha/2}} \right\}^2$$

where $z^{1-\alpha/2}$ and $t_d^{1-\alpha/2}$ are the $1 - \alpha/2$ percentiles, respectively, of a normal distribution and a t -distribution with d degrees of freedom, and α is the significance level for testing, or one minus the confidence level for confidence intervals. For example, if $\alpha = 0.05$ for a trial of $d = 40$ social units, any standard set of statistical tables gives $z^{0.975} = 1.96$ and $t_{40}^{0.975} = 2.02$. The inefficiency equals 5.8%, which is so small that accounting for clustering imposes little penalty on statistical power. With decreasing degrees of freedom, however, the inefficiency of accounting for clustering by analysis of social units becomes far greater. For a diabetes prevention project involving two social units, one intervention community and one comparison community, $t_2^{0.975} = 4.30$, and the inefficiency equals 79.3%. In this situation, decisions about accounting for clustering require that sampling and statistical theory be tempered with knowledge of the similarity of the two groups and their similarity to the population to which one wishes to generalise results.

As a guideline for studies for which the number of degrees of freedom is less than 20, corresponding to an inefficiency of 10% or more, Korn and Graubard (1991) suggested that

accounting for clustering by analysis of social units is inefficient and should not be performed. They propose the use of alternative adjustment procedures to deal with clustering; for example, nested mixed effects analyses, or estimating the design effect and adjusting summary statistics and significance values. For studies involving small numbers of social units with variability in the number of individuals within clusters, the available procedures can only approximate the variance of the parameters of interest (Skinner *et al.*, 1989). Alternative solutions to clustering are potentially more efficient, however, than analyses based on the unit of allocation, which amount to remedial overkill and cause a great deal of information to be lost.

Nested mixed effects analyses modelling the community factor as a random effect nested within fixed treatment effects comprise the best analytic approach for studies involving anywhere from three to twenty communities per treatment condition (Dwyer *et al.*, 1989; Koepsell *et al.*, 1991). Analysing the community factor as a random effect may be inappropriate for studies with only two social units per treatment condition, and is impossible when there is only one social unit per treatment condition (Jackson & Brahlers, 1994). To estimate and adjust for clustering in fixed effects analyses of studies involving one or two social units per treatment, Salonen *et al.* (1986) suggested inflating by a factor of 2.0 the individual-level error variance, in keeping with the concept described by Kish (1965) and elaborated by Donner *et al.* (1981). This approach assumes that a fixed, external estimate is valid for the population and the nature of the study of concern. However, as the design effect for social groups is usually in the range of 1.0 – 2.0 for many community intervention measures (Dielman *et al.*, 1989; Hannan *et al.*, 1994), inflating variance estimates by 2.0 may be overly conservative, resulting in a high rate of Type II errors.

An alternative to the fixed variance inflation factor approach for fixed effects analyses is to estimate for each respective outcome variable the study-specific ICC. For individuals (I) nested within communities (C), the intra-class correlation for measures within communities is given in terms of the expected mean squares (MS) variance components by

$$\hat{\rho} = \frac{MS_c - MS_{i(c)}}{MS_c + (\bar{n} - 1) MS_{i(c)}} ,$$

where MS_c is the community-level or between-cluster variance, and $MS_{i(c)}$ is the individual-level or within-cluster variance, \bar{n} is the harmonic mean group size across communities, and $\hat{\rho}$ is the

estimated intra-class correlation. This calculation requires at least two social units per each treatment condition and is based on variance estimates from univariate tests (Abouserie, 1992; Jackson & Brahsers, 1994). A two-level hierarchical linear model (either one-way analysis of variance with random effects or two-factor nested analysis) can provide efficient estimates of the ICC (Raudenbush, 1992). The design effect (DE) (Kish, 1965) is then computed for each outcome variable according to the equation

$$DE = 1 + \rho (\bar{n} - 1),$$

and used to adjust variance estimates and summary statistics (e.g., by multiplying the standard error of the estimate being used to account for the intra-class correlation). Because the ICC is calculated from the actual data to be analysed, the study-specific approach is an internal estimate. It is not, however, as robust an estimate as may be achieved using a nested mixed effects analysis of several communities per treatment condition. Thus, this approach is subject to the criticism that the group-level variance of the few communities sampled is not representative of the true group-level variance for a population of communities. Biased estimates of the group-level variance may cause the estimated design effect to be either too high or too low (Judd *et al.*, 1995).

The study-specific internal and fixed external variance inflation techniques are crude strategies by which to estimate and account for the additional variance imposed by the assignment units. They nevertheless serve a purpose in affording some protection against biased estimates of treatment effects for studies involving few social units. These corrections may be used when there exists an actual or nearly one-to-one correspondence between social units to treatment conditions (i.e., when there are few, if any, independent replications of treatment combinations). The study-specific approach has been used most often in social sciences research for cluster-type analyses (Campanelli *et al.*, 1989; Dielman *et al.*, 1989; Stevens, 1995). The fixed external inflation factor approach has been applied to analyses of early cardiovascular disease prevention programmes (Salonen *et al.*, 1986).

The choice between internal and external variance inflation factors depends on the number of clusters as well as the statistical procedures to be applied. Study-specific internal factors may be appropriate given two communities per treatment condition and the suitability of

univariate tests for evaluating treatment effects. For studies with one community per treatment condition, an external inflation factor may be the only solution, especially if multivariate procedures are to be used for analysis. An external inflation factor could also be used for instances in which there are two communities in either or both treatment conditions. The external estimate need not necessarily be fixed at 2.0 for all variables, however.

Hannan *et al.* (1994) have published ICCs of the community-level component of variance as estimated in the Minnesota Heart Health Program for a variety of community survey variables. Of the 23 variables assessed, including attitudes, behaviours, blood measures, physical and anthropometric indicators, only weight and body mass index had negative estimates for the intra-class correlation. With the exception of systolic blood pressure and diastolic blood pressure, most of the ICCs were modest: all had values under 0.01, and 13 of the 23 had values under 0.005. Half of the upper 95% confidence limits were under 0.01, and all but that for diastolic blood pressure were under 0.05. These estimates agree with reports from prevention studies in school-based settings, for which intra-class correlations for varied outcomes have been found to be quite small, typically ranging from 0 to 0.05 (Campanelli *et al.*, 1989; Dielman *et al.*, 1989; Murray & Hannan, 1990). When matched by variable or class of outcome variable, specific external estimates of ICCs can be used to calculate variance inflation factors by way of the formula

$$\frac{1 + \hat{\rho} (\bar{n} - 1)}{(1 - \hat{\rho})}$$

where $\hat{\rho}$ is the estimated intra-class correlation and \bar{n} is the harmonic mean group size across communities. This provides for adjustment of individual-level variance estimates when it is impossible or inappropriate to specify the nested community factor as a random effect in a mixed effects analysis (Hannan *et al.*, 1994). Conversely, the *F*-test for treatment effects can be deflated by the same value. These adjustments assume a fixed effects analysis of communities nested in treatment conditions, or an analogous model that includes the assignment units as fixed effects.

Insofar as individual-level variance estimates can be inflated or *F*-tests deflated by way of external estimates of ICCs, it is not clear whether adjusted tests should include any correction for the degrees of freedom. The choice of degrees of freedom for adjusted tests is a topic of

considerable debate. The traditional but inefficient approach using clusters as units of analysis bases the degrees of freedom on the number of clusters assigned to treatment conditions. Kish (1965) suggested an intermediate approach that involves dividing the degrees of freedom based on individuals by the design effect, to reflect loss of independent information from individuals in clustered surveys. Hannan *et al.* (1994) proposed an intermediate but more complex approach by which the degrees of freedom are calculated according to the precision (inverse variance) of the external estimate of the ICC, but difficulties in determining the variance of either the external or pooled internal and external estimates limit the utility of this strategy. Others have argued that given sufficiently precise estimates from similar studies, the adjusted tests need not include any correction for the degrees of freedom (Blair & Higgins, 1986; Jacobs *et al.*, 1988). Making no adjustment may be justified on the basis that analyses of corrected individual-level observations have a close relationship to analyses that treat the community-level means as elementary observations, especially when means are weighted for the number of individuals surveyed (Glass & Stanley, 1970; Hopkins, 1982; Koepsell *et al.*, 1991). Means models and weighting issues are discussed in a subsequent section.

For evaluating a quasi-experimental diabetes prevention and control programme involving one community per condition, the above review suggests that statistical adjustments for fixed effects analyses offer a viable strategy by which to account for the impact of clustering on variance estimates and summary statistics. In terms of analytic efficiency, this is the only realistic approach for analyses of small quasi-experiments. The issues associated with these adjustments and their rationale are not widely understood among public health and intervention researchers. More controversial and even less appreciated is whether or not or how degrees of freedom should be adjusted along with adjusted summary statistics. Kish's (1965) strategy of re-calculating degrees of freedom by dividing by the design effect seems most reasonable at present, even if it is rarely applied in public health research.

Community Allocation and Sampling

Having discussed definition and sampling of units, allocation of units to treatment conditions is now reviewed.

Randomisation (Random Assignment)

Some authors have argued that randomisation is warranted even when few experimental units, whether people or communities, are available for study (Lachin, 1988). Limitations peculiar to community-based trials must be considered, however, before randomisation can be endorsed whole-heartedly (Farquhar, 1978). First of all, it is often the case that the number of communities similar in size and demographic characteristics that are sufficiently close to any “parent” institution is limited. Generally it is required for logistical reasons that the communities involved in a study are close to the “parent” institution (the programme sponsor or research institution responsible for administering a project). Secondly, the intended use for intervention of media campaigns, social marketing and community-wide organisation and activation may restrict the initial choice and the freedom of randomisation to communities. Unacceptable consequences of randomisation could occur if the intervention and comparison communities were put into the same media market or if they ended up adjacent to each other, leading to cross-contamination (Jacobs *et al.*, 1986).

Koepsell *et al.* (1992) argued in favour of randomisation of communities, despite its limitations and risks, stating that these are outweighed by: (a) a firm basis for formal hypothesis testing; (b) public perceptions of fairness; (c) the option of applying a restricted randomisation process to deal with the difficulty of shared media markets by ruling out unacceptable study configurations in advance and selecting one of the remaining acceptable configurations at random; and (d) the option for achieving balance through matching or stratification techniques used along with randomisation, given few communities. Resentful demoralisation and jealousy among comparison sites may occur, however, irrespective of the use of randomisation (Cook & Campbell, 1976). Furthermore, it is unlikely that randomisation at the cluster level alone can achieve comparison groups that represent the appropriate non-treatment state with completeness, no matter the methodologies employed to overcome self-selection issues and the statistical methods invoked to control for selection bias (Grossman & Tierney, 1993).

In general, the viability of randomisation as a method to attenuate bias depends on the availability of sufficient numbers of communities. For a small number of units it is questionable whether randomisation accomplishes any practical benefit. The random allocation of a small number of units to treatment conditions is not likely to facilitate equivalence or prevent the introduction of systematic bias into a social experiment. The implication for a quasi-experimental community trial is that the threat of systematic differences among a small number of sites exists with or without randomisation.

Matching of Communities

A primary reason for matching is its potential to enhance statistical power for detecting effects of the one or two main hypothetical causal variables. For non-randomised studies it can also improve the comparability of treatment groups, thus reducing bias,^{*} though there are limits to which the deficiencies of a poor control group can be attenuated by matching alone (Cochran, 1968). Matching can improve power for a sufficient number of communities, but a matched design will generally have less power than an unmatched design if the number of communities is small (Murray *et al.*, 1994b). The loss of power is due to the loss of degrees of freedom for the variance estimate in a matched design, through use of the community pair (not the individual community) as the unit of analysis. For a small number of communities, the loss of power counteracts the value of matching on any but the strongest correlates of the outcome variables. In a general discussion on matching, Kleinbaum *et al.* (1982) note that in some cases matching may be less efficient than a simple random allocation.

Martin *et al.* (1993) reviewed matching issues for community-based trials and presented power calculations for matched and unmatched designs, assuming matching based on a single primary factor. For studies with few matched pairs, large correlations between the matching and outcome variables are required before a matched design and analysis become effective. With $\alpha = 0.05$ and $\beta = 0.20$ (power = 0.80), for five pairs, the correlation must be approximately 0.51, and for two pairs the correlation is required to be approximately 0.92. Correlations this large are

^{*}The bias issue formally does not apply to randomised designs, where randomisation reduces the expected bias to zero across studies. In practice, however, the potential for bias is reduced for randomised studies in proportion to the number of units allocated, and the degree to which the random assignment procedure itself is truly unbiased and actually worked.

difficult to find, and *a priori* determinations of which matching factors will predict changes in the outcome variable are tenuous at best. Paired analyses are inappropriate when matching is of limited effectiveness. On the other hand, when an unpaired analysis is used on matched data with a positive correlation, the unpaired analysis overestimates the variability and has lower power in direct relation to the strength of the correlation (Billewicz, 1965).

Whether or not a matched analysis is used, to attenuate bias in the design stage the best factors to match on are those most highly correlated with or thought to be related to change in the outcome variables. Geographic proximity and community size have been demonstrated to work well in forming matched pairs similar in terms of pre-programme outcome event rates, the prevalence of the baseline risk factors, and determinants of these (Freedman *et al.*, 1990; Jacobs *et al.*, 1986). Salonen *et al.* (1986) emphasised that communities should be similar in terms of baseline outcome event rates and risk factor levels, and that there be no marked heterogeneity in the rate of change in either disease rates or risk factor levels before the programme. They caution, however, that matching should not result in the selection of communities unrepresentative of the population to which generalisations are to be made.

A reasonable strategy for a small trial would appear to be to match communities to increase baseline comparability but to conduct an unmatched analysis so as not to compromise power.

Statistical Power

Statistical power is affected when individuals are the unit of observation but the unit of allocation is the community. Simpson *et al.* (1995) reviewed a variety of methods for estimating sample size and power for studies involving allocation by community. The utility of such methods is limited, however, in that they do not fully correspond to the more complex designs used to evaluate community-based intervention programmes, which involve nested factors, concern with change over time, and longitudinal or cross-sectional samples of individuals. Moreover, most methods to calculate sample size and power require estimates of relative treatment effects and community-level variance. Appropriate estimates of these parameters are rarely available for behavioural and lifestyle variables. Notwithstanding the modest utility of existing methods, the limited availability of

suitable estimates of parameters makes difficult the estimation of the sample size necessary to find the true treatment effect for the outcome measures to be studied in a community-based trial.

For a diabetes prevention project with one intervention community and one comparison community, or for a trial involving very few communities per treatment group, methods to calculate sample size and power on the basis of community units cannot be used. For such studies the between-community variance must somehow be estimated and incorporated into sample size and power calculations based on individuals. One solution is to incorporate a multiplier by which the individual-level variance (the variance among individuals) is increased, analogous to using a variance inflation factor to correct for the design effect in statistical analyses. Increasing the individual-level variance to account for clustering will increase the number of individuals required to achieve a given effect size. As for analytic procedures, a reasonable approximation may be achieved by inflating the individual-level variance by a factor of 2.0 (Salonen *et al.*, 1986); further solutions are the use of intraclass correlation coefficients derived from other population-based studies (Hannan *et al.*, 1994) or variance estimates from previous studies (Newhouse *et al.*, 1981; Wagner *et al.*, 1991).

Sampling and Measurement in Communities

Measurement strategies to assess progress toward or achievement of a diabetes intervention programme's objectives can be broadly conceived in terms of (a) those oriented towards changing risk factors or diabetes rates among particular groups of individuals, or (b) those intended to change the prevalence of risk factors or diabetes rates in a community (Altman, 1986). One of these objectives is likely to be of greater priority than the other. Individuals with or at risk for diabetes may be the primary target of a project with most, but not all, strategies applied to the community in general. Environmental manipulations in support of behavioural changes among high-risk individuals may bring about changes at the community level by affecting individuals directly targeted to receive behavioural and educational interventions as well as those unexposed to individual-level strategies. Two strategies can be applied to measure change at these different levels (Murray & Hannan, 1990; Murray *et al.*, 1994b): (a) a longitudinal follow-up in intervention and comparison communities of the same individuals (i.e., a cohort design); and (b) a repeated

cross-sectional design, where new samples of individuals are drawn in each community on each survey occasion. In a quasi-experimental context, a minimum of two measurements will be required for each individual observed under each treatment condition, the first at the baseline, and the other at some point following implementation.

Longitudinal samples are better suited to isolating programme effects on risk factors among individuals, while repeated cross-sectional samples are best for measuring programme effects on the prevalence of risk factors across a community (Koepsell *et al.*, 1992). Three analytic advantages specific to longitudinal samples are: (a) the ability to adjust for baseline differences between communities at the individual level (Cupples *et al.*, 1988; Williams *et al.*, 1981); (b) the greater power of individual-based analyses because test-retest correlations allow smaller within-community sample sizes (Cook & Ware, 1983; Schlesselman, 1973a; Schlesselman, 1973b) and (c) the ability to examine interactions between baseline characteristics, risk factor and other changes including those in various sub-groups, and the potential to analyse individual-level associations for change in a variety of variables (Farquhar, 1978; Salonen *et al.*, 1986). One additional advantage beyond the experimental design analysis is that longitudinal data on individuals allow for analyses of causal order of changes between variables; for example: Did attitude changes precede behaviour changes or follow them? The primary limitation of longitudinal samples, relative to cross-sectional samples, is greater susceptibility to bias affecting estimates of treatment effects (Campbell & Stanley, 1966; Koepsell *et al.*, 1992).*

The repeated cross-sectional samples approach is best applied to evaluate interventions in large communities where the threat of overlapping of samples is minimal (Pietinen *et al.*, 1988; Trelli *et al.*, 1985). The principal limitations to the repeated cross-sectional design are its unsuitability for studying developmental patterns within cohorts and its inability to resolve issues of causal order; both of these limitations result directly from the fact that the same individuals are not measured repeatedly or for multiple periods (Menard, 1991). Since measurement of change in repeated cross-sectional designs can be made only at the aggregate level, the strategy may be appropriate for measuring aggregate period trends if causal order is well-established and if the lag

*Longitudinal samples are more susceptible than cross-sectional samples to bias threatening internal validity through the effects of history, maturation, testing, selection bias and attrition. Threats to external validity are the interaction effects of testing and an intervention, interaction effects of selection biases and an intervention, and reactive effects to research arrangements.

between cause and effect can be assumed to be short relative to the interval between measurement periods (Menard, 1991).

For evaluating a diabetes prevention programme of relatively short duration involving small communities, the utility of the repeated cross-sectional design is more limited than the longitudinal design. Longitudinal follow-ups may be unavoidable for small communities, given the specific probability of repeated cross-sectional samples leading to an unacceptably high level of repetition (Salonen *et al.*, 1986). The longitudinal design, however, may leave unanswered the question of penetration or community-wide effects if the longitudinal cohort is unrepresentative. The implication is that both cross-sectional *and* longitudinal approaches should be applied where feasible to the design of community-based intervention programmes.

Data Analysis Issues

Data analysis is perhaps one of the least understood aspects of evaluating community trials. Statistical conclusion validity is easily compromised by analytic techniques inappropriate for the “messy” data that characterise community interventions. Well-intentioned but misguided approaches to analysis have generated valid criticism of community trials, especially those involving small numbers of communities. Such criticism has not generally been accompanied, however, by efforts to derive or delineate cogent solutions to serious analytic problems specific to small community trials. Statistical texts provide little assistance in such matters. Issues relevant to the analyses undertaken in this dissertation are reviewed in this section. Coverage includes: (a) fixed and random effects; (b) balanced and unbalanced data; (c) effects models and cell means models; (d) unweighted and weighted marginal means; (e) strategies for unbalanced data; (f) nested classifications and hypothesis testing; (g) repeated observations; and (h) missing data. Some of these issues have been referred to under the rubric of design considerations, but not fully explained as to their implications for analysis and interpretation.

Fixed and Random Effects

Experiments generally contain one or more experimental factors (independent variables), each of which has at least two levels. In classifying data by way of factors and their levels, the object of

interest is the extent to which different levels of a factor influence the variable of interest, known as the *effect* of a level of a factor on that variable. This is the essential concern of the analysis of variance, as originally set forth by R.A. Fisher (1925, 1935). Fisher's unambiguous structural approach to data analysis involved partitioning certain quadratic forms in the data as "sums-of-squares" due to various sources, having properties under various null hypotheses which allow tests of those hypotheses. The structural approach was supplanted in the 1940s by parametric model-based approaches allowing the specification of desired additional properties, including the cases of fixed and random effects, and mixed effects models (Eisenhart, 1947). While allowing the freedom to specify exactly what is being estimated or tested, the model-based approach may nevertheless lead to confusion where parameter-specific assumptions vary and alter the meaning of terms in the model according to the form of additional assumptions imposed as constraints (Hocking, 1973). These issues will be discussed shortly.

Fixed effects are the effects attributable to a finite set of levels of a factor that occur in the data and which are there because of interest in them (Kirk, 1982). For example, the effect on fasting glucose concentrations of a factor called treatment could correspond to two different experimental conditions used to evaluate a diabetes intervention programme. Thus there would be two specific or "fixed" conditions of definite interest, the effects of which one could quantify from the data to be collected from a behavioural experiment.

Random effects are the effects attributable to a theoretically infinite set of levels of a factor, of which only a random sample are deemed to occur in the data (Lindman, 1974). For example, one may wish to test the hypothesis that there are differences in peoples' knowledge about diabetes risk factors across different communities within a particular geographic area. In this instance "community" would represent a random effect. If one's hypothesis were more specific, for example, that knowledge in rural communities is better than in isolated communities, then the community factor would be a fixed effect. As it stands, however, the original hypothesis requires that one draw a random sample of communities from the population of communities in a defined geographic area. Individuals within each selected community would then be surveyed. Thus, each level of the community factor does not represent a distinct level of the factor, but instead represents one possible level chosen from a population of levels. One might wish to conduct a

study in this way so as to be able to generalise from the selected levels of community to an entire population of levels; that is, to test an hypothesis pertaining to any differences between communities in a particular geographic area.

Models in which the only effects are fixed effects are called fixed effects models. Models having only random effects (apart from a single, general mean common to all observations) are called random effects models. Models that contain both fixed effects and random effects are called mixed models. Mixed models in which main effects are completely crossed with random effects have as their error term not the usual within-groups mean square, but the two-way interaction of the respective fixed factor with the random factor (Kirk, 1982).

An example of a mixed model is a community intervention trial in which knowledge of diabetes risk factors is measured among individuals drawn from each of six communities exposed to different treatment conditions. Whereas the effects due to treatment would be considered fixed effects, the effects due to community would be considered random effects because the communities chosen would be deemed to be random samples from some hypothetical, infinite population of communities. As there is a definite interest in evaluating the differences between treatments, the statistical concern is to estimate the treatment effects; they are fixed effects. In contrast, there is no particular interest in the individual communities, because those that occur in the data are considered to be just a random sample of communities. There is, therefore, no substantive interest in quantifying individual community effects, but there is great interest in estimating the variance of those effects, in order to calculate the test statistic on which hypothesis tests are based (Graubard & Korn, 1994). Such data are considered as having two sources of random variation: cluster-specific community variance and, as usual, individual-level error variance. It has been discussed how certain indirect methods can be used to account for random variation due the community factor, such as when there exists only one community per treatment condition and it is not possible to specify and analyse community as a random effect.

Balanced and Unbalanced Data

Balance depends on whether or not the number of observations in a data set are the same for each cell corresponding to a given combination or subclass of factors and levels (Searle, 1987).

When each cell contains the same number of observations, the data are said to be balanced. Unbalanced data are those where the numbers of observations are not equal in the cells defined by one level of each factor. These numbers may be quite unequal, including some cells with no data at all. Unbalanced data often arise from surveys where data are collected simply because they exist, such that the numbers of observations in the cells are just those that are available. This is generally the case in the evaluation of community-based intervention studies, whether geared towards the prevention of diabetes, cardiovascular disease or any other condition or problem.

Balanced data most often arise from designed factorial experiments that have been executed as planned (Armitage & Berry, 1994). Computing the correlation matrix for balanced data will reveal that the main effects and interaction effects are all uncorrelated. This property of the effects is referred to as *orthogonality*. The data are said to be balanced because the effects are orthogonal, or independent, of each other. Put another way, balanced data ensure that tests of main effects and interactions are not confounded statistically.

Procedures for the analysis of balanced data are recorded in numerous texts on the design and analysis of experiments (Montgomery, 1991). These procedures, primarily standard analyses of variance, are relatively straightforward, well known, and widely accepted. For a given experiment and the resulting data set, most statistical software packages will produce essentially the same analysis and results. Moreover, when all treatment combinations are observed in a balanced experiment, the different kinds of sums of squares available for testing distinct hypotheses are all equivalent, substantially easing interpretation. That is, of the four different sets of sums of squares (Types I, II, III, and IV) (Freund *et al.*, 1986) that originate from the underlying philosophy of analysis of variance (of partitioning the total sum of squares), where each kind corresponds to a specific hypothesis tested, all sets are equivalent for balanced data and will produce the same results for a given test of effects (Milliken & Johnson, 1992).

There is often no unique, unambiguous method for the analysis of unbalanced data encountered in community trials. The orthogonality property of main effects and interactions present in balanced data does not carry over to the unbalanced case. Although the application to balanced data of analysis procedures for unbalanced data may result in a simplification to standard analyses, analyses for unbalanced data are neither natural nor simple extensions of standard

analyses. An artificial dichotomy is often imposed, however, with analysis of variance procedures considered to be appropriate only for the analysis and interpretation of linear models of balanced data arising from perfectly executed experiments, and regression procedures considered as if the only suitable means by which to analyse and interpret the effects simultaneously of two or more factors in an unbalanced data set. It is widely held that for unbalanced data, models analogous to experimental design situations cannot be analysed except by way of multiple regression.

It is true that multiple regression is a powerful method for studying the simultaneous effect on a random variable of several predictor variables, and that no special conditions of balance are imposed on their values (Neter *et al.*, 1983). Most applied texts include coverage of a variety of regression and analysis of variance procedures for testing hypotheses about the means observed in subclasses of unbalanced data (Dunn & Clark, 1987; Judd & Kenny, 1981a; Leukefeld & Bukoski, 1991). Analysis of variance and multiple regression are both special cases of the general linear model, and there is a close relationship between them (Bock, 1975). Few texts, however, address a heuristic distinction relevant to different strategies for analysing and interpreting linear models of unbalanced data: the *effects model* versus *cell means model* (Milliken & Johnson, 1992; Searle, 1987). Historically, the effects model is related to regression analysis (Gauss, 1889) whereas the cell means model is closely related to analysis of variance procedures (Fisher, 1925). When properly specified the two models are mathematically equivalent, but the effects model is often chosen over the cell means model because of its broader theoretical utility.

The analyses reported in this dissertation are based on analysis of variance procedures using the cell means model. The next several sections provide a theoretical basis for the statistical approaches used, through examination of distinctions between cell means models and effects models. Aspects of the following exposition are relatively formal, but the material reviewed is, in general, not especially well-known to epidemiologists and public health researchers. The review is relevant because one finds oneself in a statistical “no-man’s land” when faced with analysis of a small diabetes intervention project involving an incomplete design and unbalanced data. A variety of routes can be navigated through the field, but whichever the way taken, the evaluation results will be very much a function of the statistical decisions made and the theory behind them. Matters

are clearer when several communities are involved per study condition, with results less sensitive to different analytic procedures. In these instances, a detailed review would be unnecessary.

Effects Models and Cell Means Models

The effects model and the cell means model are different approaches for partitioning sums of squares for testing different kinds of hypotheses of interest in experiments (or survey-type approximations) with two-way factorial structures. Using the effects model does not enable one to answer questions that cannot be answered by using the cell means model, and vice versa. The following provides a brief overview of the two models, relying mainly on Searle (1987).

For data classified by two factors, in the form of a rows and b columns, let y_{ijk} be the k th observation in row i and column j for $i = 1, 2, \dots, a$ and $j = 1, 2, \dots, b$, with n observations in every combination of row and column, so that $k = 1, 2, \dots, n$. The effects model for equation y_{ijk} is

$$y_{ijk} = \mu + \alpha_i + \beta_j + \gamma_{ij} + \epsilon_{ijk},$$

where μ is a general mean, α_i is the effect due to the i th row, β_j is the effect due to the j th column, γ_{ij} is the effect due to the interaction of the i th row and j th column, and ϵ_{ijk} is a residual random error term. Without going into detail, the effects model has broad utility and appeal because it specifies parameters (μ , the α s, β s and γ s) in a way that enables clear expression of what one might like to estimate. For example, for row effects, there may be interest in estimating a difference such as $\alpha_1 - \alpha_2$. This advantage, however, is offset by the fact that the effects model involves more parameters than there are observed cell means to estimate them from. There are $1 + a + b + ab$ parameters but only ab cell means

$$\bar{y}_{ij\bullet} = \sum_{k=1}^n \frac{y_{ijk}}{n},$$

for $i = 1, \dots, a$ and $j = 1, \dots, b$. Thus there are too many parameters to be able to estimate them as linear functions of the observed $\bar{y}_{ij\bullet}$ cell means. Furthermore, the row and column means and the grand mean (the mean of all observations), respectively (using dot notation for sums, and dot and bar notation for means)

$$\bar{y}_{i..} = \sum_{j=1}^b \frac{\bar{y}_{ij.}}{b}, \quad \bar{y}_{.j.} = \sum_{i=1}^a \frac{\bar{y}_{ij.}}{a} \quad \text{and} \quad \bar{y}_{...} = \sum_{i=1}^a \sum_{j=1}^b \frac{\bar{y}_{ij.}}{ab}.$$

are of no help in this regard, additional to the cell means, since they are just linear combinations of those cells means. Because the effects model has more parameters than can be *uniquely* estimated from the data collected, it is referred to as an overspecified, or “overparameterised,” model (Milliken & Johnson, 1992).

To circumvent the feature of having more parameters in a model than there are cell means to estimate them from, one of two procedures is usually invoked, either (a) the use of estimable functions, which confines attention to certain functions of the parameters that can be estimated satisfactorily from the data, or (b) “reparameterisation,” where relationships are defined among parameters of an “overparameterised” model, which has the effect of rewriting the model for no more than the maximum number of “new” parameters as can be estimated from the data (Searle, 1987). These procedures, or constraints, are straightforward to apply and interpret for balanced data. In contrast, for unbalanced data, “overparameterised” models involve complexities that estimable functions and “reparameterisation” may not simplify (Milliken & Johnson, 1992). There can be a very wide choice of constraints for unbalanced layouts. It is possible to test a constrained hypothesis for unbalanced data, but the nature and meaning of the hypothesis may not be clear or open to straightforward interpretation. Nevertheless, the complexities of “overparameterised” models are mathematical and have known solutions. The complexities are of concern only if one’s goal is to estimate the ideal parameters that are the focus of designed experiments. If one is content with real population parameters, the effects model yields straightforward analyses.

The cell means model is an alternative to tests of constrained hypotheses using “overparameterised” models. This approach confines attention to estimable functions in a completely unconstrained model and allows a clear conception of the hypothesis tested (Hocking & Speed, 1975). As it is computationally simpler and open to straightforward interpretation, the cell means model has been recommended as the strategy of choice in the literature on analysis of unbalanced data. Detailed discussions can be found in Dodge (1985), Heiberger (1989), Lindman (1974), Milliken and Johnson (1992), Searle (1987), Searle *et al.* (1981), Speed *et al.* (1978) and Woodward *et al.* (1990). The cell means model is not generally used because most

statistical software is based on the effects model. Some computing packages, however, enable implementation of the cell means model.

In contrast to the effects model, the cell means model is given by

$$Y_{ijk} = \mu_{ij} + \varepsilon_{ijk}$$

where μ_{ij} is defined to be the mean of a conceptual population in cell i, j , from which the available data y_{ijk} are considered to be a random sample. There are ab parameters and ab observations.

Using E to represent expectation over repeated sampling gives

$$E(y_{ijk}) = \mu_{ij},$$

which is the foundation of this form of the linear model. Because y_{ijk} and $E(y_{ijk})$ are not, in general, equal, associated with the observations y_{ijk} is a random error term defined to be

$$\varepsilon_{ijk} = y_{ijk} - E(y_{ijk}),$$

thus giving

$$y_{ijk} = \mu_{ij} + \varepsilon_{ijk}.$$

The random error term accounts for everything that contributes to y_{ijk} being different from its expectation $E(y_{ijk})$. By its definition, ε_{ijk} has expected value zero. To each ε_{ijk} is attributed a common variance σ^2 , with zero covariance between every pair of different ε_{ijk} s. It is also assumed that the ε_{ijk} s are normally distributed and independent.

The μ_{ij} s are usually estimated by the method of least squares. The estimator that minimises the sums of squares is calculated, and a set of equations obtained that the estimator must satisfy, called the *least squares equations* or the *normal equations* for the model. For the cell means model the matrix form of the model is nonsingular, its inverse exists, and the least squares estimator is unique. Thus, the least squares estimator of μ_{ij} is

$$\hat{\mu}_{ij} = \frac{Y_{ij\cdot}}{n_{ij}} = \bar{y}_{ij\cdot}.$$

Weighted and Unweighted Marginal Means

When analysing a cross-classified data set by way of analysis of variance, one is interested in estimating the means of particular effects or cells. The marginal mean is a linear combination of the parameters averaged over specific classes as if there were one observation in each cell (Searle *et al.*, 1980). All marginal means are estimable if every cell has at least one observation, though this is not so if some cells are empty. Weighted marginal means are computed by assigning as weights to the cell means the respective cell frequencies; each cell mean in a row is weighted according to the number of observations in the cell. Further, the weighted mean exists even if a cell is empty: since the cell will get zero weight the actual cell mean is immaterial. Unweighted marginal means are computed by adding up the cell means and dividing by the number of means in the respective marginal mean; every cell mean in a row is weighted the same.

A consequence of the unequal cell size in unbalanced designs is that the weighted marginal means are not the same as the unweighted marginal means. The issue of whether to use weighted or unweighted marginal means in analyses of small quasi-experiments with unbalanced survey-type data is of critical importance. Depending on the data, the wrong approach could lead easily to biased estimates of treatment effects. For analysis of unbalanced data using the effects model, weighted marginal means analyses are those based on Type I sums of squares. Thus, a Type I analysis may be referred to as a "population-weighted" analysis. Unweighted analyses of unbalanced data are based on Type IV sums of squares. In the terminology of cell means models, one simply refers to "weighted" or "unweighted" marginal means analyses.

Weighted marginal means are appropriate for analysis of community interventions, where differences in cell sizes represent true differences of interest in a population. That is, if the number of observations per treatment combination is proportional to the frequency with which those combinations actually occur in the population, it is relevant to calculate weighted averages of the row means and the column means with the weights proportional to the observed sample sizes. Thus, a weighted analysis of variance yields results identical to the regression approach (Type I analysis). The decision on which kind of marginal mean to use for analyses should reflect whether the trial is a controlled experiment or a less structured survey-type intervention. In the latter context, a weighted analysis can yield an unbiased estimate of the population effect of an

intervention or the association between a risk factor and a disease, whereas an unweighted analysis can lead to the wrong conclusions (Korn & Graubard, 1991; Skinner *et al.*, 1989). On the other hand, if the mean in each cell is the best estimate for the population that is represented by that cell, then to assign weights to it may make little sense. Unweighted marginal means are independent of the numbers of observations in each cell (and thus are independent of the population structure).

A general sufficient condition for when weighting can be ignored is when the distribution of the outcome variable for given levels of the independent variable and covariates does not depend on any variables used in the sampling design or used to adjust for non-response (Korn & Graubard, 1991).^{*} It can be difficult to verify this sufficient condition not only for surveys involving random selection but also for quasi-experimental interventions, suggesting that weighted marginal means should be used unconditionally. If the above sufficient condition holds and the unweighted analysis is valid, however, it may be considerably more powerful than the weighted analysis. The weighted marginal means analysis may be inefficient compared to an unweighted analysis, especially when the cell sizes are quite variable or when the number of primary sampling units (i.e., communities) is small. For analyses of variance on unbalanced data, the inefficiency of the weighted (Type I) versus unweighted (Type IV) analysis can be defined as

$$1 - \left\{ \frac{SE_{\text{unweighted}}}{SE_{\text{weighted}}} \right\}^2,$$

where $SE_{\text{unweighted}}$ and SE_{weighted} describe, respectively, the weighted and unweighted standard errors of the mean difference.[†] The inefficiency increases when the cell sizes are more variable, and is zero when the cell sizes are the same.

^{*}This general sufficient condition is expressed in regression language simply as "higher order interactions are zero." The gain in efficiency is realised in the regression approach (Type I) simply by omitting the corresponding interaction terms from the model; since the interactions are known to be zero, there is no need to estimate them.

[†] The calculation of the inefficiency is different for linear regression models, and depends on the distribution of the sample weights and independent variables. Korn and Graubard (1991) provide the following approximation of exact formulae given by DuMouchel and Duncan (1983):

$$\text{Inefficiency} = 1 - \frac{(w_1 + w_2 + \dots + w_n)^2}{N(w_1^2 + w_2^2 + \dots + w_n^2)},$$

where w_1, w_2, \dots, w_n are the sample weights for the n sampled individuals.

As the inefficiency of a weighted analysis can be substantial for small studies, a potential compromise is to perform an unweighted analysis but to control for factors that determine differences in cell sizes (Korn & Graubard, 1991). For the convenience samples typical of many community-based trials, however, the factors responsible for such differences are largely unknown (Judd & Kenny, 1981a). Moreover, using weighted marginal means is the only valid approach for some kinds of analyses of unbalanced data (e.g., planned orthogonal contrasts for incomplete designs with empty cells) (Searle, 1987) and often must be used to standardise adjustments for time varying covariates across groups of different sizes (Murray & Wolfinger, 1994). In general, weighted comparisons are required to ensure that the sums of squares computed for an effect are orthogonal to other main effect or interaction hypotheses when the data are unbalanced.

Korn and Graubard (1991) suggest that if the inefficiency of a weighted analysis is less than 10%, then the weighted analysis should be used. If the inefficiency is greater than 10%, they recommend considering the effect the inefficiency will have on the standard errors compared to an expected clinically meaningful treatment difference, and if the effect is not unacceptably large, to conduct a weighted analysis, otherwise using an unweighted analysis with some attempt to control for factors influencing the cell frequencies observed. There is, however, a theoretical problem that limits the utility of the latter recommendation, beyond the more technical analytic problems that can arise with an unweighted analysis of unbalanced data: the fact that controlling for confounders at the individual level may not attenuate bias at the group level (Greenland & Morgenstern, 1989). An analysis of weighted marginal means is in essence a group level adjustment that may attenuate the impact of ecological bias between groups, whereas controlling for individual-level confounders as proxies for group-level differences can actually worsen bias.

Whether the cell means model or the effects model is used for analysis, an unweighted analysis has the consequence of reducing the error terms against which effects are tested. This is why an unweighted analysis can be more efficient than a weighted analysis. Thus, controlling for individual-level confounders but not group-level differences can reduce further the error term and increase the impact of ecological bias (Morgenstern, 1995). The best strategy is to control for individual- and group-level differences together.

For a small quasi-experimental diabetes intervention project involving unbalanced data, the literature suggests that analysis of weighted marginal means is a defensible strategy, though potentially inefficient. This conclusion is based on the utility of a weighted analysis to provide unbiased estimates of treatment effects, while attenuating the impact of ecological bias. It is also supported for particular analytic procedures such as planned orthogonal contrasts, and longitudinal analyses involving time-varying covariates.

Analytic Approaches for Unbalanced Data

Methods appropriate for a design involving unbalanced data may not be as easily interpreted as methods for balanced data. Not all statistical software packages will perform the same analysis for the same set of unbalanced data, nor will they realise the same results. Given four types of sums of squares available from statistical packages based on the effects model, it is helpful to consider those types most useful for analysis of unbalanced data, as well as the correspondence between specific hypotheses tested by the effects model and cell means model.

Searle (1987) distinguished between two scenarios that determine how unbalanced data should be analysed. The first is *all-cells-filled* data, where no cells are empty, and all treatment combinations are observed. For a quasi-experimental diabetes project, this scenario will not concern analyses of treatment effectiveness between intervention and comparison conditions, since a nested design will have empty cells for missing treatment combinations. It could apply, however, to analyses within conditions, for example, differences in outcomes between individuals cross-classified in terms of diabetes, impaired glucose tolerance and normoglycaemia, and participation status (assuming no empty cells). The second distinction is *some-cells-empty* data, where some cells have no data, and treatment combinations are missing. An example of this latter scenario is communities nested within conditions, as a community can appear in one condition only. This is usually the case for community interventions. The two distinctions for unbalanced data affect the kinds of analyses that may be undertaken.

All-Cells-Filled Data

All-cells-filled data can be analysed using with-interaction models by means of the “weighted squares of means method” (Yates, 1934). When all treatment combinations are observed, the hypotheses tested (main effects and their interactions) by the weighted squares of means method are the same as those for balanced data (Milliken & Johnson, 1992).

For the cell means model, the sums of squares for the different effects in the design are computed for linear combinations of the cell means, but the terms in the sums of squares are weighted in inverse proportion to their variances (Speed *et al.*, 1978). An effects model analysis of Type III sums of squares yields results identical to a cell means model analysis; the main effects and interactions are not confounded statistically. Hypotheses tested by Type IV sums of squares are equivalent to those tested by Type III sums of squares for a weighted squares of means analysis for all-cells-filled, but not some-cells-empty, data.

Some-Cells-Empty Data

Factorial designs with missing treatment combinations are said to be incomplete. For such data, not only are some factors usually not orthogonal, certain hypotheses cannot be tested without making some additional assumptions about the parameters in the model. Hypotheses involving parameters corresponding to the missing treatment combinations generally cannot be tested. For example, one cannot test in a community intervention the interaction between survey occasion, condition and community, because a nested design is, in effect, incomplete.

For the cell means model, a weighted squares of means analysis cannot be undertaken for some-cells-empty data. Because some rows or some cells in some rows are empty, some or all of the terms by which sums of squares would be weighted in inverse proportion to their variances are undefined. For with-interaction models, the solution is analysis of subsets of the data that are available. Analyses of subsets can be conducted weighted or unweighted according to the number of observations in each cell. Subsets are identified by reviewing the data grid from the perspective of a cell means model, seeking sets of filled cells that can yield information about relevant interactions. Having formulated relevant linear combinations of cell means for cells that

contain data, these combinations can be tested, the sampling variance of each estimate can be estimated, and tests of hypotheses can be made (Searle, 1987).

Although interactions involving missing treatment combinations cannot be tested, what can be tested are hypotheses about specific sets of linearly independent contrasts measuring interaction, where such contrasts are functions of estimable parameters. For example, the survey occasion-by-study condition interaction term could be tested in a community intervention (controlling separately for community). The basic issue that must be addressed using the cell means model, then, is the identification and specification of meaningful linear functions of means of filled cells that correspond to the research question.

For the effects model, analysis of some-cells-empty data is relatively straightforward. In some older statistical packages derived from mainframe-based versions (e.g., BMDP® and SPSS®), which basically analyse analysis of variance designs by way of multiple regression, the default way of handling incomplete designs is to code the factors in the design as if the design were complete, and then to perform the multiple regression analysis for those dummy-coded factors that can be estimated. Algorithmic strategies (e.g., the SAS® GLM routine) based on the generalised inverse of the design matrix have been developed to generate the appropriate coefficients for such comparisons. Of the hypotheses tested by different kinds of sums of squares the Type I and Type IV results will be relevant, depending, respectively, on whether a weighted or unweighted analysis is warranted.

The cell means model and the effects model, when properly specified, are mathematically equivalent and yield the same results. Analyses of unbalanced data may be undertaken by either approach, using analysis of variance or regression analysis. Analysis of variance has a history of use in analyses of classical experiments and approximations thereof. Regression analysis is mathematically elegant and highly flexible. Of greater import than the analytic approach taken, however, is the decision on whether to conduct weighted or unweighted analyses, in relation to the nature of the experiment and the hypotheses tested. This distinction is critical in drawing valid conclusions from analyses of small community trials, given the potential for biased results.

Nested Classifications and Hypothesis Testing

A nested design involving community as a nested secondary factor, and condition or treatment as the primary factor, is an incomplete factorial design. Levels of community occur only once within each level of condition, creating a component of variance attributable to the nesting. Because every level of community does not appear within every level of condition, there can be no interaction between the two factors (Montgomery, 1991). Were the design complete and community crossed with condition, this extra variation would only increase the variance against which effects are tested. For a nested classification it is necessary, therefore, to estimate the variance of the nested effect in order to prevent confounding the variation associated with the primary factor with that associated with the nested secondary factor.

The appropriate statistics for analysing the effects of the primary and secondary factors in a two-way nested design depend, in part, on the individual or joint correspondence of these factors to fixed or random effects (Jackson & Brahsers, 1994). In a community-based trial the correct conception of community will almost always be as a random effect. Taking community to be a random effect in a mixed model analysis theoretically allows generalising from the selected levels of community to the entire population of levels. An alternative strategy is a quasi-mixed model analysis, taking community as a fixed effect when it can be specified no other way, as when there exists only one community per condition, and to use an external estimate of the intra-class correlation to estimate the additional community-level variance.

Beyond the condition to which communities are assigned, factors that may affect the response of an outcome variable include the communities themselves, the time or occasion at which responses are measured, and the individuals who are measured. Thus, there are four factors influencing the response of an outcome variable: (a) condition; (b) community; (c) time; and (d) individual. To develop a statistical model by which hypotheses can be tested, the relationships between each pair of these four design factors must be classified as either nested or crossed, because interaction effects can be included only for crossed factors.

A Prototypical Model

Koepsell *et al.* (1991) described a prototype design for evaluating community-based studies. In this design, community is nested within condition, as a given community belongs to either the intervention or comparison condition, but not to both. Time is crossed with both community and condition, as surveys take place on the same schedule in all communities for intervention and comparison conditions. In a study using repeated cross-sectional samples, individual is nested within condition, community and time, because a given individual is surveyed at only a single point in time and resides in only one community subject to either the intervention or comparison condition. For longitudinal samples, individual is nested within community and condition but is crossed with time, as the same individual is surveyed at each point in time.

Given the nesting of community within condition, under both repeated cross-sectional and longitudinal sampling schemes there are three types of effects that are typically tested for significance: condition effects, time effects, and condition-by-time effects (Murray & Wolfinger, 1994). The terms against which these effects are tested will differ according to whether community is specified as a random or fixed effect, whether the data are unbalanced or not, whether individual is crossed with or nested within time, and whether individual or community is the unit of analysis (Jackson & Brahlers, 1994; Koepsell *et al.*, 1991; Montgomery, 1991). *In all cases the test of interest is the condition-by-time interaction, as that term reflects differential change over time between conditions, and formally tests the null hypothesis of no treatment effect.* The condition-by-time interaction is the basis for inference about co-variation between the conditions associated with an intervention programme and its effect on a given outcome variable.

Under quasi-experimental conditions the separate main effects of condition and time will almost always be irrelevant as a basis for evaluation (Jennings, 1988). In the absence of random assignment the communities in the intervention and comparison conditions could differ even in the absence of a true treatment effect, and a significant time effect would simply indicate that for unknown, non-specific reasons, differences in the outcome variable existed across time periods independent of condition. In contrast, for “true” experiments involving random assignment, the main effect of condition could be meaningful in itself in the absence of a condition-by-time

interaction, but a time effect is not in itself a valid indicator of programme effect whether the design includes random assignment or not.

The irrelevance of the main effects of condition and time and the fundamental importance of the condition-by-time interaction in quasi-experimental designs would appear to be poorly understood. It is not uncommon for researchers analysing repeated measures in non-randomly formed groups to interpret significant main effects of condition and even time factors as indicative of a positive programme effect, when in fact the condition-by-time interaction is not statistically significant (e.g., Jack, 1989). Such conclusions are invalid, as condition (and time) differences are meaningless by themselves as indicators of programme effect in a quasi-experimental context.

Omnibus Versus Planned Contrasts

Testing condition effects by way of the condition-by-time interaction is usually an omnibus contrast, in that all differences between groups are evaluated and any difference in the pattern of variation in an outcome between the intervention and comparison conditions can lead to rejection of the null hypothesis. Sometimes the structure of the condition-by-community combinations will suggest main effects of particular interest, where these give rise to special interaction contrasts of greater relevance in testing treatment effects than the more general omnibus test. An example of this situation is when there exist unequal numbers of communities nested within conditions, such as the two comparison communities and one intervention community analysed here.

An attractive feature of analysis of variance is that it can be adapted to yield test statistics for a variety of hypotheses beyond the omnibus contrast. These alternative statistics are based on planned orthogonal contrasts, seen as the preferred strategy for data analysis in applied field research (Judd *et al.*, 1995). Planned orthogonal contrasts have two distinct advantages over traditional analytic approaches: (a) the particular strategy employed can permit use of a more specific and powerful test of treatment than an omnibus contrast, thus avoiding the need for post-hoc tests to define the nature of a general difference (Winer, 1971); and (b) the technique is flexible and encourages testing hypotheses of primary theoretical interest to the researcher, rather than the relatively unfocused questions that are typical of traditional approaches.

To test orthogonal contrasts in the interaction effects of condition and time, it necessary to specify linear combinations of the cell means by which orthogonal partitions of the basic sums of squares can be obtained (Milliken & Johnson, 1992). This is required in “true” experiments as well as quasi-experiments where the main effects are not meaningful in themselves, since orthogonal contrasts in the main effects are required for generating orthogonal contrasts in the interaction effects. For the cell means model, any contrast or set of multiple contrasts between the means of communities within conditions is estimable, even for unequal numbers of communities. The estimator of the error variance is obtained by pooling the variances of the observations within the condition-by-community combinations (Bancroft & Chien-Pai, 1983).

Estimating variance components from unbalanced data is easier if community is analysed as a fixed rather than random effect, with the individual-level error variance subsequently inflated to reflect the additional community-level variance. In this instance, analysis of variance methods can be used to yield unbiased estimators and unbiased estimates of sampling variances of these estimators. Such models involve but a single variance component, because the nesting occurs in the treatment structure, and this does not affect estimation of other parameters (the fixed effects). *It is reasonable to use this strategy only for situations where one or two communities are nested within each condition.* With greater numbers of communities per treatment condition, mixed effects analyses should be conducted, and with these models both the individual-level error variance and the community-level variance (in addition to any other random effects) must be considered. In this case there are two error terms, because the nesting is considered to occur in the design structure as well as in the treatment structure.

This review has considered issues and statistical theory associated with analysis of a small quasi-experimental intervention study involving a nested (incomplete factorial) design and unbalanced survey-type data. Such analyses are not particularly straightforward, and statistical conclusion validity may easily be compromised by misinformed or inappropriate procedures. Analytic approaches were described relevant to the diabetes intervention project reported here. This elaboration addressed the basis of a quasi-mixed model mimicking the classification of the primary nesting factor (community) as a random effect, as well as the details and merits of the cell

means approach to analysis. Procedures for analysis of unbalanced data were described, and it was concluded that use of weighted marginal means is helpful to ensure an unbiased estimate of treatment effectiveness. Four design factors relevant to modelling the effect of a community intervention with a nested design were outlined, in terms of how the classification of these factors as either nested or crossed influences the kind of hypotheses that can be tested. The primary importance of the condition-by-time interaction term was made explicit as the only valid and relevant test of interest in a quasi-experimental context, where the separate main effects of condition and time are essentially meaningless in themselves. Finally, the use of planned orthogonal contrasts was discussed as a viable and efficient solution to testing specific differences in the pattern of variation in an outcome between intervention and comparison conditions, useful when unequal numbers of communities are nested within particular conditions.

The next section describes issues associated with analyses of longitudinal data relevant to the diabetes intervention project reported here. Topics include change score analysis versus covariance approaches for pre-test–post-test data, and strategies for repeated measures (three or more repetitions), since both situations were encountered in this project. As with the previous material, controversy exists as to the “best” analytic approach. The merits of various procedures are reviewed in determining the most viable options for analysis of this project.

Repeated Measures

For groups of individuals exposed to different levels of a treatment, where each individual is measured at several occasions, the results of these measurements will form a response profile (i.e., curve, or trend) for each individual within each group (Hand & Crowder, 1996). The aim of a repeated measures analysis is to model the mean response profiles in the groups. The fact that mean response profiles are modelled distinguishes repeated measures from time series analyses, because the concern is with a number of relatively short series of observations, one for each individual, rather than the single long series of observations derived from time series data. Repeated measures analyses require use of procedures that incorporate dependencies within individuals. The analysis becomes more complicated when there are more than two scores per individual, and when nonequivalent groups of individuals must be contrasted, as in evaluating a

quasi-experimental community intervention project. The following reviews summary measure analyses and other methods incorporating data from all measurement occasions. The focus is on continuous outcome measures.

Summary Measures

Two summary measure approaches relevant to evaluating a diabetes intervention programme are: (a) change score analysis, the difference between average post-treatment and average pre-treatment scores; and (b) analysis of covariance, by which post-test means are analysed while taking the mean of baseline measurements for each individual as a covariate in a linear model, to account for between-individual variations in baseline measurements (Everitt, 1995).

Early community-based cardiovascular disease prevention projects used both change score (Pietinen *et al.*, 1988) and analysis of covariance (Williams *et al.*, 1981) techniques for evaluation purposes. It is not advantageous, however, to use summary measures for analyses of designs involving measurements at more than two occasions (Cupples *et al.*, 1988). Using only the final follow-up and baseline scores ignores data gathered at each intermediate occasion, and prevents analysis of response profiles over time (Gornbein *et al.*, 1992). The pattern of change is likely to be more meaningful than any single difference measure (Lee, 1994; Mathews, 1993). Beyond this general issue are other concerns regarding the validity of analysis of covariance and change score analysis under quasi-experimental and “true” experimental conditions.

Change score analysis and analysis of covariance are strategies for adjusting for baseline scores in studies contrasting treatment changes between two or more groups. There are two basic reasons for using baseline corrections. First, differences among individuals within treatment groups constitute a major source of variation that should be controlled for precise evaluation of change. This is the purpose of baseline corrections in “true” experiments, as it can be assumed that randomisation justifies the comparability of groups. The second motivation for baseline correction is a perceived need to correct for observed differences between groups at baseline. Such differences are common under quasi-experimental conditions where groups have not been formed by random assignment, though baseline scores may differ even with randomisation (Wainer, 1989). Given the null hypothesis for community interventions of no differential change

over time between communities in intervention and comparison conditions, the concern is with treatment-induced change in the difference between groups, where the difference may or may not have been nonzero at baseline. It might seem that change is the difference between baseline and follow-up scores and that tests of the simple pre-test–post-test difference scores are suitable for analysis. Complications are introduced, however, by measurement errors and differences in the magnitude of true change among individuals within groups, both of which attenuate the correlation of pre-test and post-test scores.

All methods of baseline correction have been subjected to serious criticism (Kaplan & Berry, 1990). Several authors have demonstrated the inadequacies of analysis of covariance as a means of equating groups in quasi-experimental research (Campbell & Stanley, 1966; Lord, 1960; Overall & Woodward, 1977; Rubin, 1973). In covariance analysis, or equivalently, in multiple regression, the post-test is regressed on the pre-test and the residual from the regression is taken to be the dependent variable. Many authors have argued that no method of statistical adjustment is suitable to provide unbiased tests of significance when groups truly differ at baseline (Campbell, 1975; Lord, 1967, 1969). These criticisms have contributed to the questionable practice of using tests of significance conducted on baseline scores to justify assumptions of the comparability of treatment groups.

The use of change scores has long been condemned for compounding individual measurement errors (Cronbach & Furby, 1970; Guilford, 1954; Werts & Linn, 1970). Kenny (1975) developed a method for standardised change score analysis, and other forms of correction have been proposed (Campbell & Erlebacher, 1971). These and related attempts to increase the reliability of measures of effect have also been criticised (Greenland *et al.*, 1986). In general, there has been widespread criticism of *any* use of change scores in statistical analyses (Overall, 1989; Overall & Woodward, 1975). The essential concern is with regression towards the mean, a statistical artefact, where persons with high change scores would tend to be below the mean of the pre-test, and those with low change scores would be above the mean of the pre-test, assuming equal variance for the pre-test and post-test.

Change score analysis has been criticised on the basis that change may be correlated with the pre-test, and that this contraindicates its use under quasi-experimental conditions where

groups cannot be considered to be equivalent. The pre-test, however, is not the variable by which the treatment groups are distinguished in terms of their inherent differences; rather, some other, unknown, variable is. This unknown variable is called the "assignment rule" in quasi-experimental theory; it is neither known nor random (Judd & Kenny, 1981a). One might assume that the assignment rule is the unit of allocation, such as "community," and that to attenuate the impact of the assignment rule on change scores one need simply control for community in the analysis. Yet community is confounded with treatment; technically, because of perfect collinearity, the effects of community and treatment cannot be estimated simultaneously. Community can, however, be taken as a proxy for the reasons that sort people into different communities. Such reasons might include ethnicity, culture or occupational group, age, and so on; none of which would likely be perfectly correlated with treatment. Thus there can be merits in controlling for a cluster variable even if the variable has no relationship to the outcome, insofar as the cluster variable may control for important confounding variables (Graubard & Korn, 1994; Rosenbaum, 1984).

For a given set of pre-treatment measures, it is possible to argue on the basis of theory, previous research, or regression towards the mean that the difference between groups over time will remain constant, diminish, or even increase (Judd & Kenny, 1981a). The answer depends on how the assignment rule relates to the pre-test and post-test. In brief, analysis of covariance and regression adjustment are theoretically valid when the true pre-test mediates the effect of the assignment variable on the post-test (i.e., the pre-test mediates the assignment variable post-test relationship). However, if the pre-test and post-test are both caused by the assignment rule, and if it can be assumed that the effect is the same on both the pre- and post-test, then change score analysis is the superior method under quasi-experimental conditions.

Change score analysis presumes that the assignment rule directly affects both the pre-test and post-test and that these effects are of equal magnitude; this is known as the assumption of "stationarity of causal effects" (Judd & Kenny, 1981a). Variables that might be modelled as proxies for the assignment rule in a change score analysis should neither be caused by the pre-test nor change over time, because (a) a changing variable could be influenced by the pre-test and (b) covariation between variables is greatest when they are measured concurrently, such that

a changing assignment variable would tend to correlate more highly with the pre-test than with the post-test. Stable assignment variables might include ethnicity, gender, socioeconomic status, marital status, or community (Rosenbaum, 1984).

Overall and Ashby (1991) studied the utility of analysis of covariance and change score analysis using computer-generated simulated sampling data for testing the significance of the difference in treatment-induced change on a primary dependent variable in randomly and non-randomly constituted groups. Each method was examined in experimental situations where baseline means differ significantly in spite of random assignment, and in quasi-experimental designs where baseline means are not found to differ even though the populations from which samples are drawn do differ. A total of 10,000 artificial data sets were generated for 30 subjects per each of two treatment groups, once for an experimental design with random allocation to treatment groups, and again for a quasi-experimental design with non-randomly grouped individuals. The results, reviewed below, support the theoretical argument for using analysis of covariance or regression adjustment when the pre-test mediates the assignment variable-post-test relationship, and change score analysis when it can be assumed that the effect of the assignment rule is the same on both the pre- and post-test.

For treatment-induced change in randomly constituted groups with a correlation between baseline and follow-up measures of 0.5, analysis of covariance provided appropriate Type I error protection and superior power regardless of the significance of chance baseline differences. Tests of change scores had low power and yielded excessive numbers of Type I errors when baseline means differed significantly in spite of randomisation. For quasi-experiments where treatment groups constituted samples from pre-defined populations, analysis of covariance produced excessive numbers of Type I errors whether or not there existed a statistically significant difference at baseline. Tests of change scores were superior to analysis of covariance for quasi-experimental designs, yielding an overall Type I error probability of 0.053 which agrees closely with the (pre-specified) atheoretical $\alpha = 0.05$. Change score analyses had essentially identical power under opposing conditions when the treatment effect was either promoted or negated by a pre-existing baseline difference. In contrast, the power of analysis of covariance under quasi-experimental conditions depended strongly on the direction of the treatment effect. Overall and

Ashby (1991) concluded that the results support the use of change scores as superior to analysis of covariance when randomisation cannot be relied on. The generality of this conclusion is dependent on the correlation between the pre-test and post-test as being no lower than the 0.5 used in generating data sets for the simulation analysis, though higher correlations strengthen support for the use of change scores in quasi-experimental analysis.

Univariate Analysis of Variance

The univariate analysis of variance approach for analysing repeated measures data is popular in social sciences disciplines where there has been a traditional emphasis on the design and analysis of structured experiments (Lindquist, 1953). The usual models involve fixed and random effects, fixed effects corresponding to treatment variables, and random effects corresponding to individual effects and individual-by-treatment interactions (Winer, 1971). Repeated measures analysis of variance is therefore a special example of a mixed model analysis. Covariates that vary across time or that are constant across time can be included in this model.

Details on the univariate approach for analysis of repeated measures data are described elsewhere (Hand & Crowder, 1996; Lindsey, 1993; Munro, 1986). An issue especially relevant to the cohort designs used in community trials, however, concerns repeated measures factors with more than two levels. Two special assumptions arise in this situation: compound symmetry and sphericity. These conditions apply to the nature of the variances and covariances of the repeated measures, and affect the validity of the F -tests, in addition to the usual assumptions of normality, homogeneity of variances, and independence of errors. The compound symmetry assumption requires that the variances (pooled within-group) and covariances (across individuals) of the different repeated measures are homogeneous. Compound symmetry, however, is not a necessary condition; it is a special case of a more general situation under which the F -tests are valid (Huynh & Feldt, 1970). The sphericity assumption is a necessary and sufficient condition for the F -test to be valid; it states that the within-individual "model" consists of independent, orthogonal components.

When the compound symmetry and sphericity assumptions have been violated, the univariate analysis of variance table will result in a greater rate of Type I errors. Approximations

have been developed to compensate for violations, of which the two most well-known strategies are the Greenhouse and Geisser (1959) and Huynh and Feldt (1976) corrections. The purpose of these strategies is to adjust the univariate results of repeated measures analysis of variance for violations of the compound symmetry assumption. It can be difficult to establish whether the assumption of compound symmetry is violated, however.

Tests do exist for compound symmetry (Rouanet & Lepine, 1970), but most statistical software packages emphasise the more general condition of sphericity. Many software packages report the results of Mauchly's (1940) test of sphericity. This test evaluates the null hypothesis that sphericity holds; however, Monte Carlo studies have shown the Mauchly test to be very sensitive to non-normality (Keselman *et al.*, 1980) and thus of limited practical use. On the other hand, even minor (non-significant) violations of the sphericity assumption can lead to erroneous conclusions (Bock, 1975). It is widely held that in many situations the compound symmetry assumption is likely to be questionable *a priori*, suggesting that in the univariate case, adjusted tests should always be performed unless one has strong theoretical reasons to suppose that sphericity holds (Hand & Crowder, 1996).

It is possible to generalise analysis of variance techniques for the unbalanced data typical of community-based interventions to the case of univariate repeated measures analysis (Blair & Higgins, 1978; Keselman & Keselman, 1988; Speed *et al.*, 1978). This generalisation requires that the data fit a multivariate normal distribution, which is evaluated by the Box M test. This test is an approximation to the likelihood ratio statistic for testing the hypothesis that the populations have identical covariance matrices (Box, 1949). If the Box M test is significant, then it means that the variance-covariance matrices in the different between-group cells in the design differ from each other. As the Box M test is very sensitive to deviations from the normal distribution its results are usually viewed with skepticism. Significant results can be verified by examining the within-group variance-covariance matrices for major heterogeneity problems. Violations of the homogeneity of variances-covariances assumption are thought not to threaten seriously the validity of inferential tests, and on this basis Sen and Puri's (1968) nonparametric alternative to the Box M test has become increasingly popular.

Given unbalanced data, the test statistic should be based on weighted marginal means and a weighted average of the pooled sample covariance matrix (Jennings, 1978; Keselman & Keselman, 1988; Milliken & Johnson, 1992). Degrees of freedom for such tests must be approximated, usually by the method suggested by Satterthwaite (1946). Test statistics derived in these ways are not without complexities, but empirical examinations of these procedures suggest that they offer reasonable hypothesis tests (Maxwell & Bray, 1986).

The primary obstacle to the use of the univariate approach for repeated measures data from community trials concerns the compound symmetry and sphericity assumptions. Univariate procedures may be well worth consideration if compound symmetry and sphericity are supported by the data, even given the complexities of unbalanced data, simply on the basis of the high level of statistical power. The low power typical of most quasi-experimental community trials supports serious consideration of the univariate approach.

Multivariate Analysis of Variance

Whereas the univariate analysis of variance approach for analysing repeated measures data requires that the covariance matrix of the repeated measures satisfy the sphericity assumption, the multivariate analysis of variance approach has the advantage of imposing no restrictions on the covariance matrix. On this basis the multivariate approach is generally more justifiable than the univariate approach.

Given its potentially greater utility and validity, the less restrictive multivariate analysis of variance approach has become the preferred strategy for analysis of repeated measures in the social sciences, especially psychology. It is particularly amenable to the analysis of small quasi-experimental intervention studies. Covariates can be included in multivariate repeated measures analyses in the same way covariates are included in the univariate model (Hand & Taylor, 1987). Although multivariate methods can only be applied to data sets where either all repeated measures variables on a given individual are present or all are missing, the numbers of individuals per treatment combination need not be balanced (Milliken & Johnson, 1992). The multivariate procedure is at least as, and usually more, powerful than the univariate model when the univariate assumptions are untenable (Davidson, 1972). The assumptions are those of the typical

multivariate analysis of variance procedure for a between subjects design. The dependent variables must demonstrate multivariate normality but can have different variances and any pattern of correlations. It is assumed, however, that the variance-covariance matrices of the dependent variables are equal in the various between-group cells of the design.

Complex Models

The multivariate procedure is less restrictive than the univariate approach in terms of the form of the covariance matrix, but it does not allow missing data or irregular intervals between measures. More complex approaches can permit relaxation of the sphericity assumption while allowing the structure of the covariance matrix to be arbitrary. Such techniques also permit individuals to be measured on different numbers of occasions. This has the merit that individuals with an incomplete set of measurements can be included in a longitudinal analysis, and that individuals can have different sets of covariates. A class of generalised linear models alleviates these and other restrictions (Dunlop, 1994; Gornbein *et al.*, 1992). Such models estimate the parameters of the covariance matrix separately from the other parameters in the model. This approach is flexible but can be disadvantageous as a potentially large number of covariance parameters must be estimated, causing inefficient estimation and biased estimates of the variability of mean response profiles (Hand & Crowder, 1996; Schluchter, 1988).

As discussed in the earlier contrast of cell means models with effects models, one solution to "overparameterisation" is to restrict the form of the covariance matrix to a particular function of a vector of parameters. This is the general approach of a more specific class of regression procedures, known as random effects, or two-stage models (Feldman, 1988; Ware, 1985). Random effects are a flexible way of modelling correlations between successive error terms while introducing few parameters. A technical discussion is beyond the scope of this review. The essence of the approach, however, is the assumption that parameters vary from individual to individual, thus reflecting natural heterogeneity caused by unmeasured factors. Data from an individual augmented by information based on the population trend across time is used to estimate person-specific level time trends that are most probable given (a) the individual's data and (b) the population from which the individual was drawn. The idea is to obtain a better estimate

of the response profile for an individual, “borrowing strength” from the information provided by other individuals with similar characteristics. The random effects model is especially useful when the objective is to make inferences about individuals (i.e., the “subject-specific” approach), rather than just about the population average (i.e., the “population-averaged” approach), since this can be done equally well with the marginal approach given by the cell means model (Liang & Zeger, 1993). Graubard and Korn (1994) discuss the merits of the subject-specific and population-averaged approaches in relation to the underlying statistical models.

Complex models offer two primary advantages over traditional approaches to the analysis of repeated measures data: (a) choice of a wide range of correlation structures by which to model response profiles; and (b) use of the method of maximum likelihood to estimate parameters and their standard errors. On the first advantage, complex models should not be adopted uncritically, and any analysis should include an assessment of modelling assumptions in relation to the scientific objectives of a study (Everitt, 1995; Liang & Zeger, 1993). The results of analyses based on complex models can be unique to the form of the model specified, resulting in specification bias. The potential for specification bias should always be addressed by careful modelling and by examining the sensitivity of results to changes in the models (Greenland & Finkle, 1995).

The method of maximum likelihood is advantageous because: (a) it yields estimates with known properties under the assumed model; (b) it deals directly with missing data; (c) estimates are asymptotically efficient under the assumed model; and (d) standard errors of estimates automatically take into account the incomplete nature of the data (Gornbein *et al.*, 1992). Maximum likelihood has two disadvantages: (a) estimation requires the specification of a full model and results may be vulnerable to departures from normality; and (b) inferences are based on large sample theory and may be unsuitable for small samples. It is known that maximum likelihood estimation has a downward bias caused by ignoring the degrees of freedom spent in estimating fixed effects (Feldman, 1988), but the potential for biased estimation may be attenuated by using a modified approach referred to as restricted maximum likelihood (Hand & Crowder, 1996).

To summarise, repeated measures data are collected in a variety of circumstances for a variety of purposes, and there is no single “best” method applicable to all cases. Regardless, all-

inclusive claims have been made as to the superiority of complex regression models (Feldman, 1988), multivariate analysis of variance (Ekstrom, 1990) and summary measures (Frison & Pocock, 1992). Everitt (1995) noted that in many cases, there will be no major difference between the results of different methods, and that the essential concern is not to overlook important aspects of the data, including the nature of missing data. The implications for analysis of repeated measures data from a community trial are that the univariate approach might be considered as a first choice if its assumptions are justified. If the univariate assumptions are not upheld, the choice is between the multivariate approach or more complex analytic models. The multivariate approach may be viable if there are even intervals between measurement occasions and if the number of measurement occasions is not great, even if missing data is an issue. The ability of complex models to handle uneven numbers of observations is not a substantial benefit when there are relative few numbers of observations, as the strength of the information available to improve the estimated response profile for individuals with missing observations is low.

Missing Data

The fact that likelihood-based estimation enables the analysis of data-sets with missing values does not mean the approach necessarily provides a solution to the problems of missing data in longitudinal analyses of community trials. A “complete-subject” analysis of only those individuals with all measures recorded for each occasion can have merit in some situations. The advantages and disadvantages of methods for handling missing data depend primarily on the nature of the “missingness,” of which there are three recognised categories: (a) missing completely at random; (b) missing at random (ignorable non-response); and (c) non-ignorable non-response (Greenland & Finkle, 1995; Little & Rubin, 1987). The following addresses each of these in turn. Simple imputation techniques are not considered here, because they have little to recommend them (Gornbein *et al.*, 1992; Greenland & Finkle, 1995; Miettinen, 1985).

Data missing completely at random. In this situation, the values that are observed provide a simple random sample of the values for all individuals such that whether a value is observed for a given variable is independent of the values of any other variable, observed or not (Greenland & Finkle, 1995). In this case, the observed data provide an appropriate, unbiased representation of

the population sampled. This occurs, for example, when the probability of non-response is equal across time and does not depend on the response of interest. Determining to what degree data loss is random is primarily an inductive process given the nature of a project and characteristics of the individuals for whom data are missing. In addition to the inductive process, the degree of randomness can be assessed in several ways. One strategy is to create dummy variables for each level of a repeated factor. If a value is present, it is coded zero. Otherwise, a missing value is coded 1. Intercorrelations of all the dichotomous dummy variables are then calculated. If values are missing at random, the intercorrelations should approach zero (Frane, 1976).

When data are missing completely at random, a univariate analyses of variance for unbalanced data is a valid method and will yield unbiased results. Similarly, a complete-subject analysis using the multivariate approach will also yield valid, unbiased results (Dunlop, 1994). Likelihood-based methods have the potential to be more efficient than analysis of variance methods, as likelihood-based estimation assumes that the data available for each individual adequately represent that individual's deviation from the estimated group trend over the time frame of the study (Gibbons *et al.*, 1993). Whether likelihood-based estimation is actually more efficient than traditional methods depends on the number of individuals studied, the number of occasions over which data are collected and the amount of missing data. For studies with repeated measures on relatively few occasions with more than a small amount of missing data, differences between the results of likelihood-based methods and univariate or multivariate analysis of variance can be minor. Efficiency will be improved for large samples for which measures are collected on more than a few occasions, with only occasional missing data.

Data missing at random. In this situation, the probability that an observation is missing can depend on the values of observed items, but not on the value of the missing observation itself. Put another way, conditional on the values observed, "missingness" occurs at random. An observation missing at random is not in itself informative; thus, the non-response mechanism is said to be ignorable in terms of any need to estimate parameters for missing data to obtain valid tests of treatment effects (Murray & Findlay, 1988). Insofar as the probability of non-response depends on the observed data, these observed data include the values observed while an individual is in a study and factors such as treatment group. Therefore, if the level of attrition is

greatest in a comparison group, a model including the treatment factor will fulfill the condition of ignorable non-response, since the probability of a missing value is predictable from treatment status (Gibbons *et al.*, 1993).

It is possible for the results of both complete-subjects and likelihood-based analyses to be biased when the missing at random condition holds (Little & Rubin, 1987). In general, valid effect estimates require testing data dependent hypotheses (by way of weighted marginal means and planned orthogonal contrasts), as opposed to those that are independent of group sizes. Using likelihood-based methods, it is necessary to specify accurate models used for weighting estimates of effects and their standard errors, and this can be difficult (Greenland & Finkle, 1995).

Non-ignorable non-response. In this situation, the probability that an observation is missing depends on unobserved characteristics of the individual or responses that the individual would have made had he or she remained in the study (Gibbons *et al.*, 1993). Valid inferences can be made only by modelling the non-response mechanism. The model must concurrently predict the observed outcomes as well as the probability of non-response, usually by assuming a non-response model with unknown parameters that must be estimated from the data. Methods for non-ignorable non-response involve extremely complicated statistical theory; they are difficult to apply, and are very sensitive to the missing data model assumed (Little & Rubin, 1987). Computations involve the presence of variables that predict non-response but are independent of outcome, yet such values may not even be available. Whereas ignorable non-response may be detected by examining the data, non-ignorable non-response cannot be detected similarly.

The nature of missing data has been reviewed in relation to procedures suitable for analysis of longitudinal data from a community trial. For data missing at random or completely at random, maximum likelihood-based approaches may offer little benefit over complete-subject analyses using traditional techniques. This conclusion is most reasonable only for studies with repeated measures on relatively few occasions with more than a small amount of missing data, since likelihood-based methods offer advantages over traditional methods when measures are collected on more than a few occasions, with only occasional missing data. This section also described the inductive process of determining the nature of missing data, an important analytic

procedure for any longitudinal study. These issues are all relevant to the diabetes intervention project reported here. The next, and final, section considers the utility of various software packages in relation to analytic issues reviewed in this chapter, with an emphasis on capabilities relevant to small-scale community intervention trials.

Computer Software

Almost any contemporary statistical software package will be appropriate for analysing repeated measures by way of summary statistics. A more restricted selection of software is suitable for complex longitudinal analyses, where user-flexibility, programming ability, assumption checking and diagnostic capabilities are important. Comprehensive packages with a history of use in public health include SAS® (SAS Institute, Inc.) and BMDP® (BMDP Statistical Software, Inc.); an increasingly popular package is STATA® (STATA Corporation). Similar platforms in the social sciences include SPSS® (SPSS, Inc.) and STATISTICA® (StatSoft, Inc.). Two other specialty packages with the required capabilities are SUDAAN® (Research Triangle Institute) and MLn® (Institute of Education, University of London), though these are reportedly not entirely straightforward to use and are not supported in the same way as other packages.

For fitting models with structured covariance matrices and to use all values when missing data are a concern, only SAS (PROC MIXED) and BMDP (5V) are truly suitable. STATA, SUDAAN and MLn have variance estimator options for correlated data, and offer generalised estimating equations for the estimation of generalised linear models for grouped data, with choices for different correlation structures. These options are not at the level of SAS PROC MIXED and BMDP 5V, if only in terms of longitudinal data analysis; STATA, SUDAAN and MLn are each powerful packages with strengths in other areas. For analyses involving contrasts between groups, as opposed to building global models, both SPSS and STATISTICA offer utility and relative ease of use. Complex weighted orthogonal contrasts are difficult to perform using SPSS, whereas STATISTICA allows the specification and analysis of contrasts in a more straightforward manner. STATISTICA also allows complex univariate and multivariate analyses to be performed using the cell means model.

To the degree that the objectives of a study can be addressed by longitudinal analyses that essentially either model or contrast response profiles in testing hypotheses of differential change over time, software for each respective approach can be reduced to a choice between SAS or STATISTICA. SAS is the more comprehensive of the two packages and is preferred for analyses involving several communities within each treatment condition, as it allows modelling community as a random effect. SAS PROC MIXED may estimate too many denominator degrees of freedom under a certain conditions, however, and is inflexible when computing adjusted means, requiring the data to be balanced across all factors (Milliken & Johnson, 1992; Murray & Wolfinger, 1994). It is doubtful that SAS offers a substantial improvement over STATISTICA for analyses of trials involving a single community nested in one or both treatment conditions.

In contrast to SAS, STATISTICA accurately estimates denominator degrees of freedom and allows computation of adjusted means with unbalanced data for both time-constant and time-varying covariates. Quasi-mixed model analyses mimicking multi-level models can be conducted by inflating the error variance to reflect the nested community component. Such analyses are the sole option for designs involving a single community nested within any given treatment condition, using SAS or any other package. Insofar as any efficiency gain associated with likelihood-based estimation may be minor for studies with few measurement occasions, moderate or small sample sizes and more than a small amount of missing data, STATISTICA is a viable alternative to SAS when the emphasis is on data analysis rather than statistical modelling.

Summary

This chapter has reviewed methodological issues relevant to structuring and evaluating community-based intervention programmes as social experiments. From concepts of validity to the theoretical model and design and data analysis issues, social experiments involve a broad array of methodological challenges. This complexity must be anticipated and addressed if social experiments are to be perceived as viable strategies for achieving and generating knowledge about social change. Perhaps because of the difficulties involved in such initiatives, the scientific — if not social — value of community-based trials has been a topic of considerable debate.

The strength of criticisms about the quality of knowledge drawn from social experiments might be reduced by greater awareness of fundamental challenges and suitable responses for achieving scientifically sound results. Much of the material compiled in this chapter, however, has not previously been integrated under one heading. The relevant literature draws from statistical and experimental theory, and spans the disciplines of epidemiology, psychology, education and sociology. Disciplinary conditioning could inhibit widespread awareness. Nevertheless, the advancement of community-based trials for health promotion and disease prevention depends on an informed basis for conclusions about effectiveness, positive or negative.

The topics reviewed in this chapter were chosen for their relevance to the research reported in this dissertation. This exploration served to guide methodological and analytic decisions, and it provides a rationale for the strategies employed. Such an appraisal serves an important purpose because there is no single “best” way of designing, conducting and analysing a community-based trial; rather, the pathway chosen should balance contextual realities with the need for scientifically sound information and appropriate techniques for obtaining such information. Such a balance may be difficult to achieve, but the challenges need not preclude the generation of valid conclusions. Part Two describes the research undertaken and the context of the work, drawing on the material reviewed thus far in laying out the methodology employed and the research results.

PART TWO — THE OKANAGAN DIABETES PROJECT

CHAPTER 5

CONTEXT AND AIMS

The purposes of this chapter are (a) to identify and describe the demographic characteristics of the population and communities involved in the Okanagan Diabetes Project, (b) to describe the process by which the project was planned, along with background and organisational issues influencing the planning and conduct of the project, and (c) to present the goals and research questions addressed by the project.

Target Population

Provincial Context

In 1991, there were 77,705 registered Indians* in British Columbia, accounting for approximately 2.6% of the total provincial population. Of these, nearly 72,100 (93%) were members of Indian Bands or other Indian affiliations, and 37,880 (49%) resided on designated reserves and settlements (Statistics Canada, 1993a). For the same year, 41% of the general population in the province was under age 30 years, whereas 59% of provincial Indians were under 30 years of age. Of the total number of registered Indians in British Columbia in 1991, 48% were male and 52% were female, compared with an even division among males and females for the province overall.

Little information exists on the impact of diabetes among indigenous people in British Columbia. The ratio of observed diabetes deaths to expected diabetes deaths for registered Indians in British Columbia, age-standardised against rates of diabetes deaths from the 1971 Canada Census per 10,000 population, for the six year period 1987-1992, was 1.82 (Medical Services Branch, 1995, p. 117). By comparison, the provincial age standardised mortality ratio (ASMR) for diabetes deaths for the same period was 0.89. Nationally, the risk of death from

*Use of the terms *registered Indian* and *Aboriginal* in this section is in accordance with definitions footnoted on page 2. Some data are specific for registered Indians as defined under the Indian Act of Canada. Other data pertain to persons reporting Aboriginal identity, which may or may not correspond to registered Indian status.

diabetes for Aboriginal Canadians is greater by a factor of two for men, and by a factor of four for women, than the risk for the general population (Mao *et al.*, 1986).

Regional Context

The Okanagan Diabetes Project targeted on-reserve residents of the registered Indian population in the Okanagan region of central British Columbia. The Okanagan has the only semi-arid desert in Canada. Its seasons are more extreme than temperate British Columbia coastal areas. Persons indigenous to the Okanagan are part of the Interior Salishan linguistic group and the Plateau area culture (Ministry of Native Affairs, 1990). The Salishan linguistic group (combining Coastal and Interior Salishan groupings) accounts for the largest proportion (41.6%) of registered Indians in British Columbia, followed by the Tsimshian (21.7%), Athapaskan (16.9%), Wakashan (15.7%), Haidan (3.1%) and Kutenian (1.0%) groups (Medical Services Branch, 1995).

The Okanagan falls into the South Mainland Zone quadrant as defined by the Medical Services Branch, Pacific Region, of Health Canada. A 1987 survey showed that the prevalence of diabetes among registered Indians aged 35 years and older in the South Mainland Zone (5.2%) was greater than the provincial prevalence (4.5%) for registered Indians 35 years and older for all Pacific Region zones pooled (Martin & Bell, 1990). The 1987 diabetes prevalence rate for registered Indians in the South Mainland Zone was comparable to the 1987 rate for Native American communities directly south of the Okanagan region, in the state of Washington, where the age and sex adjusted prevalence of diabetes ranged from 5.2–7.5% (Freeman *et al.*, 1989). In a 1995 Medical Services Branch follow-up survey, the prevalence of diabetes among registered Indians aged 35 years and older in the South Mainland Zone was 6.6%, whereas the provincial prevalence for registered Indians in the same age group was 6.3% (Medical Services Branch, 1995). Diabetes incidence data are not available.

Health care in the South Mainland Zone, as in other Pacific Region zones, is provided by Medical Services Branch nurses with the support of community health representatives. This arrangement provides access for registered Indians to medical, dental and other services available through the provincial health care system. The Medical Services Branch also facilitates other programmes concerning nutrition, addictions, health education, communicable disease control,

environmental health services, training and health careers, Health Services Transfer activities, mental health and family violence services, and specific community-directed initiatives.

Schooling and employment characteristics for Aboriginal people in the Okanagan can be estimated from provincial Aboriginal data from the 1991 Canada Census (Statistics Canada, 1993c). Of adults aged 15-49, about 50% will have completed secondary school, and of adults aged 50-64, about 40% will have completed schooling between grades 1 to 8. Of this older portion of the population, about 26% will have completed secondary school. Of the total adult population (15 years and older) approximately 44% will be employed, 16% will be unemployed and 40% will not be involved in the labour force. The majority of adults (65%) who work for income will work at one job only, and about 30% will work at more than one job. For the provincial adult Aboriginal population, the 1991 Canada Census indicates a median income of between \$2,000 and \$9,999, with the mean income between \$10,000 and \$19,999 (Statistics Canada, 1993c).

Local Context

Three rural Aboriginal communities participated in the project. The Okanagan Indian Band, on a rural reserve 35 km west of the town of Vernon, agreed to serve as the intervention community. The selection decision was made non-randomly, on the basis of the large size and more proximal location of the Okanagan Band to Okanagan University College (the institution to which funds were awarded for the project). It was thought that the size of the Okanagan community offered a potential for public health benefit greater than might be achieved in smaller communities. Vernon is 53 km north of Okanagan University College, in Kelowna. Two smaller but demographically similar communities in the same region, the Spallumcheen and Penticton Indian Bands, agreed to serve as comparison communities. The Spallumcheen Band reserve borders the town of Enderby, 37 km northeast of Vernon, 72 km northeast of the Okanagan Band. The Penticton Band reserve borders the town of Penticton in the southern Okanagan, 120 km south of Vernon. The Penticton Band was recruited into the project after baseline screening in the Spallumcheen community, due to a low rate of participation for Spallumcheen Band members. Concern about the feasibility of a quasi-experimental evaluation required that a second community be added to supplement the comparison condition.

The 1995 on-reserve populations for the three Bands were as follows: Okanagan, 707; Spallumcheen, 331; and Penticton, 380. The Okanagan Band population distributes evenly across age intervals and between genders. The Spallumcheen and Penticton Band populations distribute evenly between genders but unevenly across age intervals: the majority of individuals in the comparison communities are less than 45 years of age (Statistics Canada, 1993a). Lifestyle, socio-economic status and education levels are similar across the three communities (Statistics Canada, 1993b, 1993c). Local economies in all three communities revolve around ranching and agriculture. Access to physician services is available in the towns of Vernon, Enderby and Penticton. Vernon is home to the North Okanagan regional hospital (Vernon Jubilee). A local hospital is available in Penticton, and limited hospital services are provided in Enderby. Standard medical and nursing follow-up was provided in all communities for established diabetes cases and for persons diagnosed with diabetes over the course of the project. The Okanagan Band received the further benefit of diabetes prevention and control strategies implemented in the context of the project. The Spallumcheen and Penticton Bands were scheduled to develop their own diabetes programmes once the study was completed.

Planning Process

Background

The impetus for the project was the community health nurse for the Okanagan and Spallumcheen Bands. Through her work and discussions with residents and community health representatives, the community health nurse had become increasingly concerned about the rising prevalence and impact of diabetes in these two communities. A review of case records for the period January 1, 1988, through December 31, 1991, indicated that the prevalence of diabetes among Okanagan Band members aged 35 years and older had increased from 3.5% to 6.4%. In the Spallumcheen community, for the same period and the same age group, the prevalence of diabetes had risen from 3.2% to 5.8%. These figures in hand, the community health nurse approached nursing faculty at Okanagan University College, in Kelowna, proposing a collaborative diabetes project linking community members, Medical Services Branch personnel and academic researchers.

The timing of the community health nurse's contact with nursing faculty early in 1992 coincided with the dissemination by Health Canada's National Health Research and Development Program (NHRDP) of a request for letters of intent on research on diabetes in the Canadian Aboriginal population. A meeting was arranged with the Band Councils in the Okanagan and Spallumcheen communities about a submission for research funds to develop and implement a community-based, community-directed project to counter diabetes. Given commitments to support the project, a five-page letter of intent was submitted in April 1992 to the NHRDP, proposing a quasi-experimental study to evaluate the impact of a project to reduce the incidence of diabetes and to improve glucose control among established diabetes cases. A two-year project was proposed, for a total cost of \$72,600. Okanagan University College was named as the institution responsible for the study, with Diane Gamble, M.N., R.N., a member of the nursing faculty, as the principal investigator. Formulation funding in the amount of \$5,000 was requested to hire a researcher (the author) to develop a full research proposal.

The NHRDP responded in August 1992, inviting a detailed proposal for formulation funding, along with an expanded description of the project and the methodology to be used. As a research associate with the Division of Health and Social Programmes at Okanagan University College, the author undertook the development of an expanded proposal for formulation funding. This preliminary proposal was approved and funding of \$5,000 was received in December 1992 to develop a full research proposal, to be submitted by March 1993. The author developed the full proposal in collaboration with members of the Okanagan and Spallumcheen communities. Meetings were held to explain the study and to foster community support. The anticipated cost of the two-year project grew from \$72,600 to \$182,124. Band Council Resolutions and letters from the Chief in each community supported participation in the project. Diabetes was recognised as a significant problem in each community, and diabetes mortality and morbidity were high in relation to the greater society. The ratio of observed diabetes deaths to expected diabetes deaths for the town of Vernon, standardised against the provincial rate of diabetes deaths, for the five year period 1988-1992, was 1.20. This standardised mortality ratio was greater than that for all-cause death, all cancer, circulatory system, ischaemic heart and cerebrovascular deaths, all of which were less than 1.00 (Division of Vital Statistics, 1992).

The full proposal was submitted to the NHRDP in March 1993. The Okanagan Band was named as the community scheduled to develop a community-directed intervention programme, with the Spallumcheen Band to serve as a comparison community. As discussed above, the Penticton Band became involved later. The research team included two nursing faculty members at Okanagan University College, the author, the community health nurse, the nurse co-ordinator of the diabetes education programme at Vernon Jubilee Hospital, and two community health representatives from the Okanagan Band. While none of the members of the research team held a doctorate, three were Masters-prepared. The proposal detailed a community-based project directed at the entire Okanagan community, although the evaluation was limited to high-risk individuals only. The project was to be of 24 months duration. The plan was to use qualitative methods as the basis for developing diabetes interventions in the first phase of the project, with both qualitative and quantitative methods to be used in the second phase to evaluate changes in levels of risk factors. The original plan to evaluate the project by reductions in the incidence of diabetes was discarded.

In May 1993 the NHRDP responded, noting that the full proposal had been received favourably by the review committee, but that additional information was required before a decision on funding could be made. This information concerned (a) sample size and statistical power calculations, (b) support for the argument that metabolic changes could be achieved within a 16 month intervention period, (c) an outline of the logic model elaborating how behavioural end-points were to be achieved, (d) further details on qualitative methods and procedures to be used to develop intervention strategies, (e) details on screening and tracking procedures, and (f) plans for handling missing data. The author addressed these issues in a letter submitted in June 1993. There was then no response from the NHRDP until March 1994 when a letter arrived at Okanagan University College indicating that the project had been funded. During this time the author had relocated to Vancouver to begin doctoral studies.

A flurry of activity began with notification of the funding award. Over one year had elapsed since submission of the full proposal, and community enthusiasm had dissipated. Considerable efforts were needed to re-build support to initiate the project in April 1994. Given the opportunity afforded for dissertation research, the author, now a holder of an NHRDP National Health Ph.D.

Fellowship, wrote to the NHRDP for permission to expand the project as the basis for a doctoral dissertation, and to undertake this work as both a fellowship holder and co-investigator. This request was granted. Between April 1994, when the project began a seven month intervention planning period, and October 1994, when baseline data were collected before implementation, the original evaluation plan was supplemented and strengthened in several areas. Additional indicators were added to the protocol for monitoring high-risk individuals, including metabolic, behavioural and psychosocial measures not considered in the original plan. Cross-sectional surveys were added to assess the impact of the project at the community level, and surveys of community systems were planned to monitor changes in norms and the social environment. As a co-investigator the author received no remuneration for work on the project.

This dissertation presents all data gathered and evaluates the Okanagan Diabetes Project in its entirety. Upon completion of the project in April 1996, a series of preliminary analyses were undertaken. A preliminary evaluation addressing the more limited objectives of the original proposal was submitted as a final report to the NHRDP later that year (Daniel & Gamble, 1996). The NHRDP accepted and endorsed the forthcoming dissertation as the primary statement on the effectiveness the project. At the suggestion of the NHRDP, the project report referenced the forthcoming dissertation. Reported here are the augmented objectives, methodology, and results for the project, based on its expansion for dissertation research.

Organisational Issues

The project was sanctioned by the Medical Services Branch, Pacific Region. The local Medical Services Branch unit co-operated fully in the development and implementation of the project, through the provision of educational resources and staff involvement. Vernon Jubilee Hospital, home of a regional education programme for persons with diabetes, was briefed and sanctioned co-operation with the Okanagan Band. The co-operation of the hospital was considered key to the success of the project, for the provision of educational resources and the potential to tailor in-house educational strategies to the needs of Aboriginal people.

Representation of the local medical community was achieved; a diabetes specialist in Vernon acted as a liaison for the project with local medical practitioners. This alliance was as

important as the co-operation of Vernon Jubilee Hospital, since changes involving diabetes case management would require the informed co-operation of local practitioners. For example, an increase in informed decision-making ability among persons with NIDDM about the merits of diet and exercise for glucose control, relative to insulin and oral hypoglycemic therapy, requires that practitioners be informed and prepared to monitor patient-motivated changes in care regimens. A practitioner liaison also served to buffer irregular reactive criticism from local medical practitioners.

Faculty at Okanagan University College supported the project, as collaborative research driven by social needs, and as a means to involve nursing students in community-based health promotion research. Some difficulties were encountered, however, with the University College administration, which was reluctant to bear the overhead cost of administering the grant. Further, mechanisms were not available to enable the partial release of nursing faculty from teaching and clinical responsibilities for work on the project. These organisational difficulties were only partially resolved. Granting agencies do not allow budgeting for the overhead associated with grant-funded research projects, though they do for contract research. Such costs are expected to be borne by institutions responsible for the research. Comprehensive infrastructures support research as a primary activity in large universities, but administrative support is limited in smaller institutions with a primary focus on teaching. Major granting agencies will not provide salary support for investigators with academic positions, even if reductions in academic responsibilities can be negotiated. The University College eventually agreed to administer the grant, but nurse researchers were hard-pressed to commit as much time as they wished to the project.

The issue of sufficient time to commit to the intervention process was an organisational concern from the time of inception of the project. A collaborative arrangement between academic researchers, community representatives and workers, and representatives from Vernon Jubilee Hospital and the Medical Services Branch required that all stakeholders be able to contribute fully through active participation. Because a detailed understanding of research methods, theory and previous research on the problem was limited among practitioners and community collaborators, it was necessary that academic researchers be able to contribute technical expertise in a variety of areas. Beyond using technical skills in planning and to obtain grant funds, further contributions were required to stimulate community change processes and to promote community initiative as

the project progressed. Such actions were expected to include: (a) facilitating the establishment of co-operative working relationships among community groups; (b) encouraging the creation of self-maintaining community problem solving structures; (c) stimulating efforts to promote interest and participation in community affairs; (d) fostering collaborative attitudes and practices; and (e) encouraging and facilitating the development of indigenous leadership. Such contributions would be expected to relate to the development and implementation of community-directed initiatives against diabetes, and the penetration of various interventions across the community.

Goals

The goals of the project were to contribute to improvements in the health of an Aboriginal population through better understanding of ways: (a) to facilitate meaningful community participation; (b) to develop and implement interventions against diabetes in response to needs and processes identified by community members; (c) to monitor and evaluate individual and community-level responses to actions and processes to reduce levels of risk factors for diabetes; and (d) to provide a model framework for successful control and reduction of diabetes risk factors that could be adopted for use by other communities.

Research Questions to be Addressed

The research questions focused on the effectiveness of the project at several levels of analysis. Primary questions addressed the extent to which the 24-month community-based, community-directed diabetes prevention and control programme was effective in achieving:

- (a) individual risk reduction among "high-risk" individuals with or at familial risk for diabetes, as measured by improvements in (i) physiological, anthropometric and behavioural variables and (ii) psychosocial constructs associated with self-efficacy and well-being;
- (b) individual coping among individuals with diabetes and impaired glucose tolerance, as measured by improvements in (i) quality of life, (ii) beliefs associated with self-care behaviours, and (iii) knowledge of diabetes symptoms, risk factors and complications;

- (c) community-wide diabetes risk reduction, as measured by aggregate individual-level improvements in (i) diabetes knowledge, (ii) awareness of the project, and (iii) behavioural and anthropometric risk factors for diabetes; and
- (d) social environmental change, as measured by (i) sub-system actions in support of the project by community groups, (ii) interactions and sustained relationships between sub-system groups and supra-system organisations outside the community, and (iii) whole system shifts in community norms and values supporting healthful living.

Secondary questions were contingent on positive changes as assessed by the primary research questions. Specifically, at the level of individuals, secondary questions sought to establish (a) the nature of relationships between changes in psychosocial, behavioural, physiological and anthropometric variables, and (b) to determine whether these relationships were consistent with patterns predicted by theory. At the level of the community, secondary questions sought to assess whether aggregate individual-level improvements in knowledge and awareness co-varied with positive changes in behavioural and anthropometric variables. Changes among individuals were also to be appraised in relation to changes in the community environment.

This chapter has described the population and communities involved in the Okanagan Diabetes Project, as well as contextual issues related to the planning and conduct of the project. The goals and research questions addressed by the project have also been outlined. The next chapter presents the methodology used by the project.

CHAPTER 6

METHODOLOGY

This chapter describes the methodology used to address the goals and research questions outlined in the previous chapter. The design and sampling strategies are described first. This is followed by a review of the theoretical model on which the project was founded. The programme logic model or “treatment” theory by which effects were to be achieved is described, along with the manner by which formal theory and previous research were applied in the community context. A section on methods and procedures covers issues ranging from the development of interventions — using qualitative methodology — to intervention implementation, monitoring and programme evaluation, data preparation and statistical analysis. Measurement procedures for the cohort, cross-sectional and community systems surveys are described in detail.

Study Design

The study was structured to test the effect of a community-directed diabetes prevention and control programme at the population level. The design was a variation of the quasi-experimental non-equivalent control group design (Campbell & Stanley, 1963). The presence or absence of conditions to enable and facilitate a community-directed intervention programme was the independent variable manipulated. The Okanagan community was nested within the intervention condition, and the Spallumcheen and Penticton communities were nested within the comparison condition. As discussed, communities were non-randomly assigned to conditions. Most measures were taken at the level of individuals. Since communities, however, were the unit of allocation by which aggregates of residents were assigned to conditions, the “participants” were naturally assembled collectives of people. As a consequence of this allocation process, individuals were not independent. Outcomes included knowledge, physiological, behavioural and anthropometric risk factors, and psychosocial constructs.

The evaluation involved contrasting change over time between participants in the intervention and comparison conditions while controlling for the nesting of (a) communities within conditions and (b) individuals within communities. The null model projected no programme effect and hence no difference over the 24-month project between the intervention and comparison conditions. An initial pre-intervention period of seven months' duration involved worker training and qualitative data gathering, during which knowledge, attitudes and cultural values were explored in relation to potential diabetes prevention and control strategies. At the beginning of the eighth month, baseline measures were obtained using three sampling strategies. Programme implementation then began in the intervention community. A population approach was taken to prevention and control. Changes were monitored over the next 16 months for "high-risk" individuals and at the level of communities and the social environment. Repeated measures were made for "high-risk" individuals at the midpoint and end of the project. A single follow-up was made for aggregate community-level measures at the end of the project.

Sampling and Participant Selection

Three sampling strategies were used: (a) a longitudinal follow-up in each community of "high-risk" cohorts; (b) cross-sectional community surveys; and (c) systems surveys in the intervention community. Each of these strategies is described below. All participants provided their informed, written consent. Pregnant women and minors under the age of 18 years were excluded from the project. The research protocol was approved by the Okanagan University College Ethics Committee and the University of British Columbia Behavioral Sciences Screening Committee.

Cohort Surveys

The purpose of using cohort samples was to isolate programme effects on individual-level risk factors for diabetes prevention and control. Although most, but not all, intervention strategies were to be applied to the community overall, the goal of changing levels of risk factors among individuals at particular risk for diabetes and its complications was weighted more heavily than the related goal of changing the prevalence of diabetes risk factors at the community level. This strategy reflected the greater potential for change among individuals at risk for diabetes, and the

potentially greater efficiency of this approach, at least in the short term. Most measurement efforts were therefore directed towards tracking changes among cohorts. In Norway, the Finnmark County Study intervention on cardiovascular disease risk factors used a similar approach, invoking a high-risk strategy based upon screening tests and individual-level interventions in the context of a health education programme directed at all residents of the county (Tretli *et al.*, 1985).

“High-risk” cohorts composed of persons with established diabetes and first and second degree relatives of diabetes cases were assembled in each community. Recruitment began with meetings in the intervention and comparison communities to explain the study and to foster community support. Recruitment and selection strategies in the intervention community did not differ from those applied in the comparison communities. Persons with established (physician-diagnosed) diabetes were identified using records maintained by Medical Services Branch units. Cross-referencing these records with Band membership lists, community workers constructed family pedigrees for all individuals with established diabetes; they also identified persons related to non-residents with diabetes. Diabetes cases and individuals at familial risk were approached about participating in three waves of data collection to be conducted at the intervention baseline, at mid-intervention 8 months later, and at the end of the intervention after 16 months.

Although the target population for cohort samples was on-reserve diabetes cases and relatives of individuals with diabetes, the sampling frame could not be determined precisely. From Medical Services Branch records, the research team could document 20 cases of established diabetes in the Okanagan community, and 16 and 4 cases each, for Spallumcheen and Penticton respectively. The total population of first and second degree relatives of individuals with diabetes could not be verified by academic researchers, however, because Band membership lists were accessible to community workers only. Sample size calculations (Appendix A) suggested that the *optimal* number of participants for each of the two conditions was 172. Calculations assumed a moderate programme effect and risk of Type I (α) and Type II (β) errors of 0.05 each. A moderate effect was taken to be that in which the difference between conditions is half the standard deviation (Cohen, 1977). The variance attributable to individuals was inflated by a factor of two to account for clustering. Community workers estimated that for each known diabetes case, four to five on-reserve residents qualified as first or second degree relatives. Power estimates were

therefore calculated based on 90 individuals per condition. Assuming a moderate programme effect, with $\alpha = 0.05$ and variance estimates doubled for clustering, statistical power was estimated at 0.77 ($\beta = 0.23$). This level of power was deemed sufficient to proceed with recruitment.

All participants were recruited through face-to-face meetings with community workers, and all participants were volunteers. It was not possible to select randomly individuals for participation in cohorts. Certain commitments and assurances were made to participants in the comparison communities, verbally by community workers, and in writing in information packages by academic researchers. These were that (a) participants would not receive an intervention programme, but (b) all results would be made available to them, and (c) their community would be offered the opportunity to develop its own diabetes prevention and control programme upon completion of the project. It was also emphasised that standard medical and nursing care would continue to be available to all residents of the comparison communities.

Cross-Sectional Surveys

Cross-sectional surveys were conducted to assess the impact of the project at the community level, distinct from changes among “high-risk” cohort samples. The target population was the on-reserve adult population aged 18 years and older in each of the three communities, given as follows: Okanagan, 475; Spallumcheen, 212; and Penticton, 238. The sampling frame was up-to-date Band membership lists that identified individuals as the sample units. Band membership lists were reviewed by community workers for completeness, and duplicates and out-of-scope persons (e.g., individuals who had moved, or who were not on-reserve residents) were removed prior to sampling. Each membership list contained sufficient information to identify and locate each person (e.g., an address or a telephone number). Two cross-sectional surveys were conducted, one at baseline (just prior to intervention), and the other 16 months later at the end of the intervention. Surveys were conducted in each community approximately two weeks following the first and final waves of data collection from the “high-risk” cohorts. Data collection was conducted either by telephone for homes with service or by home visit for those without telephone service.

Simple random sampling was used to select individuals to be surveyed. Thus, each individual in the target population in each community had an equal chance of being selected. Between the two conditions, the probability of selection was set at 0.2. This setting allowed oversampling to account for an estimated response rate (r) of 0.70, yet the probability of selection was low enough to avoid saturating communities with surveys and to reduce the expected size of overlapping samples where individuals selected for participation in the baseline survey might also be selected for participation in the end-of-project surveys. For each condition, the adjusted sample size (n') (93 individuals) was calculated from the efficient sample size (n) (65 individuals) by way of the equation $n' = n/r$. The efficient sample size was determined through calculations of statistical power (Appendix A), with both α and β set at 0.05, based on being able to detect an increase in the prevalence of regular physical activity (more than once per week) from 40% to 80%. The variance of the change in prevalence was inflated by a factor of two to account for clustered observations within communities (thus increasing the size of the sample required).

Although statistical power is the relevant concern for an analytic study, the level of the precision of the estimates was also considered to be important. Taking ± 0.10 as the maximum permissible error (ϵ) at a 95% level of confidence, sample size was calculated to guarantee this level of precision for a population proportion of $p = 0.50$ to assess the maximum size that would accommodate all ranges of population proportion estimates (Wang *et al.*, 1995). The average number of eligible individuals to be surveyed across conditions was calculated as $475_{\text{Okanagan}} + (212_{\text{Spallumcheen}} + 238_{\text{Penticton}}) + 2 = 463$. Thus,

$$n \text{ (95\% level of confidence)} = \frac{2.706 N (p - p^2)}{(N - 1) \epsilon^2 + 2.706 (p - p^2)}$$

$$= \frac{2.706 (463) (0.5 - 0.5^2)}{(462 - 1) 0.1^2 + 2.706 (0.5 - 0.5^2)} = 60,$$

which is less than the efficient sample size required (65) as determined by power calculations.

Adjusted sample sizes for the comparison communities were determined by weighting the overall size required for the comparison condition (93) by the number of persons participating in these communities in baseline cohort measurements relative to the number participating in the Okanagan intervention community. Thus, since participation in cohorts in Spallumcheen was two-

thirds that in Okanagan and participation in Penticton was one-third that in Okanagan, the sample sizes for the two comparison communities were determined to be 61 and 32, respectively.

To select random samples from lists of eligible Band members in each community, workers assigned each member an identification number. Samples were selected by: (a) selecting a random start in a table of random numbers; (b) using the number of digits in the random number table that was equal to the number of digits in the highest identification number; (c) selecting each population member that had a number corresponding to the random number selected; (d) discarding any random number that did not have a corresponding number in the population; and (e) repeating the process until the required number of members had been selected (93 for Okanagan, 61 for Spallumcheen, and 32 for Penticton). Community workers, not researchers, were responsible for the actual selection process, since Band membership lists were available only to workers. Procedures were reviewed in detail, using sham lists.

Community Surveys of Systems

The purpose of systems surveys in the intervention community was to supplement community-level assessments involving aggregates of measures made on individuals. Aggregated individual-level data enable monitoring specific responses to interventions, but are not representative of whole-system changes in the social environment. Other kinds of measures were used to assess changes in community systems.

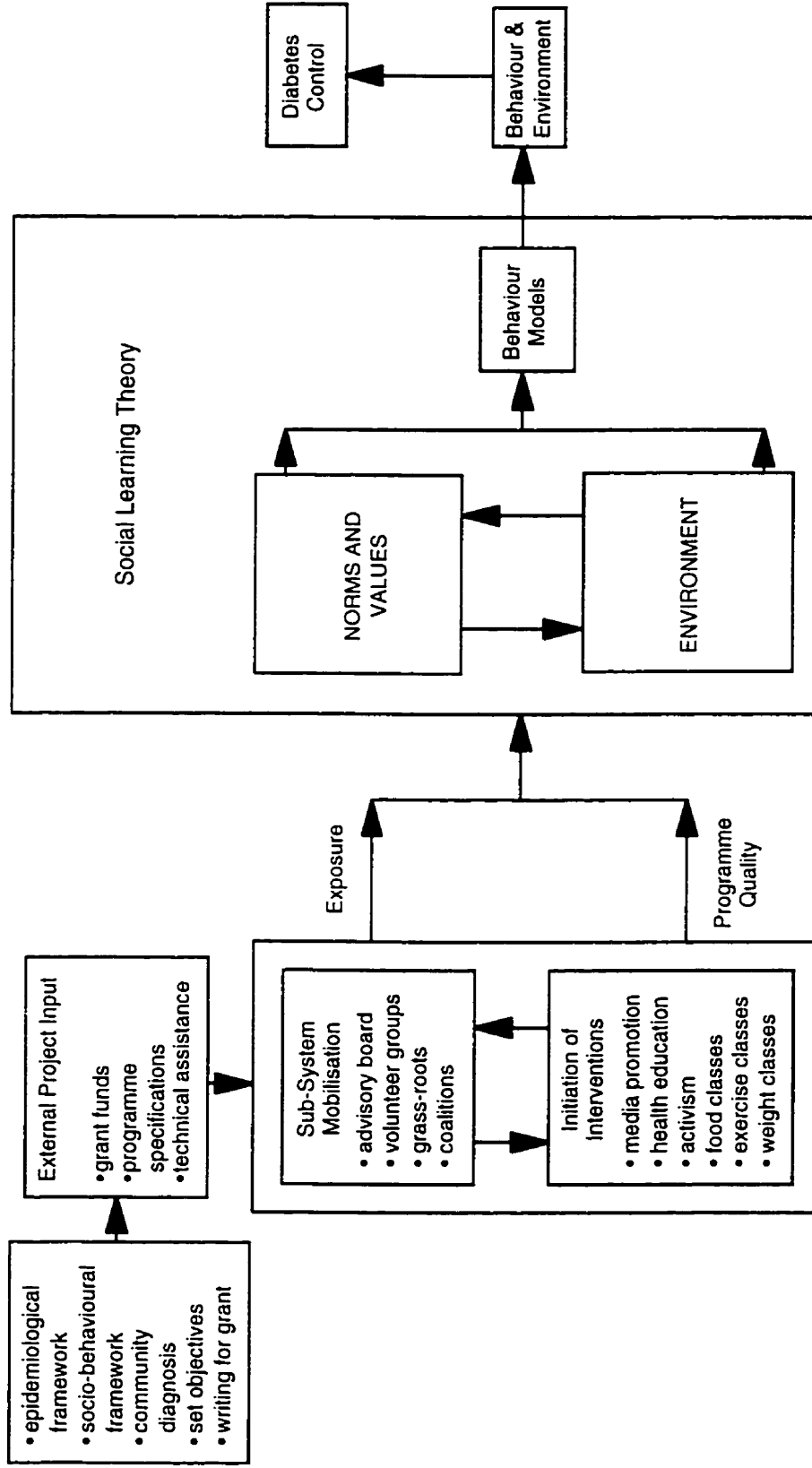
Systems surveys were undertaken at three strategic periods throughout the project: (a) during the pre-intervention planning phase (project months 0-7); (b) during the early intervention phase (project month 12, or, analogously, intervention month 4); and (c) during the late-project phase (project month 20, or, analogously, intervention month 12). Surveys were conducted during special meetings involving researchers, project workers, community health nurses and community health representatives. The respondents were community-level research personnel who were residents in the community.

Theoretical Model

The project was modelled on the conceptual framework guiding the Henry J. Kaiser Family Foundation's Community Health Promotion Grants Programme (Wagner *et al.*, 1991). The theoretical model (Figure 2) specifies the basic pathways by which the project was to achieve its objectives. The programme or "treatment" theory was that interventions developed, implemented, and controlled by community members would facilitate and promote personal and collective efficacy, whereby people work together to effect change at the community level. It was hypothesized that a community-directed, culturally appropriate diabetes prevention and control programme would invoke positive psychosocial responses associated with positive behavioural, physiological, anthropometric, and environmental outcomes. The Precede-Proceed model was used as a guide for planning, implementation and evaluation (Daniel & Green, 1995). Specifically, the Precede-Proceed model helped to focus the application of socio-behavioural theory and previous research to guide strategies for change processes. The Precede-Proceed model also had been used in the development of the Kaiser Family Foundation community programmes and their evaluation (Green & Kreuter, 1991).

Social Learning Theory served as the foundation for the intervention programme in directing attention to the development of programme components that would provide realistic modelling of positive behaviours and change processes (Bandura, 1977). Social Learning Theory recognises the power of family, mentors and peers, as well as other external forces, as part of every individual's environment. It also recognises the inherent ability of individuals to stand back and look critically at their environment and deal with it. Aboriginal values tend to emphasise the needs of the group rather than those of individuals (Brant, 1990). Social Learning Theory linked the promotion of self-belief and individual efficacy to collective efficacy. Reciprocal determinism suggested that improvements in individual and collective efficacy could predispose and reinforce behavioural and enabling environmental changes. Integrated concepts from other theories and models of health behaviour were also applied; specific examples are outlined in the section on methods and procedures. Models of community change were used in both the planning and process phases of the project.

Programme Planning Community Activation Programme Inputs Behavioural and Environmental Change Process Programme Outputs



Month 0 Month 3 Month 6 Month 9 Month 12 Month 15 Month 18 Month 21 Month 24

Figure 2. Theoretical Model by Month of Project. (Adapted from Wagner *et al.* (1991). The evaluation of the Henry J. Kaiser Family Foundation's Community Health Promotion Grant Program: design. *Journal of Clinical Epidemiology*, 44(7), 685-699.)

Programme planning activities were undertaken with the active involvement of people in the intervention community. This process drew on and applied the epidemiological data and socio-behavioural theories reviewed in previous chapters. External input involved the technical assistance of academic researchers (the author and two nursing faculty members at Okanagan University College) to obtain research funding and to outline programme specifications (Figure 2). In collaboration with community groups and leaders, strategies were developed to “activate” and “mobilise” the community to initiate interventions involving media campaigns, health education, activism and training. These activities were directed towards achieving and disseminating quality intervention components, conceived as programme inputs. Exposure to inputs provided the basis of a behavioural and environmental change process targeting structural modification of the social environment and changes in norms and values. These shifts were intended to predispose, enable and reinforce modelling healthful behavioural and environmental change. Anticipated outcomes of this process, conceived as programme outputs, were positive shifts in psychosocial constructs, health behaviour, environment, and clinical variables related to diabetes control.

Methods and Procedures

Development of Intervention Strategies

The activities described in this section correspond to the “community activation” phase illustrated in Figure 2. During this phase, intervention community workers and participants, not external researchers, developed all programme initiatives during a seven month pre-intervention period. The relationship between indigenous community workers, external researchers, health personnel and community representatives was such that a collaborative approach based on principles of participatory research (Green L.W. *et al.*, 1995) prevailed at all levels of the project. A particular concern among representatives of the intervention community was that a diabetes prevention and control programme not be imposed, but that diabetes interventions be generated and implemented by the community. This concern with autonomy and control over health issues is aligned with the literature on quality of life and empowerment (reviewed in Chapter 2). Related principles of operation were that Band members conduct most of the field work, and that social and cultural issues important to the community be respected and given precedence in planning

and implementing interventions. The Okanagan vision statement was as follows: "A community empowered through responsibility for and control over diabetes, through a focus on Aboriginal cultural health belief and value systems associated with the principles of holism and balance."

The Ecological System Perspective (Fellin, 1987) of community organisation was used to focus initial attention on population characteristics including size, density, and the social structure of the community. In seeking to develop culturally acceptable diabetes prevention and control strategies, it was also necessary to determine how the community perceived the disease *diabetes* and what might be done about it. To accomplish this task, the community was engaged in a two-part self-study of perceptions and needs regarding diabetes. The first part of the process applied an updated version of the social reconnaissance method (Felix, 1990) originally developed in Boston in the 1930s by Erwin Saunders (Nix & Seerly, 1971). Data on the prevalence and community impact of diabetes were presented at public meetings with the Band Council, Band members and elders. A Social Systems Perspective was used to frame the community impact of diabetes in terms of interactions between economic, political and social changes in the external environment (Fellin, 1987). Opinions and attitudes were assessed about history, institutional, environmental and individual relationships. Challenges and barriers to conducting the project were appraised. Because these initial task-oriented activities were guided primarily by external researchers, the initial part of the activation phase was aligned with the Social Planning model of community change (Rothman & Tropman, 1987).

The second part of the self-study process involved recruiting (hiring) community workers to promote participation in the study, to conduct interviews with key individuals and, ultimately, to be responsible for championing diabetes prevention and control initiatives. The purpose of the interviews was to identify common needs regarding diabetes as defined by community members, and to promote collective problem solving, collaboration and co-ordination among community sectors and groups. These activities provided information while stimulating the mobilisation of people within the community to make decisions on the information they provided. This focus set the tone for the remainder of the project, which was process-oriented and intended to enable people to take control of their lives and environment. The aim was to facilitate community competence (Iscore, 1980), integration and capacity-building (Ross, 1955) in diabetes prevention

and control. The community organisation emphasis shifted from the Social Planning model to the Locality Development model (Rothman & Tropman, 1987) soon after the activation phase began, but the two models were blended throughout the project. Themes of voluntary co-operation, self-help, indigenous leadership and educational objectives promoted the active participation of the community and reliance on community initiative (Poland, 1996).

Worker Training

Given adequate training, there is strong support for using indigenous community health workers in data collection and health education (Office of Disease Prevention and Health Promotion, 1987). Indigenous community workers can improve resident compliance and data sensitivity and reliability for health promotion initiatives in distinct ethnic groups (Gottlieb & Green, 1987).

Several studies have demonstrated the value of lay health educators in producing evidence of behaviour change in populations with distinctive cultural features (Brownstein *et al.*, 1992; Dignan *et al.*, 1996; Lacey *et al.*, 1991). In this project, two indigenous health workers were hired per community, and agreements were reached to enable the active involvement of community health representatives (funded through the Medical Services Branch). Office space and telephones for use of the community workers were made available at the Band Council office in each community.

Health workers and community health representatives underwent an intensive three-week training programme at the outset of the project at a regional training centre and retreat. Because interviewing and interacting with people would involve a large part of the day-to-day activities of the workers, the training programme targeted psychosocial interviewing skills and group dynamics principles (Lieberman *et al.*, 1980; Yalom, 1975) in combination with similar ethnographic interviewing techniques based on participant observation (Denzin, 1989; Fetterman, 1990). Sessions focused on how to establish rapport and facilitate use of self; that is, to perceive what questions to ask and how, while simultaneously using listening skills. Knowledge of diabetes and instruction in genealogy was also provided.

Diagnostic Pre-Intervention Interviews

Upon completion of their training, workers in the intervention community were equipped with tape recorders for interviews with key informants; tapes were later transcribed for analysis. Working from lists of known cases, workers approached and interviewed Band members with established diabetes. An ethnographic approach was used to document knowledge, attitudes and cultural values about diabetes and general health. Risk factors for the development and control of NIDDM were introduced and discussed, and perspectives sought on challenges, barriers and solutions to diabetes prevention and control. Workers also interviewed Band members at familial risk for NIDDM and Band Council members and elders. Only Band members living on-reserve in the Okanagan community were interviewed.

The interview structure was similar for persons with diabetes and others who did not have the disease. Researchers made suggestions to assist workers in applying theory and previous research to the selection of questions to be asked during interviews. Questions that explored individual barriers to behaviour change, and strategies for improving people's level of self-belief about their ability to behave in ways necessary to produce desired outcomes, were based on the concept of self-efficacy (Bandura, 1986). Questions about susceptibility to diabetes and the severity of the disease, and people's perceptions of the benefit of community-directed interventions, derived from the Health Belief Model (Rosenstock, 1974). The Theory of Reasoned Action was the basis of questions exploring beliefs and intentions about physical activity and healthful eating, and perceptions of the importance of these behaviours to diabetes prevention and control (Carter, 1990).

A total of 59 interviews were conducted in the intervention community. Seventeen of 20 individuals with established diabetes were interviewed; three individuals with diabetes refused to be interviewed. Forty-two interviews were conducted with persons who did not have diabetes, including first degree relatives of persons with diabetes, elders, Band Council members and Band members-at-large. Beyond an effort to target people with diabetes, systematic sampling was not used, nor were probability sampling procedures used. Workers decided who to interview. The pool of persons surveyed was technically a convenience sample. Theoretically-based, purposive selection, however, is fundamental to qualitative research that seeks to describe phenomena by

analytic rather than enumerative induction (Brannen, 1992). Analytic induction is often employed in ethnographic work (Hammersley & Atkinson, 1983). The basic question in theoretical “inductive” sampling is which case or group to turn to next and with what theoretical purpose. Once the pool of diabetes cases had been exhausted, workers selected informants on a case-by-case basis, seeking individuals who could address unanswered questions and help form links between isolated concepts. This continued until workers felt they had reached a point where further information could not be achieved by additional interviews (i.e., “theoretical saturation”).

Features of analytic induction are shared with grounded theory (Glaser & Strauss, 1967), but the two approaches are not the same. A major difference is that analytic induction is geared towards developing and assessing relatively straightforward explanatory hypotheses in a manner closer to the hypothetico-deductive method that characterises epidemiological research (Buck, 1975). In contrast, the intent of grounded theory is to represent concrete situations in their complexity and to produce (and sometimes test) abstract theory (Hammersley, 1992). Qualitative sampling criteria (Morse, 1989) suggest that whatever the theoretical approach used, the choice of informants should be in keeping with the objectives stated (i.e., the sample should be “appropriate”) and that the information collected be relevant, complete and sufficient in magnitude (i.e., the sampling should be “adequate”) to meet the objectives stated. These criteria were addressed by selecting informants with perspectives relevant to community-based diabetes prevention and control, focusing on beliefs, values and knowledge in relation to meaningful intervention strategies.

Qualitative Analysis

Consistent with qualitative methods (Chenitz & Swanson, 1986; Strauss & Corbin, 1990), data collection and analysis of recurrent themes and factors took place concurrently as community workers and researchers assessed incoming data. The analysis was done manually, without using qualitative data analysis software. Tapes and transcripts were reviewed and the content of the data analysed, focusing on informants' perceptions of diabetes aetiology and pathophysiology, health beliefs, attitudes, values, and benefits and barriers to community-based actions. Thus, elements of intervention strategies were identified from issues raised by community members in

their own words. These perspectives reflected personal and cultural beliefs, attitudes, values and knowledge of diabetes, and perceptions of factors hindering and facilitating the achievement of health and quality-of-life issues.

The accuracy of transcriptions of interviews in relation to audio recordings was assessed by reviewing both at the same time, for a subset of the data (42 of 59 interviews overall). Phrases or statements relating to content areas were coded and grouped according to code. Categories emerged, comprising more than one code and indicating relationships between codes. These categories were grouped into themes reflecting relationships between categories. The validity of themes and categories was assessed by verifying informants' stories and researchers' interpretations and observations. Constant comparative analysis was used to restructure and focus issues. This procedure entails constant comparisons of informant to informant, informant to emerging category, category to category, and categories to theory and previous research on the issue of concern (Swanson-Kauffman, 1986). The process was emergent, in that the focus was continually refined to provide a deeper understanding of knowledge, cultural values and attitudes toward diabetes. Although contraindicated in some traditions of analytic empirical research, the flexibility and responsiveness of an emergent process is an essential feature of humanistic, nonreceived view research that seeks to understand meaning from the subjects' perspective (Cobb & Hagemaster, 1987; Munhall & Oiler, 1986; Spradley, 1979).

The benchmark against which qualitative analyses were assessed is the concept of *rigour*, defined as the sum of its components: credibility, fittingness, auditability and confirmability (Sandelowski, 1986). *Credibility* relates to the immediate recognition of interpretations representing a given human experience by the persons having that experience, as their own. Credibility was addressed by the verification and validation of qualitative themes and categories, and the suitability of potential intervention strategies, by the individuals interviewed as well as by members of a community advisory committee (eight people). *Fittingness* reflects the degree to which the findings are meaningful and have application; fittingness was addressed by seeking and incorporating criticism and comments from community health workers and the community advisory committee into the data analysis procedure. *Auditability* refers to the relative clarity of the methodological reasoning process defined and followed during data analysis; other researchers

should be able with clarity to follow the process. *Confirmability* was addressed through the review of portions of the data collected by an experienced qualitative researcher not involved in the main analysis, to determine appropriateness.

Knowledge, Attitudes and Cultural Values

Knowledge of diabetes was limited, in terms of comprehension of diabetes symptoms, aetiology, pathophysiology and prevention strategies. Participants knew the disease was related to blood sugar but only a few understood the link to insulin. Although a number of diabetes cases had hypertension, stroke and heart disease, they tended to view diabetes as a separate entity that was unrelated to other conditions. Poor diet, especially the consumption of too much sugar or too much alcohol, was seen to result in problems with blood sugar. Many individuals attributed a shift away from traditional foods and the development of a culture of “can opener cooks” as a major factor in diets that were not healthful. Some individuals identified heredity as a factor in diabetes development. Obesity was also seen as a causative factor. Further, stress was seen to cause the body to break down and not have the defenses to deal with diseases such as diabetes.

There were clear issues with how and what information was presented by physicians. The prevailing perception was that local physicians do not provide sufficient information to Aboriginal people. Individuals were hesitant to ask questions because they perceived themselves to lack basic understanding of the disease. If they did ask questions about tests or results, explanations were not provided in a way that acknowledged the subjective meaning diabetes held for these individuals. Participants were also uncomfortable attending diabetes educational programmes at Vernon Jubilee Hospital because the programmes were developed for non-Aboriginal people and did not address the unique circumstances and special needs of Aboriginal groups.

It was apparent that most knowledge of diabetes was learned from social communication with family and friends. Thus, individual experiences with the disease influenced the meaning diabetes held for the community as a whole. There were many misconceptions about diabetes, ranging from a belief that diabetes was a death sentence to concerns that it was a contagious condition. These misconceptions were accompanied by a sense that there was nothing that could be done to prevent diabetes and little that could be done to alter its course when it

occurred. These were powerful images that many individuals felt prevented them from enacting lifestyle changes. Further, these images tended to contribute to diabetes being viewed as an individual and personal problem. Diabetes was seen to be a result of "bad" lifestyle choices, and individuals tended to personalise this and feel that they were somehow "bad" individuals.

These perceptions led to attitudes of denial, resistance and lack of acceptance of diabetes. Lack of awareness further hindered the ability of people, individually and collectively, to be able to respond to diabetes in a proactive manner. People acknowledged that increased awareness of diabetes and its related issues could result in greater sharing of information and the ability to make positive lifestyle changes. They were concerned that information directed at the administrative levels of the Band did not always find its way to people in the community. Some individuals with diabetes were not aware of health resources available through the Band. Others did not know about the Diabetes Day Programme at Vernon Jubilee Hospital; neither their physicians nor anyone else had informed them of it. There was a general sense of not knowing what to do about living with or preventing diabetes.

Aboriginal values that were evident were those of non-competitive sharing, familial and communal support, and hospitality. Standard recommended clinical interventions were often seen as isolating individuals from their peers by causing them to be different or refuse hospitality. For example, in social settings people were unhappy when not able to participate in culturally dominant ways of eating. As a result, these interventions were viewed as punitive and inhibited others from making positive behavioural changes. Further, the perceived punitive nature of these interventions was incongruent with the Aboriginal value of non-judgement. There was a strong belief that healthful lifestyle behaviours needed to be normalised in the community so diabetics would not be singled out. As well, there was a strong sense that any strategy developed must draw from the knowledge of past generations and contribute to the health of future generations. A recent comprehensive qualitative analysis of issues related to diabetes among the James Bay Cree (Boston *et al.*, 1997) was consistent with each of the findings reported here.

Needs and Strategies for Diabetes Prevention and Control

The results of the qualitative analyses can be viewed as a local theory or model which emically^{*} frames the community situation and thus may serve as a template for directing the intervention process (Elden, 1983). The greatest need identified in the interviews was awareness of options and opportunities for healthful living. Therefore, provision of information on diabetes aetiology, complications, prevention and management was a major intervention process and intermediate objective. Specific strategies recommended included the provision of information about healthful diets and exercise programmes that assisted in weight control. It was acknowledged that diverse presentation formats were needed to address various participants' needs. A common theme was that any intervention needed to include a social component, occur in a non-threatening environment and be fun. To this end, the majority of activities planned occurred on-reserve, were participant-directed, and included refreshments.

Before baseline testing, diabetes was seen as an individual problem of concern only to those experiencing it. This perspective served to isolate individuals. Many persons with diabetes were not referred by their physicians to appropriate sources of information, resulting in further isolation. Peer support was identified as crucial in reducing isolation, normalising the experience and providing needed information and coping strategies. Interventions thus targeted the provision of information framed within the context of the larger community's role in creating an environment conducive to diabetes prevention and control. It was advisable that information be provided in a manner that stressed individual and community strengths and capabilities to deal with diabetes. Strategies were needed that would increase awareness and generate support for the programme, and provide opportunities for participation in activities and actions promoting healthful lifestyles.

It was clear that information coming from outside sources must reach beyond administrative levels to the general Band membership. This is important because people cannot be influenced by materials or initiatives of which they have no awareness. Promotion of general membership involvement is challenging because people resent and avoid participating in "top down" attempts

^{*}From *emic*, originating in cognitive anthropology, and used to refer to first-order concepts such as the local language, concepts, or ways of expression used by members of a particular group or setting to frame their experience. A contrasting distinction, *etic*, refers to second order concepts such as the language used by researchers to describe the same phenomena. The distinction is relevant to an effort to perceive "insider's" perspectives while linking these to scientific, technical or practical aims, through a dialectic of experience and interpretation (Schwandt, 1997, pp. 35-6).

to deal with issues. As people are sensitive to co-optation and imposition from above, there was a need for grass-roots efforts and norms supporting shared processes and voluntary co-operation. Similar needs were identified among the James Bay Cree (Boston *et al.*, 1997) as important for diabetes prevention and control.

Intervention Implementation

Initiatives that evolved and were implemented in the intervention community can be grouped into (a) educational and activity-oriented responses intended to predispose, enable and reinforce behaviours for the prevention and control of NIDDM, and (b) environmental actions in support of behavioural interventions and recommended behaviours. These initiatives and the results of qualitative analyses are reported here in the Methodology chapter rather than in the Results chapter, as inputs in the theoretical model by which the project was to achieve its objectives. The outcomes of the community change process, conceived as outputs, are reported in the Results chapter (see Figure 2 for distinctions between programme inputs and outputs). Both inputs and outputs can in some sense, however, be seen as “results.” The adequacy of implementation is reviewed in the Discussion chapter, in terms of relationships between inputs and outputs.

Intervention implementation began immediately after baseline screening. All strategies required time before nearing their effective potential. Overall, the actualisation of initiatives was variable and, in some cases, incomplete. Most initiatives were targeted at the entire intervention community. Some initiatives, however, were specifically tailored for persons with diabetes (e.g., diabetic support group meetings, and changes in the Diabetes Day Programme at Vernon Jubilee Hospital). Small and attainable accomplishments were emphasised to promote mastery through a sense of achievement. Simply showing up to take part in activities was rewarded with positive responses. Great personal strides were publicised in an acceptable way, to motivate and allow modelling of behaviour by others. Prizes and certificates were provided for many activities, as cues to actions that, it was hoped, would become internally sustaining over time.

Interventions for Behavioural Change

A variety of activities were implemented to counter obesity, physical inactivity and inappropriate

diet. Weekly aerobics classes were started for men and women in a local hall, led by community workers. For less robust individuals a weekly "Gentle Exercises" group was initiated, involving chair exercises and light movement. A walking group formed for regular walks outdoors during the warmer months, and indoor walks through shopping malls in Vernon (35 km away) during the winter months. These activities led to the formation of a "100 Mile Club" to promote walking for health; competitive and non-competitive prizes were offered, and a competition held to select a logo for the club. A four-day "Fun-o-Rama" and "Fit Fest" was held during the second summer of the project; this event involved diabetes and health-related educational demonstrations, information and group activities, and culminated with the formation of several eating, activity and smoking cessation groups that remained active beyond the completion of the project.

Workers organised weekly get-togethers on nutrition and healthful eating: individuals from the "Community Kitchens" organisation gave group demonstrations on planning and preparing low-fat, nutritional menus, emphasising cooking for single persons and large groups with limited financial resources. Workers also recruited professional speakers and organised community forums on healthful eating, weight control and active living. Monthly supermarket and restaurant tours with nutritionists were conducted in Vernon, resulting in several requests to managers for more healthful fare. Discussion of lifestyle issues (nutrition, weight control and exercise) was incorporated into the local "Nobody's Perfect" parenting group. A monthly Diabetic Support Group was started and run by nurses, and regular attendance promoted for diabetics at the diabetes day programme at Vernon Jubilee Hospital. These activities and actions were intended to facilitate the development of personal self-care and skills for healthful living.

As data were collected and preliminary analyses undertaken, the research team hosted public meetings to present and discuss the implications of aggregate community results. At these meetings participants received or had updated booklets by which to monitor progress in blood measures, weight, fatness and fat distribution measures. Meetings were held approximately two months following each of the three waves of data collection, each attended by 25-35 participants. Out-of-range metabolic results were discussed confidentially with members of the research team and community health nurses. A computer program (Daniel, 1987) was used by research assistants (nursing students) to calculate and generate comparisons of anthropometric indicators

to age- and gender-specific norms from the Canada Fitness Survey. Participants received printouts of percentile ratings of their profiles relative to Canadian norms, and these were also discussed and explained confidentially by members of the research team. Previous research has shown that active participation where individual life situations are discussed is more effective in producing (and maintaining) behaviour change than traditional passive education methods (Lasater *et al.*, 1984; Lefebvre *et al.*, 1987). More than just results were reviewed; people had an opportunity to talk about the challenges and rewards of their efforts, and workers, nurses and researchers were able to offer helpful comments and suggestions.

A local newspaper, "Senk'l'iP," carried regular articles on the project, as well as helpful hints for safe weight loss, active living and healthful eating (written by community workers). Workers also started and distributed a monthly "Diabetes Project Newsletter," complete with "factoids" — suggestions on exercise, diet and weight loss, and the dates, times and locations of upcoming project activities and special events. Community workers' and MSB nurses' promotion of the project resulted in two major stories in Health Canada's "First Nations Health" newspaper, published by the Medical Services Branch, Pacific Region (July 1995, Vol. 4, No. 1; and August 1996, Vol. 5, No. 3), and a television story on the project was aired by a local station (CHBC, November 21, 1995). Connections were established with, and educational resources obtained, from the Canadian Diabetes Association, the Heart & Stroke Foundation and Vernon Jubilee Hospital. All resources were publicised and made available through community workers to all interested community members. Media attention and use of media to promote the project was intended to strengthen community action and promote supportive environments.

Environmental Support for Behavioural Interventions

Organisational actions were mounted in support of individual behavioural and lifestyle change. The Band Council sanctioned the weekly distribution in central community locations of flyers about diabetes, weight loss, proper diet and the importance of physical activity. Local businesses allowed posting and distribution of information from their premises. The "New Horizons" group allowed unlimited use of the old Band hall for project meetings, screening initiatives and other activities. In an uncustomary decision, the Band Council granted use without charge of the local

park for the four-day “Fun-o-Rama” and “Fit Fest” and other special events. An important action was the hiring by the Band Council, mid-way through the project, of a full-time Recreation Co-ordinator (a Band member with previous experience in co-ordinating recreation programmes) to promote physical activity and to create acceptable opportunities for exercise. This action was a direct consequence of lobbying the Band Council to fund such a position, by community workers, health representatives and nurses. The Medical Services Branch, Pacific Region, supported the role of nurses in the project, granting staff support for some activities. An Advisory Committee, composed of eight community residents, formed early in the project and met regularly with the project team, providing suggestions and comments on the intervention process.

Monitoring and Programme Evaluation

On the basis that a programme or “treatment” theory is also an evaluation model, methods and measures were selected to correspond to components of the theoretical model. Baseline measures were obtained at the end of the seven-month planning period, immediately before programme implementation in the eighth month of the project (Table 6).

Table 6. Project Timeline and Timing of Data Collection, Overall and by Month of Intervention

Project Month:	4	6	8	10	12	14	16	18	20	22	24
	← Planning →			← Intervention →							
Intervention Month:			0	2	4	6	8	10	12	14	16
Tests and Measurements:			Baseline			Mid-Project			End-Project		

Cohorts were surveyed at baseline, at mid-intervention 8 months later, and at the end of the intervention after 16 months. Cross-sectional surveys were conducted approximately two weeks following the baseline and end-of-project cohort surveys. Community systems surveys were conducted during the pre-intervention planning phase, during the early intervention phase (intervention month 4); and during the late-project phase (intervention month 12). The evaluation model and measurement strategies for monitoring programme responses are summarised in

Table 7. Cohort and cross-sectional surveys were undertaken in all communities. The community systems surveys were administered in the intervention community only. The measurement protocol for each kind of survey is outlined in the following sections.

Cohort Measurements

All testing was conducted by the research team in Band halls between the hours of 7:30 a.m. and 12:00 noon. Assistance in testing and measurement procedures was provided by laboratory technicians from Vernon Jubilee Hospital and registered nurses enrolled in a degree nursing programme at Okanagan University College (with previous clinical experience). Testing was scheduled in Okanagan and Spallumcheen for two sequential days, usually Friday and Saturday. Testing in Penticton was accomplished within a single day, usually Thursday. The testing protocol followed this order: blood samples, blood pressure, anthropometric measures, then administration of behavioural and psychosocial questionnaires. All but the following four measures were obtained at each testing occasion: (a) a demographic questionnaire; (b) two-hour post-load glucose concentrations; (c) a diabetes quality-of-life questionnaire; and (d) a diabetes health beliefs and knowledge questionnaire. The demographic questionnaire, completed only at baseline or upon later entry into the project, asked about health status, education and income (Appendix B). Two-hour post-load glucose concentrations were measured only at baseline as part a diagnostic protocol to identify previously unrecognised cases of diabetes and impaired glucose tolerance. The diabetes quality-of-life and health beliefs and knowledge questionnaires were completed for the baseline and end-of-project tests only.

Physiological Variables

For screening at their Band Hall, participants provided a fasting venous blood sample (12-hour fast) by puncture of the antecubital vein. Blood samples were collected by laboratory technicians from Vernon Jubilee Hospital. All participants had been asked previously to avoid alcohol for the five days preceding the test, and not to smoke on the morning of the test. From all fasting blood samples, concentrations were determined for glucose, glycosylated haemoglobin (HbA_{1c}), total cholesterol (CH), triglycerides (TR) and high-density lipoprotein cholesterol (HDL). Low-density

Table 7. Programme Evaluation Model: Sampling and Measurement Strategies

Sampling Strategies	Intervention Measurements	Type of Data	Collection Methods	Operational Characteristics
Community Interventions Planning phase only	<ul style="list-style-type: none"> • health attitudes and values • knowledge of diabetes 	<ul style="list-style-type: none"> • qualitative • qualitative 	<ul style="list-style-type: none"> • tapes, transcribed • tapes, transcribed 	<ul style="list-style-type: none"> • recurring themes • recurring themes
"High-Risk" Cohort Surveys Intervention phase at baseline, mid-project, and end-of-project	<ul style="list-style-type: none"> • knowledge of diabetes • psychosocial constructs • dietary behaviours • physical activity • quality of life • obesity/fat distribution • physiological variables • smoking and alcohol • participation in project 	<ul style="list-style-type: none"> • quantitative • quantitative • quantitative • quantitative • quantitative • quantitative • quantitative • quantitative • quantitative 	<ul style="list-style-type: none"> • questionnaire • questionnaire • self-report diary • questionnaire • questionnaire • anthropometric meas. • blood samples • self-reports • assigned rating 	<ul style="list-style-type: none"> • risk factors, complications • self-esteem, mastery • three-day food records • frequency, intensity, duration • specific for diabetes • weight, girths, height • glycaemic variables, lipids • nominal and ordinal indicators • objective & subjective factors
Cross-Sectional Surveys Intervention phase at baseline and end-of- project only	<ul style="list-style-type: none"> • knowledge of diabetes • awareness of project • participation in project • dietary behaviours • physical activity • level of obesity 	<ul style="list-style-type: none"> • quantitative • quantitative • quantitative • quantitative • quantitative • quantitative 	<ul style="list-style-type: none"> • phone/home interview • phone/home interview • phone/home interview • phone/home interview • phone/home interview • phone/home interview 	<ul style="list-style-type: none"> • test score • self-reported rating • self-reported rating • food frequency consumption • frequency of activity • reported weight and height
Community Systems Surveys Planning phase, 4 months intervention, and 12 months intervention	<ul style="list-style-type: none"> • policies on risk factors • organisational support • sub-system participation • community activism 	<ul style="list-style-type: none"> • qualitative • qualitative • qualitative • qualitative 	<ul style="list-style-type: none"> • interviews, monitoring • interviews, monitoring • interviews, monitoring • interviews, monitoring 	<ul style="list-style-type: none"> • environmental • environmental • environmental • environmental

lipoprotein cholesterol (LDL) was calculated from cholesterol, triglyceride and HDL concentrations according to the formulae $[LDL] = [CH] - [HDL] - ([TR]/2.2)$ (Friedewald *et al.*, 1972). Fasting glucose concentrations were monitored as well as HbA_{1c}, since the latter does not correlate well with the lower range of glucose levels characterising persons with IGT (Little *et al.*, 1988; Young & Krahn, 1988). The laboratory at Vernon Jubilee Hospital performed all analyses.

For diagnostic purposes at baseline, a two-hour oral glucose tolerance test (OGTT) was administered to persons at risk for diabetes but not to those with established diabetes. Persons at risk were given a 75-gram carbohydrate load after their fasting blood samples were drawn, and gave another blood sample two hours later to assess post-load glucose levels. World Health Organisation (1985) criteria were applied to classify individuals on the basis of their OGTT as either: (a) normoglycemic (fasting and two hour plasma glucose ≤ 7.7 mmol/L); (b) having impaired glucose tolerance (IGT) (fasting plasma glucose ≤ 7.7 mmol/L and two hour plasma glucose 7.8-11.0 mmol/L); or (c) having diabetes (fasting plasma glucose ≥ 7.8 mmol/L and/or two hour plasma glucose ≥ 11.1 mmol/L). To estimate the crude prevalence of diabetes in each community, persons with previously established diabetes were pooled with persons diagnosed with diabetes on the basis of the screening procedure.

Blood pressure was taken after five minutes of rest in a seated position, using a calibrated aneroid sphygmomanometer. The same community health nurse took all readings at all tests, using the same sphygmomanometer. Two separate readings were taken from the same arm, recording to the nearest 2 mmHg (5th phase of Korotkoff sounds for diastolic pressure). The average of the measures was recorded as the "true" value. Given the screening context, individuals were classified as having "high blood pressure" rather than "clinically important hypertension" on the basis of systolic blood pressure ≥ 160 mmHg and diastolic blood pressure ≥ 90 mmHg. Individuals receiving treatment for hypertension were pooled with individuals with high blood pressure under the latter classification.

Analytic Methodology for Blood Measures

Whole blood specimens collected in ethylene-diamine-tetra-acetate (EDTA) anticoagulant were used to determine glycosylated haemoglobin. Tests for all other measures were performed on

serum specimens. Serum was obtained on-site at each test location by low-speed centrifugation, using a portable machine. Whole blood and serum samples were stored at a temperature of 4° C for transport to the laboratory at Vernon Jubilee Hospital. All assays were performed on the day of specimen collection. Blood samples stood at room temperature no longer than 15 minutes before refrigeration or centrifugation.

Percentage glycosylated haemoglobin, standardised to percentage haemoglobin A_{1c} (%HbA_{1c}), was measured using ion capture assay kits (IMx[®]; Abbott Laboratories, Abbott Park, Illinois, USA). Assays were performed using the IMx System and IMx MEIA optical assembly for fluorometry. Concentrations were determined for glucose, total cholesterol, triglyceride and HDL using enzymatically linked kits (Kodak Ektachem[®]; Eastman Kodak Co., Rochester, New York, USA). Tests for glucose, cholesterol and triglyceride were performed unordered on a random access, discrete analyser (Kodak XR). Assays for HbA_{1c} and HDL were done in batches. All assays were monitored by quality control samples. Accuracy in comparison to control sera was within 2%. Duplicate specimens were run for 131 of the 149 individuals who participated in the third and final testing occasion. These specimens were taken from individuals at the same time, assigned different accession numbers, and analysed randomly. (Blood drawn from a single venipuncture was divided into two samples.) Coefficients of variation (CV) and technical errors of measurement (TEM) were calculated from duplicate measurements (Table 8). The coefficient of variation (CV) is the quotient of the standard deviation (SD) divided by the mean times 100 (i.e., CV (%) = 100(SD/mean)). The technical error of measurement (TEM) is given by

$$\text{TEM} = \frac{1}{\bar{x}} \sqrt{\frac{\sum_{i=1}^n (d_i)^2}{2n}}$$

where n = number of pairs of duplicates; $d_i = x_{i1} - x_{i2}$, the difference in results for the i th pair; and \bar{x} = the mean for all values (Cushman *et al.*, 1995).

Coefficients of variation for all measures were within the standard range of variation for the hospital laboratory for all analyses done in the quality control period in which the third testing occasion fell. Coefficients of variation were also within the range specified in package inserts

provided by the manufacturers of the test kits for all measures except triglyceride concentration, which was greater by approximately 1.5%.

Table 8. Precision of Tests of Blood Measures (131 duplicate specimens)

	Technical Error of Measurement	Coefficient of Variation
Fasting glucose	1.21	1.81
Glycosylated haemoglobin* (within)	4.47	6.33
Glycosylated haemoglobin* (between)	4.58	6.84
Cholesterol	1.69	2.42
Triglyceride	2.52	3.93
High-density lipoprotein* (within)	2.02	2.85
High-density lipoprotein* (between)	2.43	3.48

*Glycosylated haemoglobin and high-density lipoprotein were analysed in batches. Averaged within and between assay coefficients of variation are reported for these two measures. All other duplicates were analysed unordered on a random access, discrete analyser (Kodak XR).

Laboratory Procedures

Glucose. A 10 μ L drop of serum was placed on a multi-layered analytical coating on a chemistry slide (Curme, 1978). The uppermost layer promoted a uniform distribution of samples and even penetration of solute molecules into the underlying reagent layer. Catalysed by glucose oxidase, sample glucose was oxidised to form hydrogen peroxide and gluconate (Trinder, 1969). This reaction was followed by an oxidative coupling catalysed by peroxidase in the presence of chromatogens to produce a coloured dye. The density of the dye formed, proportional to the glucose concentration present in the sample, was measured by reflectance spectrophotometry (reflected light at a wavelength of 540 nm). The incubation period was five minutes at 37° C.

Glycosylated haemoglobin. The procedure used an analyte (ion) capture technology by which the matrix of the ion capture cell was pre-coated with a high molecular weight compound

imparting a positive charge enabling capture of negatively charged analyte complexes formed during the assay. The assay used an affinity reagent composed of di-hydroxyboronate coupled to high molecular weight polyacrylic acid. During the assay, the affinity molecules bound specifically to glycosylated haemoglobin (GHb) through the interaction between di-hydroxyboronate and the sugar moieties of GHb (Middle, 1983). GHb was separated from non-GHb by electrostatic interaction between the polyanionic-glycosylated haemoglobin affinity complex and the cationic surface of the matrix. The amount of GHb was quantified by measuring fluorescence quenching. Fluorescence measurements were converted using calibration curves to glycosylated and total haemoglobin concentrations. The GHb concentration was divided by the total haemoglobin concentration and multiplied by 100 to give the %GHb result. Percentage GHb was standardised to haemoglobin A_{1c} (HbA_{1c}) according to the calculation: $HbA_{1c} = [\%GHb + 1.76]/1.49$ (Wilson, 1993). This calculation is based on a linear relationship between the boronate affinity binding method used (which detects all GHb species) and methods specific for the HbA_{1c} species, such as ion-exchange chromatography (Little, 1986; Wey Kamp, 1993).

Cholesterol. A 10 µL drop of serum was placed on a multi-layered analytical coating on a chemistry slide. Surfactant in the spreading layer promoted the dissociation of cholesterol and cholesterol esters from lipoprotein complexes in the sample. Hydrolysis of the cholesterol esters to cholesterol was catalysed by cholesterol ester hydrolase. The cholesterol was oxidised by cholesterol oxidase to form cholestenone and hydrogen peroxide. The hydrogen peroxide then oxidised a triarylimidazole leuco dye in the presence of peroxidase to generate a coloured dye (Allain *et al.*, 1974). The density of the dye formed, proportional to the cholesterol concentration present in the sample, was measured by reflectance spectrophotometry (reflected light at a wavelength of 540 nm). The incubation period was five minutes at 37° C.

Triglyceride. A 10 µL drop of serum was placed on a multi-layered analytical coating on a chemistry slide (Spayd, 1978). Surfactant promoted the dissociation of triglycerides from lipoprotein complexes in the sample. Hydrolysis of triglyceride molecules to glycerol and fatty acids was catalysed by lipase. Glycerol was phosphorylated by adenosine triphosphate (ATP) in the presence of glycerol kinase and magnesium chloride. L- α -glycerophosphate was then oxidised by L- α -glycerophosphate oxidase to dihydroxyacetone phosphate and hydrogen

peroxide. The final reaction involved the oxidation by hydrogen peroxide of a triarylimidazole leuco dye, catalysed by peroxidase, to produce a coloured dye. The density of the dye formed, proportional to the cholesterol concentration present in the sample, was measured by reflectance spectrophotometry (reflected light at a wavelength of 540 nm). The incubation period was five minutes at 37° C.

High-density lipoprotein cholesterol. Very low-density lipoprotein cholesterol (VLDL) and LDL were separated from HDL in samples by selective precipitation using a reagent with a final concentration of 50,000 MW dextran sulfate (0.9 g/L) and magnesium chloride (45 mmol/L) (Warnick *et al.*, 1983). The precipitated proteins were removed by centrifugation. A 10 µL drop of serum was placed on a multi-layered analytical coating on a chemistry slide. Surfactant promoted the dissociation of cholesterol and cholesterol esters from high-density lipoproteins in the sample. Hydrolysis of the cholesterol esters to cholesterol was catalysed by cholesterol ester hydrolase. The cholesterol was oxidised by cholesterol oxidase to form cholestenone and hydrogen peroxide. The hydrogen peroxide then oxidised a triarylimidazole leuco dye in the presence of peroxidase to generate a coloured dye. The density of the dye formed, proportional to the HDL cholesterol concentration present in the sample, was measured by reflectance spectrophotometry (reflected light at a wavelength of 670 nm). The incubation period was five minutes at 37° C.

Anthropometric Variables

All measures were performed by registered nurses trained in anthropometric measurement. The same two nurses performed all measurements for all tests. Participants wore light clothing (sweat pants and T-shirt), with footwear removed. Clothing was adjusted to enable direct measurement. Measurements proceeded according to a detailed proforma, structured to facilitate progress by anatomical site (Appendix C). All measures were performed in triplicate and the median value taken as the "true" value. The median value was used rather than the mean, because anthropometric errors can be relatively large, and the median is less influenced than the mean by such errors. All participants were assessed in the standard anatomical position (Ross & Marfell-Jones, 1982), standing erect with eyes and head pointing forward, upper limbs by the sides with

palms forward, thumbs directed away from the sides with fingers pointing downward and the feet together with the toes pointing forward.

Waist and Hip Circumferences

Minimum waist girth was taken where the waist was best defined, approximately halfway between the costal border and iliac crest. Where a well-defined waist was not apparent, the circumference was taken halfway between the manubrium sterni and umbilicus. Measurement of waist girth was made following a normal expiration. Maximum hip (gluteal) girth was obtained at the level of the greatest posterior protuberance. The measure was taken with individuals standing erect, feet together. For all girth measurements the tape was in contact with the skin but did not compress underlying tissues. Girths were measured with a Lufkin® Executive flexible (6.5mm wide) steel tape calibrated in centimeters with millimeter graduations (model W606PM). The tape was non-extensible with a stub before the zero line. Waist-to-hip girth ratio (WHR) was calculated as waist girth (cm) / hip girth (cm).

The reproducibility of circumference measures is 2% when sites are properly landmarked, higher than for skinfold thickness measurements (for which the intra-observer variation is ~ 5%, and the inter-observer variation is 10% – 20%) (Valdez *et al.*, 1993). Wilmore and Behnke (1969) reported that the correlation between sequential measures was 0.992 for hip girth and 0.993 for waist girth, and Ross and Ward (1982) reported that the TEM for repeated measurements was 0.7 for waist girth and 0.5 for hip girth. If the errors of waist and hip girth measures are assumed to be independent, measurement theory predicts that the TEM of WHR is approximately 1.1. The validity of WHR as an indicator of the relative distribution of adipose tissue has been established by *in vivo* methods including computed tomography (Ferland *et al.*, 1989) and dual photon absorptiometry (Schlemmer *et al.*, 1990), and directly by cadaver dissection (Martin *et al.*, 1991).

Body Mass and Height

Body mass was measured to the nearest 0.05 kg on a beam balance scale calibrated before each use. For height measurements, individuals stood erect and barefoot against a wall with their heels together and arms relaxed against the sides. Height was taken as the maximum distance from the

floor to the vertex of the head. The vertex is defined as the highest point on the skull when the head is held in the Frankfort Plane, which is the position where an imaginary line joining the orbitale (most inferior position on the margin of the eye socket) to the tragion (notch superior to the flap of the ear at the superior aspect of the zygomatic bone) is horizontal. A triangular head board was brought down upon the head to form a right angle from the wall to the vertex of the skull. A mark was scribed underneath and the distance taken from a vertically placed steel tape in centimeters. Body mass index (BMI) was calculated as body mass (kg) / height (m)². The BMI has a high reproducibility and is well established as a valid index of adiposity in relation to height (Bray, 1989; Waaler, 1983).

Behavioural Variables

Behavioural measures included physical activity, smoking, alcohol consumption, and dietary intake over three days. Questions about physical activity, smoking and alcohol were contained in a Lifestyle Questionnaire (Appendix D) completed at each testing occasion. The questionnaire derived from that used in the Canadian National Population Health Survey. Smoking and alcohol consumption were assessed using straightforward self-reports. Physical activity was more difficult to determine. Specific methods used to assess physical activity are described below. Research personnel and community workers were available at each testing occasion to explain procedures and to answer questions about the Lifestyle Questionnaire. Dietary behaviour was assessed using three-day food records, completed by participants at home during the week before each testing occasion. Details for assessment of dietary intake are also reviewed below.

Physical Activity

A simple indication of physical activity was obtained through responses to these three questions: (a) "At least once a week, did you engage in any regular activity similar to brisk walking, jogging, bicycling, etc., long enough to work up a sweat?"; (b) "If yes, how many times per week?"; and (c) "What activity is this?" (Manson *et al.*, 1991). These questions have been validated as a measure of physical activity (Helmrich *et al.*, 1991; LaPorte *et al.*, 1983; Siconolfi *et al.*, 1985; Washburn *et al.*, 1987; Washburn *et al.*, 1990). Responses to the first question were used to classify

individuals dichotomously in terms of sweat-producing activity at least once per week. Responses to the second question enabled graded classifications by the frequency of sweat-producing activities per week. This simple approach based on sweat-producing activity is in keeping with epidemiological data suggesting a linear dose-response relationship between physical activity and health and functional effects, for low to moderate levels of activity (Blair *et al.*, 1992). Several previous studies that have examined the relationship between physical activity and glucose tolerance and the development of NIDDM have used similar measures that classified individuals into three or four activity categories (Cederholm & Wibeli, 1985; Jarrett *et al.*, 1987; Lindgärde & Saltin, 1981; Taylor *et al.*, 1984).

A more refined measure was used to assess total physical activity for the month preceding each survey (combined leisure-time and occupational activity). The instrument used was the Pima Indian physical activity questionnaire (Kriska *et al.*, 1990). On reliability, Kriska *et al.* (1990) reported test-retest correlations (rank order) ranging from 0.62 to 0.96 for leisure-time and occupational activity. The validity of the instrument was assessed indirectly by comparisons with activity monitors worn for one week by 17 individuals. The overall correlation between activity monitor counts per hour and activity estimates was 0.62. In scoring responses, the average number of hours per week spent on each leisure-time and occupational activity were calculated. Hours per week of each activity were multiplied by an estimate of the metabolic cost of that activity (expressed as metabolic equivalents, or METs) to take into consideration the energy requirement of that activity. The resultant values were MET-hours per week, where one MET is the ratio of the working metabolic rate of an activity divided by the resting metabolic rate. The classification system given by Katch and McArdle (1983, p. 98) was used to assign METs according to the intensity of effort associated with various activities. As an example, for an individual spending an average of 2.6 hours per week performing an activity rated at 3 METs, the metabolic cost of that activity would be 7.8 MET-hours per week. MET-hours per week were summed for analysis.

Using MET-hours per week to estimate an individual's energy expenditure involves several assumptions (Kriska *et al.*, 1990). As the calculation reflects relative energy expenditure for given activities but does not consider the individual's body weight, one assumption is that body weight is proportional to resting metabolic rate. A second assumption is that the relative

increase in metabolic cost for a specific activity above resting is constant from person to person irrespective of body weight. A third assumption is that the energy cost of an activity is constant regardless of the skill of the individual. Another issue is that although summary scores tend to have high reproducibility, the recall of time spent in any one activity (particularly activities of low frequency) is not highly reliable (Montoye & Taylor, 1984). Thus, the method only approximates total physical activity for an individual, and errors in approximations may be correlated positively with body weight (Graham-Clarke & Oldenburg, 1994).

Dietary Behaviour

Dietary behaviour was assessed using self-completed records for intake of food and drink over three consecutive days, including one weekend day (Houser & Bebb, 1981; Richard & Roberge, 1982). Household measures were used to determine quantities of food and drink consumed. Procedures for completing three-day food records were explained before testing. All records were completed by participants at home, in writing, during the week before each testing session. All records were reviewed for completeness upon submission at each testing occasion. Degree nursing students (registered nurses with diplomas and previous clinical experience) worked one-on-one with each participant to review the completeness of food records. Training for this duty included classroom sessions in nutrition and dietetics and a briefing on correct procedures for completion of food records. Ambiguous or incomplete items were clarified. Charts and models were used to help estimate food portion sizes for missing or imprecise entries.

Three-day food records were coded and nutrient intakes computed by a registered dietitian-nutritionist using a Canadian nutrient database and software system developed specifically for work on Canadian nutrition surveys (CANDI) (Thompson & Brulé, 1994a). Intake records were then reviewed and adjusted as necessary by a separate, independent registered dietitian-nutritionist, and merged into a dietary database using a supplementary module (CDP) to the CANDI software system (Thompson & Brulé, 1994b). The CANDI system has been used for nutrition surveys with the James Bay Cree in northern Québec and Kitamaat Band in northwestern British Columbia, as well as for Heart Health surveys in Québec and Nova Scotia. Total energy

consumption and the masses of protein, carbohydrates and lipid consumed over the three-day period were determined for analysis.

The reliability of three-day food records has been established (Bebb *et al.*, 1972; Tremblay *et al.*, 1983). The validity of self-reports of food intake for group comparisons has been established for accuracy (Stunkard & Waxman, 1981), construct validity (Young *et al.*, 1952c), concurrent validity (Eppright *et al.*, 1952; Owen *et al.*, 1974) and predictive validity (Eppright *et al.*, 1972; Owen *et al.*, 1974). None of these determinations, however, were made in populations comparable to the study population. Representative validity, for an instrument to assess dietary intake, is extremely difficult to establish directly (Block, 1982). The seven-day food record has often been used as the standard against which other methods have been validated (Heady, 1961; Stuff *et al.*, 1983; Young *et al.*, 1952a). Though some would object to this use (Garn *et al.*, 1978), the seven-day record compares reasonably with 28-day food records (Young *et al.*, 1952b) and provides a valid estimate of mean daily energy intake (Acheson *et al.*, 1980). There is little loss of precision, however, using a three-day record (including one weekend day) compared to a seven-day record: correlation coefficients for estimates of calories, protein and fat between the two records are > 0.90 (Heady, 1961).

Similarly, mean nutritional intakes calculated from a three-day record approximate those obtained with a seven-day record. Intra-class correlation coefficients between the two records for estimates of calories, protein, fat, carbohydrate, iron, calcium and phosphorous range from 0.74-0.91 (Stuff *et al.*, 1983). The benefit of three-day versus seven-day records is a greater response rate, since more participants are likely to co-operate and complete the full recording. Moreover, the three-day record is useful to assess dietary intake as a self-care behaviour among adults with NIDDM (Glasgow *et al.*, 1989). In the context of this project, the capacity of the three-day food record to reflect dietary behaviour was considered more important than absolute assessments of nutritional status (Stern, 1991).

Psychosocial Variables

Beyond their theoretical utility, psychosocial instruments were chosen for their brevity, simple language, acceptance and extent of use in divergent populations, and established reliability and

validity (Noack, 1991). None of the instruments chosen, however, had been validated in Aboriginal populations, and a literature review suggested that neither the chosen measures nor any other psychosocial measures had been applied in population-based settings, Aboriginal or otherwise, to diabetes prevention and control. Cross-cultural adaptations of questionnaires pertain usually to translations of original wording rather than modifications of the original structure, with consequent re-assessment of psychometric properties (e.g., Escalante *et al.*, 1996). Because translations were not required, and as funding was limited, questionnaires were simply pre-tested with community workers, nurses and Advisory Committee members not part of the cohort sample.

All participants completed surveys assessing self-esteem, mastery, depression, affect balance and social support. These scales were embedded in a pencil-and-paper type "Social Environment" Questionnaire (Appendix E). Most participants were sufficiently literate to complete questionnaires. For those persons with low levels of literacy (approximately 5% of cohorts, mainly the elderly), relatives or nurses read questions out loud and recorded responses. Individuals with diabetes and impaired glucose tolerance completed two further questionnaires assessing diabetes quality of life (Appendix F) and health beliefs (Appendix G). Appended to the health beliefs questionnaire was a subset of 13 questions assessing knowledge of diabetes risk factors, symptoms and complications, for which response categories were dichotomous (yes/no).

Self-Esteem

Self-esteem was measured using Rosenberg's (1965) 10-question scale, which collapses into six items. This Guttman-type scale has been widely applied and is an accepted measure of global self-esteem, with reproducibility of 93%, scalability of 73% for items and scalability of 72% for individuals (Rosenberg, 1965). The test-retest correlation after two weeks is high ($r = 0.85$) (Silber & Tippett, 1965), and Cronbach's $r = 0.74$ (Ward, 1977). The concurrent validity of the instrument has been established (Rosenberg, 1965), and scores correlate with clinical ratings and similar measures ($r = 0.65$ – 0.83) (Silber & Tippett, 1965). Individuals rate their level of agreement with statements such as, for example, "I feel I have a number of good qualities." Positive ratings were summed across items (maximum score = 6).

Mastery

Mastery, the extent that people see themselves as being in control of the forces that affect their lives (related to the concepts self-efficacy [Bandura, 1982] and "locus of control" [Rotter, 1975]), was appraised using the 7-item, 5-point Likert-type Mastery scale (Pearlin *et al.*, 1981; Pearlin & Schooler, 1978). Although the Mastery scale has been widely applied and is heavily cited in the literature, its reliability has not been determined directly. Examination of the factor structure of the scale by principal component analysis and varimax rotation provides a crude indication of reliability: it was reported that all the factor items loaded cleanly (0.47–0.76) (Pearlin & Schooler, 1978) and that the stability of estimates over time was robust, with errors of "small" magnitude (Pearlin *et al.*, 1981). Construct validity has been confirmed (Pearlin *et al.*, 1981; Pearlin & Schooler, 1978). Individuals rate their level of agreement on a series of seven positive and negative statements such as, for example, "I can do just about anything I really set my mind to." Scores were added and the sum divided by the number of items to yield an average response (maximum score = 5).

Depression

Depression was assessed using Hakstian and McLean's (1989) Brief Screen for Depression (BSD). The BSD is a four-item screening questionnaire for use with individuals or populations. The test-retest reliability of the instrument is acceptable: $r = 0.73$ for a one-week test-retest, and $r = 0.54$ for a three-month test-retest (Hakstian & McLean, 1989). The concurrent validity of the instrument has been established with several comprehensive criterion measures of depression and demoralisation (McLean & Hakstian, 1991). Regarding predictive validity, the instrument correctly distinguishes clinically depressed from non-depressed normal individuals over 95% of the time (McLean & Hakstian, 1991). In scoring the BSD, the response for the first item (out of 5) is multiplied by a factor of four, and summed with responses for the remaining three items (out of 10). Thus, the BSD range is 7 to 50, with greater scores corresponding to greater levels of depression. For non-Aboriginal populations, a score of 25 may indicate clinical depression.

Affect Balance

Psychological well-being was assessed using Bradburn's (1969) 10-item Affect Balance Scale

(ABS). The ABS has been widely used as a measure of affect or emotion. Though not without limitations, it has been recommended as the best available indicator of well-being in general population surveys (McDowell & Praught, 1982). The test-retest reliability of the instrument is high ($r = 0.76-0.97$) (Bradburn, 1969), and concurrent validity has been established (Bild & Havighurst, 1976; Engel, 1984; Moriwaki, 1974). Individuals answer "yes" or "no" to five positive and five negative statements. An example is, "During the last few weeks, did you ever feel particularly excited or interested in something?" Affirmative responses were counted for positive and negative items, and the sum of affirmative responses for negative items subtracted from the sum for positive items. To convert negative scores, a constant of 5 was added to the difference (maximum score = 10).

Social Support

Social support was appraised on the basis of the questions: (a) "Among your friends and relatives, excluding your partner, if you have one, how many people do you feel you can tell just about anything to, people you can count on for understanding and advice?"; and (b) "If you live with a partner, is your partner someone you can really talk with about things that are important?" (Pearlin *et al.*, 1981). These two questions, which focus on support of an emotional, as opposed to instrumental, nature, were scored differently. The first question was scored from 0 to 2, depending on whether respondents indicated no one, one person, or two or more. The second question was scored either 0 for a negative response, or 1 for a positive response. To provide a single measure for partnered and non-partnered people, scores for partnered people from the second question were added to their scores from the first question. Total scores thus range from 0 to 3. The scoring strategy does not provide equal opportunity for non-partnered people to have an alternative source of support; it assumes that partnered people have an inherent advantage.

Diabetes Quality of Life

Quality of life was assessed among persons with diabetes and IGT, using the 46-item diabetes quality-of-life (DQOL) instrument (DCCT Research Group, 1988). This instrument comprises four primary scales: satisfaction, impact, diabetes worry, and social/vocational worry. The DQOL and its

four scales have acceptable degrees of internal consistency (Cronbach's $r = 0.66\text{--}0.92$), high test-retest reliability ($r = 0.78\text{--}0.92$), and the convergent validity of the instrument has been established (DCCT Research Group, 1988). Subscales were analysed simultaneously by multivariate analysis of variance. An analysis of sum scores was inappropriate because the instrument assesses quality of life as a multidimensional variable.

Diabetes Health Beliefs

Beliefs about diabetes were assessed using the 11-item revised Health Belief Model Diabetes Scale. This instrument addresses three classes of beliefs: (a) severity of diabetes; (b) efficacy of therapy; and (c) the belief that barriers to the successful execution of therapeutic behaviours can be surmounted (Hurley, 1990). The test-retest reliability of the scale after three weeks is high ($r = 0.79$); Cronbach's $r = 0.71$; and principal component analysis yielded a theta coefficient of 0.75 (Hurley, 1990). Construct validity is established, and concurrent and predictive validity estimates support the criterion validity of the instrument (Hurley, 1990). Subscales were analysed simultaneously by multivariate analysis of variance. An analysis of sum scores was inappropriate because the instrument assesses health beliefs as a multidimensional variable.

Participation in Intervention Initiatives

Participation was assessed at the finish of the project for persons in the intervention cohort. Two community workers each provided independent ratings of participation. A two-part procedure was used, involving objective and subjective components. For the objective component, each worker rated each person enrolled at baseline in the intervention cohort on ten categories of participation. Each category corresponded to a major intervention initiative or group of smaller initiatives. The project team decided as a group how to categorise initiatives, so that differences between categories could be assumed to be reasonably similar. One point was awarded for participation in each category, and the score out of ten calculated. The ten categories were:

- (a) Read newsletter, Senk'liP, posters or any other written information about diabetes or the project, or view diabetes education videotapes;
- (b) Participate in Community Advisory Group;

- (c) Participate in Diabetic Support Group (open to all, not just persons with diabetes);
- (d) Participate in Gentle Exercises or Chair Exercises group, or mall or outside walking groups;
- (e) Participate in aerobics classes;
- (f) Participate in 100 Mile Club (formal participation, requiring points to be logged);
- (g) Participate in Fitness Festival, Diabetes Fun-o-Rama, Tai Chi or other fitness demonstrations;
- (h) Participate in Community Kitchens or Nobody's Perfect group discussions about diabetes;
- (i) Attend on-reserve seminars on nutrition, exercise, obesity, or living with diabetes; and
- (j) Attend Diabetes Day Programme at Vernon Jubilee Hospital.

For the subjective component of participation, each worker assigned each member of the cohort a score out of ten, based on aspects of participation not covered by involvement in intervention initiatives. This rating was intended to address the degree of personal effort people had made in response to the diabetes project. Because each worker had in-depth knowledge of the responses of each person enrolled in the cohort, this approach was deemed a reasonable way to tap into less objective aspects of participation.

The project team debated the merits of the two measures of participation, deciding that the objective measure had face validity, but that a composite indicator combining and weighting equally both objective and subjective dimensions would have the greatest degree of content validity. Therefore, the average of the ten-point objective and subjective scores was calculated to yield an overall participation score for each person enrolled in the intervention cohort. The decision to incorporate both objective and subjective criteria into a single measure of participation is in keeping with the psychometric conception of content validity as a function of the congruence of the dimensions of the underlying construct being assessed (Osterlind, 1990).

The reliability of workers' scores was determined by correlating scores to describe the level of agreement (Nunnally, 1978). The two sets of scores were highly correlated: the Pearson product-moment correlation coefficient (r) was 0.89 ($n = 94$, $P < 0.000$). Given strong agreement between workers, workers' overall scores were then averaged to yield a single global measure of participation. Next, to be able to assess the effect of differences in participation on change over time in outcomes, the mean global participation score (4.02) was used to dichotomise the score for each individual in the cohort into high or low levels of participation. To assess the reliability of

workers' ratings on the dichotomised scores, the mean global score was similarly applied to each worker's overall participation score to create worker-specific ratings of high and low levels participation. The kappa coefficient (κ) (Cohen, 1960) was calculated to assess the level of agreement between worker-specific categorical ratings of participation. The inter-rater reliability of the workers' ratings was high: $\kappa = 0.70$, with a 95% confidence interval (goodness-of-fit approach) of 0.53 to 0.82 ($P < 0.000$), and percentage agreement of 85%.*

Cross-Sectional Measurements

As stated, cross-sectional surveys were conducted approximately two weeks following the baseline and end-of-project cohort surveys. Data were collected primarily by telephone surveys, but home visits were also conducted for individuals who did not have telephone service. The same instrument was used for telephone interviews and home visits. The instrument (Appendix H) was pre-tested among five community workers and four nursing students before use in surveys, and revisions were made to improve readability and interpretation. The same two nursing students conducted all telephone interviews for both the baseline and end-of-project surveys, whereas one particular community worker in each community conducted all home visits.

The survey instrument focused on knowledge of diabetes, awareness of the project and participation in the project. Knowledge of diabetes was assessed as the number of correct responses to 13 questions about diabetes risk factors, symptoms and complications; response categories were dichotomous (yes/no). Questions about physical activity were the same as for cohorts, enabling dichotomous classifications for sweat-producing activity at least once per week, and ordinal classifications for the frequency of sweat-producing activities per week. Respondents provided ratings on a 10-point scale for: (a) awareness of the project; (b) perceived knowledge of diabetes (distinct from "actual" or objectively-assessed knowledge); (c) participation in the project; (d) consumption of dietary fat; and (e) consumption of complex carbohydrates. Further questions asked for self-reported weight and height.

The validity of the components of the instrument was well established only for questions on physical activity (Helmrich *et al.*, 1991; LaPorte *et al.*, 1983; Manson *et al.*, 1991). There is

*McNemar's test for bias was non-significant ($\chi^2 = 0.07$ with 1 df, $P = 0.789$). Both the prevalence-adjusted and the prevalence-adjusted bias-adjusted $\kappa = 0.70$.

some concern that self-reported weights tend to be underestimated and self-reported heights overestimated (Stewart *et al.*, 1986). Regardless, considerable support exists for the reliability and accuracy of self-reported weight and height (Miller, 1986; Stewart, 1982; Stunkard & Albaum, 1981). The psychometric properties of measures of knowledge, awareness, participation and dietary behaviour were not assessed, though questions were pre-tested before use in surveys.

Surveys of Community Systems

Community surveys of systems were conducted during the pre-intervention phase, during the early intervention phase (intervention month 4); and (c) during the late-project phase (intervention month 12). Surveys were conducted during special meetings involving researchers, project workers, community health nurses and community health representatives. The respondents were community-level research personnel who were residents in the intervention community. Standardised questions were addressed at each meeting (Appendix I). Only consensus perspectives were recorded. Community workers and community health representatives debated questions, often extensively, prompted by researchers and community health nurses. Each meeting lasted for approximately two hours.

Questions were based on the systems framework outlined by Thompson and Kine (1990) in their application of Social Change Theory to community health promotion initiatives. There were three levels of analysis. The first level was sub-system changes within community groups and organisations, including policies addressing issues of concern, support for the project, and participation and active involvement in the project. The second level was changes in inter-relationships among various subsystems, including actions such as coalition development, sub-system participation in community boards and task forces related to the project, and sub-system involvement in community-wide activities. The third level of analysis was whole-system changes in community norms and values. Changes at the third level concerned community policy on health issues related to the project, community enforcement and activism, perceptions of shifts in norms and values, and the impact on the community of external environmental changes. The focus was on the mechanism of action of intermediate steps in the social change process (Koepsell *et al.*,

1992). A required assumption for the assessment was that the community environment serves as a channel that reflects or “mirrors” the collective state of individuals in a community.

The foundation of the assessment procedure was the work of Webb *et al.* (1966) on unobtrusive measures not contaminated by reactivity or caused by awareness of measurement. Lack of reactivity in a method does not mean, however, that the data generated are valid. Simple observation of community processes was the basis of the procedure, with observations refined and synthesized through debate. There is a large social sciences literature on unobtrusive measures and classes of environmental indicators, especially in sociology (Rossi & Gilmartin, 1980). Use of unobtrusive measures and environmental indicators is restricted by a lack of persistent and credible efforts to assess and improve their reliability and validity (Bouchard, 1976; Cheadle *et al.*, 1992; Sechrest & Belew, 1983). Despite limitations, environmental measures of the community can be useful when used with other methods as indicators of (a) shared attitudes and collective behaviour, separate from the problems inherent in the use of self-reports, and (b) features of environmental links in the chain connecting interventions to behaviour. Thus, such measures can help to bridge the difficulties associated with measurement at the level of the individual, and the need to measure some of the intermediate processes in the theoretical framework linking a community-based initiative to individual change in behaviour through the environment (Gruenewald *et al.*, 1996; McKinlay, 1996; Poland, 1992).

Data Preparation and Analysis

Data were entered by a research assistant into Microsoft® Excel (Microsoft Corporation, 1992) for spreadsheet arrangement. Templates created by the author were used to structure data entry, and a systematic coding scheme was developed in advance to ensure standardised entry procedures. Separate files were used to enter data by general class of variable and the testing occasion. The author merged separate files into master files for each testing occasion. Graphs and frequency distributions were plotted and ranges and other descriptive statistics were produced for each variable for each testing occasion. Outliers were identified and correctness ascertained by cross-checking the original hard copy values. Further, for every fifth individual, all values for each variable for each testing occasion were compared with the entries on the original

hard copy forms. The quality of the original entry procedures was high: the proportion of incorrect entries was less than 1% for each case-by-variable matrix (determined by recording corrections for errors). For example, for the 207 cases-by-57 columns matrix for the “social environmental” survey for the first testing occasion, 11 corrections were made for errors in data entry.

After reviewing and cleaning the raw data, the arithmetic capabilities of Excel were used to derive composite variables and to score questionnaire responses. Separate files for each testing occasion were then merged into an overall master database containing all original and derived variables. The database was then saved and imported into the statistical software package STATISTICA (Statsoft, 1994), which was used to perform the majority of statistical analyses and data manipulations.

Before analysis, descriptive statistics were generated separately for each variable. This provided basic information about the number of cases, the minimum and maximum values, the mean, standard error and standard deviation, different measures of variation, and the shape of the distribution of the variable. For each variable to be analysed on a continuous scale, plots of frequency distributions were generated and skewness and kurtosis assessed. The Kolmogorov-Smirnov test was performed to test the hypothesis that the observed data followed the normal distribution. The Kolmogorov-Smirnov *D-max* statistic (the largest difference between the cumulative observed and expected normal distribution) was statistically significant ($P < 0.05$) for the following variables: glucose, HbA_{1c}, triglyceride, brief screen for depression, knowledge of diabetes and MET-hours per week of exercise. All six non-normal variables were positively skewed. Although the need for normality is the weakest reason for transforming variables, it is often the case that the same transformation simultaneously stabilises variance, yields linear relationships, and provides more nearly normal distributions (Armitage & Berry, 1994). Logarithmic (\log_{10}) transformations were therefore performed for those variables for which the Kolmogorov-Smirnov test was significant, and the test was run again. The only variable for which the test was then significant was knowledge about diabetes, indicating that logarithmic transformations were sufficient to normalise the other five distributions.

For knowledge about diabetes, square root transformations applied to counts of correct responses to questions did not normalise the distribution of data. Therefore, the proportion of

correct answers was calculated, and an inverse sine (arcsine) transformation applied to ensure equality of variance, as the variance of a proportion is dependent on the proportion itself (Hassard, 1991). Arcsine transformed values for knowledge followed a normal distribution. For all variables to which transformations were applied, statistical analyses were conducted using both the untransformed and transformed values. Assumptions underlying analyses were tested for both the untransformed and transformed forms of the data, to decide whether tests needed to be based on transformed values.

Statistical Analysis

The primary evaluation questions were to determine whether the community-directed diabetes prevention and control programme was associated with positive changes over time in outcome variables and, if so, whether changes were in keeping with the programme or “treatment” theory. The essence of the programme theory was that interventions developed, implemented, and controlled by community members would facilitate and promote gains in personal and collective efficacy, such that outcomes would co-vary in a sequence predicted by theory. Consistent with the model applied in the Stanford Three-Community Study (Farquhar, 1978), it was theorised that improvements in knowledge and psychosocial status would predispose positive shifts in behaviour, which in turn would predict positive changes in physiological and anthropometric variables. Further, increases in personal efficacy as inferred from positive shifts in psychosocial and behavioural variables were expected to be associated with positive environmental changes.

To test the null model of no difference in change over time between the intervention and comparison conditions, nested linear contrasts of change within communities within conditions were undertaken using a quasi-mixed model analysis strategy for unbalanced survey data. The procedure involved nesting the between factor *community* within the between factor *condition* while making direct orthogonal comparisons of change within individuals between the intervention and comparison conditions. Analyses were weighted for sampling frequencies by community to provide unbiased population-level estimates of changes between conditions. Through weighting, summary statistics and variance estimates account for the population structure in each community. All hypothesis tests were two-tailed. The level of significance (α)

was set at 0.05. The cell means model was used to test explicit questions about the means observed in the cells of the design.

The small number of communities and the fact that there was only one intervention community did not allow clustering to be controlled for by specifying community as a nested random effect. Community was necessarily presumed to be fixed. Therefore, for each orthogonal contrast, the individual-level error variance of the fixed effects was inflated to reflect additional community-level variance to approximate a mixed model analysis with community taken as a random effect. The inflation factor was calculated according to the following formula:

$$\frac{1 + \rho (\bar{n} - 1)}{(1 - \rho)},$$

where \bar{n} is the harmonic mean sample size, and ρ is an external estimate of the ICC.

The external estimated ICCs used were those published by Hannan *et al.* (1994) from the Minnesota Heart Health Program (MHHP). For variables measured in both the Okanagan Diabetes Project and the MHHP, the MHHP ICC was used. For variables for which an equivalent MHHP variable did not exist, a conservative proxy ICC was assigned based on similar variables measured in the MHHP (Table 9). Degrees of freedom were adjusted by dividing by the design effect $[1 + (\bar{n} - 1)\rho]$, separate and in addition to inflating the error variance, to reflect the lesser level of independent information obtained from the individuals sampled (Kish, 1965). All variance inflation factors were calculated manually, and manual adjustments were made to summary statistics and degrees of freedom. Both the unadjusted and adjusted results are reported. Probability values were re-calculated for adjusted statistics.

Specific analysis procedures for the cohort and cross-sectional surveys are described in the following sub-sections. All statistical procedures employed assume a simple random sample although, for cohorts, non-probabilistic methods were used in sampling. There is no correct method for adjusting tests to account for non-probabilistic sampling. Adjustments for clustering correct variance estimates for that attributable to communities but do not compensate for the non-probabilistic methods by which individuals were recruited into cohorts. Community systems surveys were not analysed using statistical procedures.

Table 9. Intra-Class Correlations (ICC) from the Minnesota Heart Health Program (MHHP)* Used to Calculate Variance Inflation Factors to Adjust for Clustered Observations

Class	Measure	Corresponding MHHP ICC	MHHP ICC Used	Basis for Proxy
<i>Longitudinal</i>				
Physiological†	Fasting glucose	no	0.00869	Highest for blood measures
	HbA _{1c}	no	0.00869	Highest for blood measures
	Cholesterol	yes	0.00641	
	Triglyceride	no	0.00869	Highest for blood measures
	HDL	yes	0.00869	
	LDL	no	0.00869	Highest for blood measures
	SBP	yes	0.01262	
	DBP	yes	0.03080	
Anthropometric	Body mass index	yes	0.00000	MHHP values were negative
	Waist/hip ratio	no	0.00000	Same as for body mass index
Behavioural‡	Dietary (all)	no	0.00256	Highest for behavioural
	Activity once/wk	no	0.00079	Percent active in leisure time
	MET-hours/wk	no	0.00053	Leisure time activity score
	Smoking (Y/N)	yes	0.00272	
	Alcohol (Y/N)	no	0.00272	Same as for smoking
Psychosocial	All variables	no	0.00401	Median for attitudes
<i>Cross-sectional</i>				
Exposure	Awareness	no	0.00864	Highest for exposure
	Participation	no	0.00864	Highest for exposure
Knowledge	Perceived	no	0.00547	Highest for knowledge
	Actual	no	0.00547	Highest for knowledge
Behavioural‡	Dietary (all)	no	0.00256	Highest for behavioural
	Activity-once/wk	no	0.00079	Percent active in leisure time
	Activity-times/wk	no	0.00053	Leisure time activity score
Anthropometric	body mass index	yes	0.00000	MHHP values were negative

*From Hannan *et al.* (1994). Parameters to aid in the design and analysis of community trials: intraclass correlations from the Minnesota heart health program. *Epidemiology*, 5(1), 88-95.

†HbA_{1c} = glycosylated haemoglobin A_{1c}; HDL = high density lipoprotein cholesterol; LDL = low density lipoprotein cholesterol; SBP = systolic blood pressure; DBP = diastolic blood pressure.

‡Activity = sweat-producing activity; MET-hrs/wk = metabolic equivalent hours per week of exercise.

Cohort Measurements

Nested linear contrasts of change within communities within conditions across the three testing occasions were conducted using multivariate repeated measures analysis of covariance (MANCOVA). The multivariate approach was used because the univariate sphericity assumption was untenable for most of the outcomes to be analysed. All models included the between variables *condition* (intervention versus comparison), *community* within condition, and *diabetes status* (diabetes, impaired glucose tolerance, or normoglycaemia). Diabetes status was included to adjust for differences in baseline glucose status among individuals in communities within conditions. The within factor was time of survey, for which there were three levels. The main covariate was age, as a continuous variable, but other covariates were included for specific analyses. Total caloric intake was included as a time-varying covariate for analyses of intake of dietary constituents. Gender was not included in models because it was not related to any outcome in preliminary analyses, and was omitted to conserve power. The impact of multiple comparisons on the statistical significance of outcomes was assessed by adjusting *P*-values within general classes of outcomes (blood measures, anthropometric and behavioural variables).

Orthogonal contrasts tested the first order condition-by-time interaction term, comparing the intervention community with the two comparison communities across all testing occasions. All contrasts were weighted for the number of observations for each condition-by-community-by-time-by-diabetes status combination. The weighted marginal means provide an unbiased population-level estimate of change between conditions. The condition-by-time term tests the primary question of whether the intervention condition experienced significantly different change over time than the comparison condition. Second order condition-by-time-by-diabetes status interaction terms were also included in models. Rao's *R*, a multivariate statistic approximating the usual *F*-statistic for ANOVA, is reported for multivariate tests.

For those variables measured twice only, at baseline and the end of the project, univariate analyses were used to determine whether net changes differed between the intervention and comparison conditions. A univariate analysis of a repeated measures factor with only two levels is equivalent to a change score analysis taking pre-test minus post-test differences as dependent. The modelling strategy was identical to that used for variables with three repeated measures. The

same between variables were included, age was the covariate, and the condition-by-time term tested whether change differed between the intervention and comparison conditions.

For multivariate analyses, the Box M test and the Sen and Puri tests were used to assess whether the variance-covariance matrices of the dependent variables were equal in the between-group cells of the design. The Box M test was significant for fasting glucose, brief screen for depression, and MET-hours per week of exercise. In these instances the Sen and Puri test was not significant, but examination of the within-group variance-covariance matrices indicated major heterogeneity problems. Plots of means versus standard deviations were generated and the correlations examined: correlations ranged from 0.48 to 0.91. Resorting to \log_{10} transformations to attempt to stabilise the variance for these variables, the Box M test and plots of means versus standard deviations were generated again. The Box M test was significant for fasting glucose and MET-hours per week of exercise, but correlations between means and standard deviations were just 0.31 and 0.37, respectively. As the Box M test is known to be sensitive to departures from normality, it was concluded that \log_{10} transformed values for fasting glucose and MET-hours per week of exercise (and the brief screen for depression) were suitable for parametric analysis. In reporting means and standard deviations for variables for which transformations were analysed, the untransformed values are tabulated for consistency with other variables. Back-transformed values for means and standard deviations did not differ substantially from the raw values.

Homogeneity of variances was assessed for all univariate analyses using Levene's test (Milliken & Johnson, 1992). The test was significant for knowledge of diabetes, not for the raw number of correct responses (which had a skewed distribution), but for arcsine transformations of the proportion of correct responses (which were normally distributed). Therefore, both sets of values were analysed, with the same conclusion. On this basis, results are presented for analyses of the raw number of correct responses, and the means and standard deviations tabulated are based on raw scores.

Half-normal probability plots of z-transformed within-cell correlations were reviewed for all parametric time-dependent analyses, to explore the distribution of correlations across groups in the population. There were no marked departures from normality. Further, the assumption of analysis of covariance that the regression models in each cell of the between-group design are

equal was tested by examining interactions between covariates and the between-group factors. The multivariate assumption that the regression planes are parallel was also tested. This involved assessing the homogeneity, or parallelism, of regression lines and planes by comparing the residual variance-covariance matrices within each cell based on a common regression model with the within-cell residual matrix based on separate models. The multivariate results assessing all levels of the time factor at once were reviewed. In no instance was the test statistically significant.

Dichotomous and categorical variables were analysed using nonparametric methods. These analyses were supplementary and intended to clarify trends in continuous outcomes; they were not considered part of the primary evaluation strategy. Within groups, Friedman's ANOVA was used to test for differences over time in graded categories of sweat-producing activity per week and in the number of drinks of alcohol per week. Cochran's Q-test was used to test changes in proportions over time in alcohol consumption, smoking status, at least one episode of sweat-producing activity per week, high blood pressure and the prevalence of clinically elevated metabolic values for blood measures. The Chi-square test and the Mann-Whitney U test were used to assess differences between groups for the same variables at different points in time.

Baseline measures were contrasted among cohorts by condition and participation status (drop-outs versus finishers). Finishers were individuals who participated in all three waves of data collection. Drop-outs were individuals measured at baseline but who did not participate in either the second or third testing occasions, or both. Means and 95% confidence intervals were calculated for drop-outs and finishers by condition.

ANOVA models for unbalanced data tested the main effects and interaction of condition and participation status. All analyses were weighted for sampling frequencies. The interaction term tested whether differences between drop-outs and finishers varied by condition; that is, whether bias operating through differentials in the characteristics of drop-outs was a threat to the internal validity of conclusions about programme effectiveness. The condition term is irrelevant in a quasi-experimental context, since inherent differences are likely to exist between conditions at baseline, requiring that conclusions be based on relative, not absolute, differences over time. The participation term assessed whether differences existed across conditions at baseline between persons who completed all measurements and others who did not. The participation

term is relevant, therefore, to the external validity of conclusions about programme effectiveness, if condition-by-participation interactions are not significant. All analyses were adjusted for clustering by way of variance inflation factors and reductions in denominator degrees of freedom by the design effect.

To test for bias inherent in missing data and to assess the randomness of missing data (i.e., the nature of the “missingness”), dummy variables were created for each level of the repeated measures factor (testing occasion). The reference variable on which dummy variables were based was fasting glucose. For each testing occasion, if a fasting glucose value was present, it was coded 0. Missing fasting glucose values were coded 1. Intercorrelations of all dichotomous dummy variables were then calculated across conditions and for each condition separately.

Cross-sectional Measurements

All but one analysis involved three-way analysis of covariance (ANCOVA) models. The exception was a test of differential change over time in sweat-producing physical activity at least once per week, a dichotomous variable. For this analysis, given independent samples for each condition for each of two surveys, the Breslow-Day homogeneity χ^2 statistic was calculated to test interaction between the two survey strata and conditions. For the ANCOVA models, classification variables were condition (intervention versus comparison), community (nested as a fixed effect) within condition, time of survey, and the first order condition-by-survey interaction term. The covariate was age, measured on a continuum. Orthogonal contrasts were used to test the main effects and the effect of the condition-by-survey interaction term, comparing the single intervention community with the two comparison communities in a single linear contrast. Results are reported for the condition-by-survey interaction term, which evaluates the main question of whether the intervention community experienced significantly different changes between the baseline and end-of-project surveys than the comparison communities. As for cohort analyses, the impact of multiple comparisons on the significance of outcomes was assessed, except that all *P*-values were adjusted together, rather than within classes of variables, given relatively few tests.

Questions about co-variation between changes in programme inputs (e.g., knowledge and awareness of the project) and outputs (e.g., activity levels, body mass index and dietary behaviour) were tested by four-way ANCOVA models similar those described above. Programme inputs were included, however, as independent variables. The second order condition-by-survey-by-input interaction term tested whether relationships between inputs and outputs varied over time between the intervention and comparison communities.

Homogeneity of variances was assessed using Levene's test (Milliken & Johnson, 1992). The test was not statistically significant for any variable. None of the outcome variables required transformation, most likely because of the greater numbers of individuals analysed. Review of normal and detrended normal probability plots did not reveal marked departures from normality for any variable. The parallelism of regression lines was also tested by examining interactions between age and the between-group factors. The test was not statistically significant for any variable.

Software

The majority of analyses were conducted using software package STATISTICA (Statsoft, 1994), based on the cell means model. Specialised epidemiological software was also used. EPI PAK (Sullivan, 1990) was used to calculate Miettinen's mid-*P* exact confidence intervals for proportions, the preferred procedure for data sets containing some cells with few numbers of observations (Berry & Armitage, 1995). MLEPID (Foster, 1988) was used to assess differential change over time in dichotomous outcomes for independent samples between conditions. For this analysis, interaction was tested between survey strata and conditions by way of the Breslow-Day homogeneity χ^2 statistic and its associated *P*-value. Probability values for statistics adjusted for variance inflation factors and corrections to degrees of freedom were calculated for the relevant distribution using the software package PEPI (Gahlinger & Abramson, 1995). PEPI was also used to calculate the Kappa statistic for determining inter-rater reliability of assessments of participation status, and for adjusting *P*-values for multiple comparisons by way of the Holm procedure (Holm, 1979). The Holm procedure is considered to be the first choice for assumption-free adjustment of *P*-values for multiple comparisons (Aickin & Gensler, 1996; Levin, 1996).

CHAPTER 7

RESULTS

This chapter is divided into three major sections. The first section presents the results of the “high-risk” cohorts tracked over 16 months for each condition, with measurements taken at baseline, mid-intervention 8 months later, and the end of the project after 16 months of intervention. The second section presents the results of cross-sectional community-level surveys undertaken at baseline and the end of the project. The third section describes the results of the community systems surveys undertaken in the intervention community only.

Cohort Surveys

Participation in Data Collection

At baseline, 207 individuals were enrolled in cohort samples: 94 in the Okanagan community, and 79 and 34 in the Spallumcheen and Penticton communities, respectively. Of these, 183 were measured at baseline: 88 in Okanagan, 64 in Spallumcheen and 31 in Penticton. The second (mid-project) wave of data collection had the lowest level of participation (Table 10) with only 130 individuals participating: 67 in Okanagan, 43 in Spallumcheen and 20 in Penticton. A total of 149 individuals participated in the third (end-of-project) wave of data collection: 77 in Okanagan, 50 in Spallumcheen and 22 in Penticton. Some individuals participated in the second and/or third waves but not the first, and others participated at baseline only. By community, the number of individuals participating in all waves of data collection was: 62 in Okanagan, 27 in Spallumcheen and 16 in Penticton (105 overall). Rates (%) for participation in all waves of data collection, relative to the number of individuals measured at baseline, were: Okanagan, 70.5; Spallumcheen, 42.2; and Penticton, 51.6. Across communities, the overall rate of participation was 57.3%.

Persons with diabetes participating at baseline numbered 16 of 20 (80%) for Okanagan, 12 of 16 (75%) for Spallumcheen and 4 of 4 (100%) for Penticton. Individuals at familial risk for developing diabetes formed the remainder of each sample. Because Band lists were not shared,

the number of eligible family members who participated, as a proportion of the total population of first and second degree relatives of individuals with diabetes, is unknown. Nevertheless, given that (a) 183 individuals participated in baseline screening, (b) 32 of the 183 participants had established diabetes and (c) all 40 individuals with established diabetes were contacted about participating in the study, the average number of family members volunteering for screening per case of established diabetes can be estimated as $(183 - 32)/40$, for which the quotient is roughly 4.0. An average of four family members participating per case of diabetes is reasonable given the demographic characteristics of the three Bands sampled.

Table 10. Non-Response as a Proportion of All Persons Enrolled at Baseline in Cohorts by Condition, Community and Time of Data Collection*

	Intervention Condition		Comparison Condition					
	Okanagan		Spallumcheen		Penticton		Both Pooled	
	mean	95%CI†	mean	95%CI†	mean	95%CI†	mean	95%CI†
	<i>n</i> = 94		<i>n</i> = 79		<i>n</i> = 34		<i>n</i> = 113	
Baseline	6.4	2.6 - 12.8	19.0	11.5 - 28.8	8.8	2.3 - 22.2	15.9	10.0 - 23.6
8 months	28.7	20.3 - 38.5	45.6	34.8 - 56.6	41.2	25.7 - 58.1	44.2	35.3 - 53.5
16 months	18.1	11.3 - 26.8	36.7	26.6 - 47.7	35.3	20.7 - 52.3	36.3	27.8 - 45.5

*The number of persons enrolled in cohorts at baseline was greater than the number enrolled and measured at baseline. Not all persons enrolled were measured at baseline.

†Miettinen's mid-*P* exact 95% confidence interval (CI).

Baseline Differences, Drop-outs, and Missing Data

Table 11 presents baseline means (\bar{x}) and 95% confidence intervals (95% CI) for most variables, classified by condition and drop-out status. The complete list of variables evaluated for baseline differences included: age, gender, post-secondary education, fasting glucose, glycosylated haemoglobin, insulin, cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, body mass index, waist-to-hip girth ratio, systolic blood pressure, diastolic blood pressure, self-esteem, mastery, depression, affect balance, physical activity, total caloric intake, and consumption of carbohydrates, protein and lipid.

Table 11. Characteristics of Persons Enrolled in Cohorts and Measured at Baseline by Condition and Participation Status*

			Intervention Condition			Comparison Condition		
			<i>n</i>	mean	95% CI†	<i>n</i>	mean	95% CI†
Age (years)‡§		Dropouts	26	45.5	39.3 – 51.6	52	38.7	35.0 – 42.4
		Finishers	62	49.1	45.6 – 52.6	43	44.1	39.7 – 48.5
Gender (%)	Males	Dropouts	9	34.6	18.4 – 54.1	22	42.3	29.5 – 56.0
		Dropouts	17	65.4	45.9 – 81.6	30	57.7	44.0 – 70.5
	Females	Dropouts	17	65.4	45.9 – 81.6	30	57.7	44.0 – 70.5
		Finishers	20	32.3	21.5 – 44.6	16	37.2	23.8 – 52.3
Post-secondary education (%)¶		Dropouts	26	64.0	44.1 – 80.8	50	60.0	46.0 – 72.8
		Finishers	62	56.5	44.0 – 68.4	43	62.8	47.7 – 76.2
Glycosylated haemoglobin (%)		Dropouts	26	6.35	5.75 – 6.95	52	5.75	5.39 – 6.11
		Finishers	62	5.85	5.56 – 6.14	43	5.94	5.30 – 6.58
Insulin (pmol/L)		Dropouts	26	78.4	61.7 – 95.0	52	89.9	76.2 – 103.6
		Finishers	61	97.9	78.0 – 117.8	43	141.9	86.3 – 197.6
Cholesterol (mmol/L)‡		Dropouts	26	5.89	5.38 – 6.40	52	5.20	4.84 – 5.56
		Finishers	62	5.68	5.44 – 5.92	43	5.24	4.89 – 5.59
Triglycerides (mmol/L)		Dropouts	26	3.02	2.08 – 3.95	52	3.01	1.84 – 4.18
		Finishers	62	2.47	1.99 – 2.95	43	2.72	2.02 – 3.42
High-density lipoprotein (mmol/L)		Dropouts	26	0.98	0.87 – 1.09	51	1.08	0.99 – 1.18
		Finishers	62	1.09	1.03 – 1.15	42	1.14	1.00 – 1.28

Body mass index (kg/m ²) [‡]	Dropouts	25	29.3	27.4 – 31.1	51	28.1	26.6 – 29.5
	Finishers	61	31.0	29.5 – 32.6	43	27.7	25.9 – 29.4
Systolic blood pressure (mmHg)	Dropouts	25	116.6	109.3 – 123.9	51	114.1	109.7 – 118.5
	Finishers	61	121.5	116.5 – 126.5	43	112.2	107.7 – 116.7
Self-esteem (6-point scale) (high score is positive)	Dropouts	24	5.12	4.66 – 5.59	49	4.90	4.57 – 5.22
	Finishers	60	5.00	4.71 – 5.29	43	4.93	4.56 – 5.30
Mastery (5-point scale) (high score is positive)	Dropouts	24	3.87	3.57 – 4.17	49	3.77	3.56 – 3.98
	Finishers	60	3.86	3.71 – 4.01	43	3.61	3.42 – 3.80
Affect balance (10-point scale) (high score is positive)	Dropouts	24	8.17	7.27 – 9.07	49	7.22	6.49 – 7.94
	Finishers	59	7.80	7.30 – 8.30	43	7.54	6.89 – 8.19
Physical activity (MET-hrs/week) [‡] (MET = metabolic equivalent)	Dropouts	19	4.13	1.74 – 6.52	34	12.26	7.13 – 17.38
	Finishers	38	9.09	6.09 – 12.08	23	14.26	7.89 – 20.62
Carbohydrate consumption (g) (three-day total)	Dropouts	19	558.1	402.0 – 714.2	37	504.8	443.2 – 566.4
	Finishers	52	593.1	531.5 – 654.7	31	499.7	418.3 – 581.1
Protein consumption (g) [‡] (three-day total)	Dropouts	19	208.1	165.8 – 250.4	37	178.0	158.0 – 198.0
	Finishers	52	219.1	196.4 – 241.8	31	182.9	146.5 – 219.3
Lipid consumption (g) (three-day total)	Dropouts	19	167.7	129.9 – 204.1	37	162.5	139.9 – 185.1
	Finishers	52	166.2	146.0 – 186.4	31	163.4	124.6 – 202.2

*Finishers participated in all three waves of data collection. Drop-outs were enrolled in cohorts and measured at baseline, but did not participate in the second or third waves of data collection. Totals vary and are less than in Table 10; of persons enrolled, not all were measured, and others did not complete all measures.

†CI = Confidence Interval; Miettinen's mid-*P* exact 95% confidence interval is given for proportions.

‡Significantly different ($P < 0.05$) between intervention conditions, adjusted for clustered observations.

§Significantly different ($P < 0.05$) between drop-outs and finishers, adjusted for clustered observations.

¶Attendance at university, community college, business, trade/vocational school, or similar institution, based on high-school graduation or equivalency.

Across levels of participation status (i.e., for finishers and drop-outs combined), baseline differences between conditions were statistically significant for the following variables only (for which statistics are provided for tests both unadjusted and adjusted for clustering):

- *age* (unadjusted $F_{1,175} = 10.48$, $P = 0.001$; adjusted $F_{1,121} = 7.21$, $P = 0.008$);
- *cholesterol* (unadjusted $F_{1,176} = 8.97$, $P = 0.003$; adjusted $F_{1,111} = 5.64$, $P = 0.019$);
- *low-density lipoprotein cholesterol* (unadjusted $F_{1,174} = 15.7$, $P = 0.0001$; adjusted $F_{1,98} = 8.79$, $P = 0.004$) (not given in Table 11: \bar{x} [95% CI]_{intervention} = 3.48 [3.27 – 3.69] mmol/L; \bar{x} [95% CI]_{comparison} = 2.90 [2.72 – 3.08] mmol/L);
- *body mass index* (no adjustment necessary for clustering: $F_{1,174} = 10.44$, $P = 0.002$);
- *systolic blood pressure* (unadjusted $F_{1,174} = 6.35$, $P = 0.013$; adjusted $F_{1,82} = 2.96$, $P = 0.089$);
- *depression* (unadjusted $F_{1,170} = 9.17$, $P = 0.003$; adjusted $F_{1,125} = 6.690$, $P = 0.011$) (not given in Table 11: \bar{x} [95% CI]_{intervention} = 16.6 [15.0 – 18.2]; \bar{x} [95% CI]_{comparison} = 20.4 [18.6 – 22.2]);
- *physical activity* (unadjusted $F_{1,108} = 8.36$, $P = 0.005$; adjusted $F_{1,105} = 8.11$, $P = 0.005$); and
- *protein intake* (unadjusted $F_{1,133} = 6.26$, $P = 0.014$; adjusted $F_{1,113} = 5.28$, $P = 0.023$).

Age was the only variable for which a difference existed between drop-outs and finishers (unadjusted for clustering: $F_{1,175} = 8.11$, $P = 0.005$; adjusted for clustering: $F_{1,121} = 5.58$, $P = 0.020$). Across conditions, the average difference between drop-outs and finishers was 4.5 years; drop-outs were in their late 30s to mid-40s, and finishers in their mid-40s to late 40s (Table 11). Condition-by-participation interaction terms were not statistically significant for any variable; thus, there were no differences between drop-outs and finishers between conditions.

Intercorrelations between dichotomous dummy variables coded for missing data for the three waves of data collection suggested that data were missing at random. Across conditions, the average intercorrelation was 0.207, but the pattern of non-response was not equal across time ($\chi^2 = 5.91$ with 2 d.f., $P = 0.016$) and was greatest for the comparison condition (Table 10). Conditional on the responses observed, the probability of missing observations appeared to depend primarily on study condition. Therefore, the non-response mechanism was considered to be ignorable (i.e., it was not deemed necessary to estimate parameters for missing data to obtain valid tests of treatment effects). It was necessary, however, to model study condition to fulfill the requirement of ignorable non-response, because the probability of a missing value was

predicted by treatment status (Gibbons *et al.*, 1993). Fulfilling this requirement was consistent with the approach taken to model the community factor and test data dependent hypotheses (using weighted marginal means) rather than those independent of the population structure.

Descriptive Characteristics of Cohort Samples

Descriptive characteristics for the 105 individuals completing at least some measures at each testing occasion are presented by community and condition in Table 12. There were no significant differences between communities or conditions in gender, established cases of diabetes, marital status, years of primary and secondary education, post-secondary education, or beliefs about the sufficiency of household income in relation the purchase of nutritious foods and participation in leisure-time physical activity.* The high proportion of persons reporting post-secondary education reflects enrollment for any purpose (e.g., an upgrading course) at a post-secondary institution, based on high-school graduation or equivalency (e.g., Grade 12 through adult education, or mature student status). Age differences approached statistical significance ($F_{1,102} = 3.00$, $P = 0.086$ [communities nested in conditions]). The mean age for the intervention community was greater by five years than that for the two comparison communities (Figure 3).

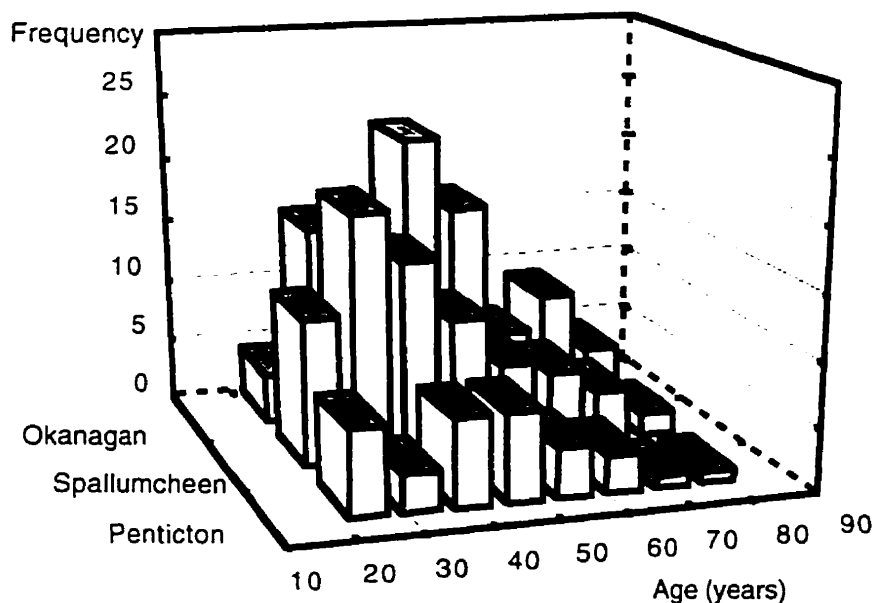


Figure 3. Distribution of Age for Cohort Samples by Community.

*The last two questions were proxy measures of income relevant to diabetes prevention and control (Community Advisory Boards did not approve direct questions about income).

Table 12. Characteristics of Cohort Samples by Condition and Community*

	Intervention Condition		Comparison Condition					
	Okanagan		Spallumcheen		Penticton		Both Pooled	
	mean	95% CI†	mean	95% CI†	mean	95% CI†	mean	95% CI†
	<i>n</i> = 62		<i>n</i> = 27		<i>n</i> = 16		<i>n</i> = 43	
Age (years)	49.1	45.6 – 52.6	44.3	39.0 – 49.6	43.8	35.9 – 51.7	44.1	39.7 – 48.5
Established diabetes at outset of project (%)	16.1	8.5 – 26.9	14.8	4.9 – 32.0	12.5	2.1 – 35.5	14.0	5.9 – 26.8
Gender								
Male (%)	32.3	21.5 – 44.6	40.7	23.6 – 59.8	31.2	12.5 – 56.3	37.2	23.8 – 52.3
Female (%)	67.7	55.4 – 78.5	59.3	40.2 – 76.4	68.8	43.7 – 87.5	62.8	47.7 – 76.2
Marital status								
Married (%)	83.9	73.1 – 91.5	77.8	59.4 – 90.5	68.8	43.7 – 87.5	76.7	62.5 – 87.5
Single (%)	9.7	4.0 – 19.0	7.4	1.3 – 22.4	6.2	0.3 – 27.2	7.0	1.8 – 17.8
Widowed or Divorced (%)	6.4	2.1 – 14.8	14.8	4.9 – 32.0	25.0	8.5 – 49.9	16.3	7.4 – 29.6
Years primary and secondary education								
1 to 5 (%)	14.5	7.3 – 25.0	14.8	4.9 – 32.0	18.7	5.0 – 43.0	16.3	7.4 – 29.6
6 to 9 (%)	17.7	9.7 – 28.7	25.9	12.1 – 44.7	6.3	0.3 – 27.2	18.6	9.0 – 32.3
10 to 12 (%)	67.8	55.4 – 78.5	59.3	40.2 – 76.4	75.0	50.1 – 91.5	65.1	50.1 – 78.2
Post-secondary education (%)‡	56.5	44.0 – 68.4	62.9	43.9 – 79.4	62.5	37.6 – 83.2	62.8	47.7 – 76.2
Respondent believes household income sufficient for purchase of nutritious foods (%)§	85.5	75.0 – 92.7	81.5	63.6 – 92.9	81.3	57.0 – 95.0	81.4	67.7 – 91.0
Respondent believes household income sufficient for leisure-time physical activity (%)§	77.4	65.8 – 86.5	70.4	51.4 – 85.2	62.5	37.6 – 83.2	67.4	52.5 – 80.1

*Pertains only to individuals participating in all three waves of data collection (baseline, 8 months, and 16 months).

†CI = Confidence Interval; Miettinen's mid-*P* exact 95% confidence interval is given for proportions.

‡Attendance at university, community college, business, trade/vocational school, or similar institution, based on high-school graduation or equivalency.

Participation in Interventions — Correlates and Impact

The mean participation score (\pm standard deviation) for individuals in the intervention cohort was 4.02 (\pm 2.1) on a 10-point scale. After dichotomisation into high and low levels of participation using the mean score as a cut-point, 52 of 94 persons (55.3%) were rated as having a high level of participation, and 42 of 94 persons (44.7%) were rated as having a low level of participation.

Forward stepwise multiple regression analysis with age and the dichotomous variables gender, post-secondary education, diabetes status and smoking status, showed that smoking status was the most powerful predictor of participation score, explaining 4.7% of the variation in participation (non-smokers had higher scores than smokers). After smoking, age accounted for a further 0.09% of participation variation. No further gain in variation could be achieved by including any other variable. Thus, the final stepwise regression equation involved two variables, smoking status and age, explaining 4.8% of participation variation ($F_{2,86} = 3.2$, $P = 0.045$).

Participation was associated with differences in change profiles for the outcomes body mass index ($R_{2,51} = 4.52$, $P = 0.015$) and triglyceride concentration ($R_{2,56} = 3.19$, $P = 0.048$). Although high and low participation categories had similar means at baseline, more healthful changes occurred for persons in the high participation category. Analyses tested the significance of participation-by-time interaction terms, controlling for post-screening diabetes status (diabetes, impaired glucose tolerance and normoglycaemia), with participation means and variances weighted for diabetes status frequencies within each group. Three-way participation-by-time-by-diabetes status interaction terms were not statistically significant for body mass index and triglyceride concentration, indicating that associations between participation and change in these outcomes did not vary with diabetes status.

Participation was not associated with change in fasting glucose, HbA_{1c}, cholesterol, high- or low-density lipoprotein, waist-to-hip girth ratio, systolic or diastolic blood pressure, metabolic equivalent hours per week of exercise, self-esteem, mastery, depression, affect balance, social support, or carbohydrate, protein, lipid, or total energy consumption. Three-way participation-by-time-by-diabetes status interaction terms were statistically significant, however, for fasting glucose ($R_{2,56} = 5.17$, $P = 0.0087$) and HbA_{1c} concentrations ($R_{2,56} = 4.65$, $P = 0.014$) (but not for other outcomes). Therefore, the association between participation and change in fasting glucose and

HbA_{1c} concentrations varied with diabetes status. Most persons with diabetes were in the high participation group, yet fasting glucose and HbA_{1c} concentrations worsened among individuals with diabetes. For persons with diabetes, mean concentrations of fasting glucose and HbA_{1c} were greater after eight and 16 months of intervention than at baseline ($P < 0.05$), and greater at each follow-up than mean concentrations for individuals with impaired glucose tolerance and normoglycaemic profiles ($P < 0.05$). Differences between the impaired glucose tolerance and normoglycaemic groups were not statistically significant at any time, nor were within group changes statistically significant for either group.

Physiological Outcomes

Diabetes Cases, Glycaemic Variables and Lipids

Diagnostic procedures at baseline identified six newly diagnosed diabetics in the comparison communities, but none within the intervention community. However, six cases of impaired glucose tolerance were identified within the intervention community; four in the comparison communities. The regional diabetes prevalence rate for on-reserve registered Indians in the Okanagan region aged 18 years and older was estimated at 36.1 per 1000 ($n = 1276$) (Daniel et al., 1995). Across the three communities, approximately 75% of individuals were classified following baseline screening as normoglycaemic (70% of men, 77% of women), 5% were diagnosed with impaired glucose tolerance (6% of men, 5% of women) and 20% were classified as having diabetes (24% of men, 18% of women). Gender did not vary with screening status: women averaged 60% across all categories; men, 40% ($\chi^2 = 1.0$ with 2 d.f., $P = 0.61$).

There were no significant changes over time between conditions in concentrations of fasting glucose, cholesterol, triglycerides, or high- or low-density lipoprotein (Table 13). HbA_{1c} increased, however, among individuals in the intervention condition, and decreased among individuals in the comparison condition. This change was paralleled by similar but non-significant shifts in fasting glucose. Poor glucose control among diabetes cases seemed to be responsible for the rise in HbA_{1c} for the intervention condition, whereas glucose control appeared to improve for diabetes cases in the comparison condition (Figure 4). Diabetes status interacted significantly with condition and time in effects on HbA_{1c} (unadjusted for clustering: $F_{4,186} = 3.66$, $P = 0.007$;

Table 13. Glycaemic Variables and Lipids (Fasting Values) at Baseline, Mid-Project (8 Months) and End of Project (16 Months), and Tests of Differential Change Over Time Between Conditions: Cohort Surveys*

	<i>n</i>	Baseline		Mid-Project		End of Project		Unadjusted Test [†]	Inflation Factor	Adjusted Test [‡]
		Mean	SD	Mean	SD	Mean	SD			
Fasting glucose (mmol/L)										
Intervention condition	62	5.68	1.76	5.69	3.06	5.84	2.54	$R_{2,94} = 1.92$	1.44	$R_{2,66} = 1.33$
Comparison condition	43	6.27	2.98	5.57	2.74	5.88	2.86	$P = 0.152$		$P = 0.271$
Glycosylated haemoglobin (%)										
Intervention condition	61	5.82	1.15	6.15	1.70	6.20	2.04	$R_{2,93} = 6.22$	1.44	$R_{2,65} = 4.31$
Comparison condition	43	5.93	2.14	5.85	1.48	5.47	1.42	$P = 0.003$		$P = 0.017$
Cholesterol (mmol/L)										
Intervention condition	62	5.68	0.97	5.50	0.94	5.51	1.03	$R_{2,94} = 0.19$	1.33	$R_{2,71} = 0.14$
Comparison condition	43	5.24	1.17	5.04	1.06	5.12	1.09	$P = 0.828$		$P = 0.867$
Triglyceride (mmol/L)										
Intervention condition	62	2.47	1.92	2.66	2.43	2.92	2.56	$R_{2,94} = 0.520$	1.44	$R_{2,66} = 0.360$
Comparison condition	43	2.72	2.33	2.72	2.17	2.81	2.45	$P = 0.596$		$P = 0.699$
High-density lipoprotein (mmol/L)										
Intervention condition	60	1.10	0.25	1.17	0.38	1.15	0.28	$R_{2,89} = 1.70$	1.42	$R_{2,63} = 1.20$
Comparison condition	40	1.15	0.47	1.29	0.35	1.29	0.40	$P = 0.188$		$P = 0.308$
Low-density lipoprotein (mmol/L)										
Intervention condition	58	3.53	0.88	3.18	0.80	3.11	0.87	$R_{2,86} = 1.19$	1.41	$R_{2,62} = 0.845$
Comparison condition	39	2.94	0.83	2.63	0.74	2.69	0.86	$P = 0.308$		$P = 0.434$

*Based on analysis of covariance models for unbalanced data, adjusting for age and glycaemic status (diabetes, impaired glucose tolerance, or normoglycaemia), with analyses weighted for sampling frequencies by community and condition. Two-tailed *P*-values denote the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

[†]Unadjusted and [‡]adjusted for clustering within communities, by way of variance inflation factors and reductions to degrees of freedom by the design effect.

adjusted for clustering: $R_{4,130} = 2.54$, $P = 0.043$) and fasting glucose (unadjusted for clustering: $R_{4,188} = 4.54$, $P = 0.002$; adjusted for clustering: $R_{4,131} = 3.15$, $P = 0.016$). Changes in fasting glucose paralleled those illustrated in Figure 4 for HbA_{1c}. Concentrations of fasting glucose and HbA_{1c} changed little within the normoglycemic and impaired glucose tolerance groups. Within group changes in fasting glucose and HbA_{1c} were significant for diabetes cases, for whom concentrations of these measures were greater at each follow-up compared to individuals with impaired glucose tolerance and normoglycaemic profiles ($P < 0.05$). Three-way interaction terms for other physiological variables and all other outcomes (anthropometric, behavioural and psychosocial) were not statistically significant.

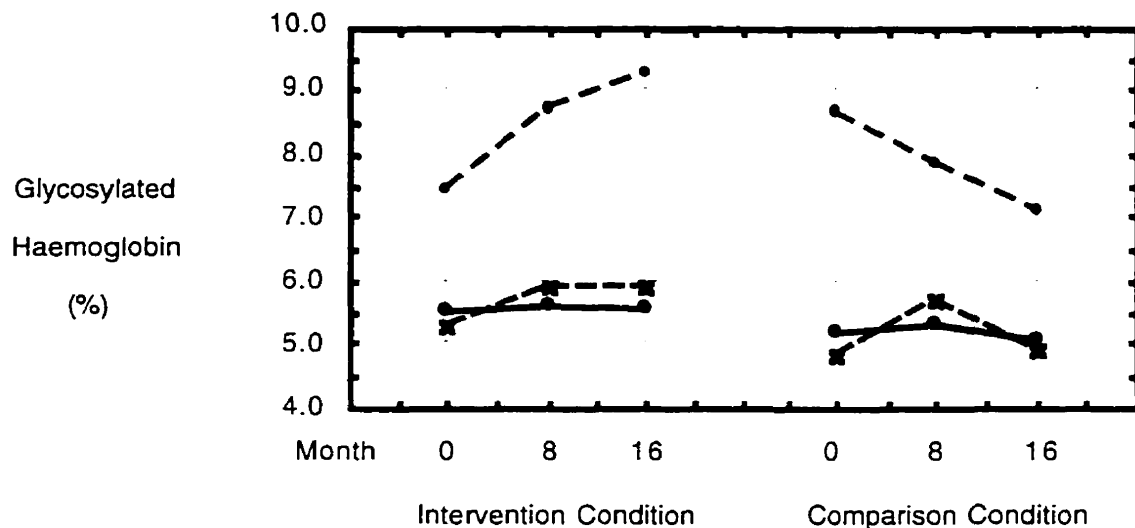


Figure 4. Percentage Glycosylated Haemoglobin by Glycaemic Status, Condition and Time, for Longitudinal Cohort Samples. Key: ● = Diabetes; × = Impaired Glucose Tolerance; ○ = Normoglycaemia. (Three-way interaction, adjusted for clustering: $R_{4,130} = 2.54$, $P = 0.043$.)

There were no significant changes over time within either the intervention or comparison condition in the proportion of persons with out-of-range concentrations of HbA_{1c}, cholesterol, high-density lipoprotein cholesterol or low-density lipoprotein cholesterol (Table 14). There was a statistically significant increase, however, in the proportion of persons in the intervention condition with elevated triglyceride concentrations. Differences between conditions were not statistically significant at any testing occasion ($\chi^2_1 > 2.43$, $P > 0.119$).

Table 14. Prevalence (Mean Proportion) of Clinically Elevated Metabolic Values at Baseline, Mid-Project (8 Months) and End of Project (16 Months), and Tests of Change Over Time Within Conditions: Cohort Surveys

	<i>n</i>	Baseline		Mid-Project		End of Project		Q-value*	d.f.	P-level
		Mean %	SD	Mean %	SD	Mean %	SD			
HbA_{1c}[†] > 6.45%										
Intervention condition	61	21.3	5.2	13.1	4.3	16.4	4.7	2.71	2	0.257
Comparison condition	43	14.0	5.3	14.0	5.3	11.6	4.9	2.00	2	0.368
Cholesterol ≥ 5.4 mmol/L										
Intervention condition	62	40.3	6.2	45.2	6.3	45.2	6.3	0.86	2	0.651
Comparison condition	43	58.1	7.5	60.5	7.5	60.5	7.5	0.17	2	0.920
Triglyceride > 2.45 mmol/L										
Intervention condition	62	38.7	6.2	32.3	5.9	56.5	6.3	6.83	2	0.033
Comparison condition	43	39.5	7.5	39.5	7.5	55.8	7.6	2.39	2	0.303
HDL[‡] < 0.69 (M) or < 0.59 (F)										
Intervention condition	60	1.6	1.6	4.9	2.8	1.6	1.6	2.00	2	0.368
Comparison condition	40	10.0	4.7	7.5	4.2	2.5	2.5	1.75	2	0.417
LDL[§] > 4.9 mmol/L										
Intervention condition	58	5.2	2.9	0.0	0.0	1.7	1.7	3.50	2	0.174
Comparison condition	39	2.6	2.5	0.0	0.0	2.6	2.5	1.00	2	0.606

*Cochrane's Q-test for changes in frequencies in more than two dependent samples. Between-condition differences were not significant at any point in time.

[†]Percentage glycosylated haemoglobin.

[‡]HDL = high-density lipoprotein cholesterol; clinical cut-points are less than 0.69 mmol/L for adult males (M) and less than 0.59 mmol/L for adult females (F).

[§]LDL = low-density lipoprotein cholesterol.

Blood Pressure

There were significant changes between conditions in mean systolic blood pressure (Table 15). Mean systolic blood pressure increased steadily among individuals in the comparison condition, but decreased for the intervention condition. Mean diastolic blood pressure showed a similar pattern, but this did not remain statistically significant after adjustment for clustering.

There were no changes over time within either the intervention or comparison condition in the proportion of persons classified with high blood pressure (not shown in Table 15). Proportions, by testing occasion (baseline, 8 months and 16 months), were: intervention condition, 17.5, 19.3, 15.8 ($n_i = 57$; $Q = 1.2$ with 2 d.f., $P = 0.549$); comparison condition, 6.8, 13.6, 6.8 ($n_c = 44$; $Q = 2.6$ with 2 d.f., $P = 0.276$). Differences between conditions were not significant at any testing occasion ($\chi^2_1 > 3.0$, $P > 0.08$).

Anthropometric Outcomes

Body mass index increased steadily within the comparison condition, but decreased within the intervention condition (Figure 5). This change was significant between conditions (Table 15). There was no significant change, however, in waist-to-hip girth ratio.

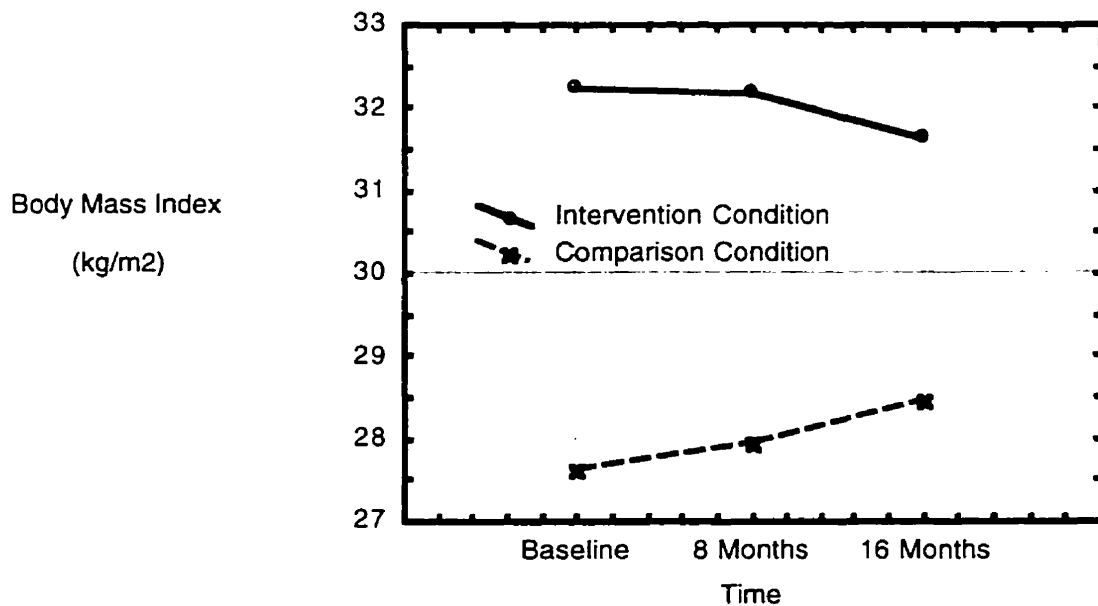


Figure 5. Body Mass Index by Condition and Time, for Longitudinal Cohort Samples. Two-way interaction: $R_{2,89} = 5.96$, $P = 0.004$. (Means are adjusted for age and diabetes status.)

Table 15. Body Mass Index, Waist-to-Hip Girth Ratio, and Blood Pressure at Baseline, Mid-Project (8 Months) and End of Project (16 Months), and Tests of Differential Change Over Time Between Conditions: Cohort Surveys*

	<i>n</i>	Baseline		Mid-Project		End of Project		Unadjusted Test†	Inflation Factor	Adjusted Test†
		Mean	SD	Mean	SD	Mean	SD			
Body mass index (kg/m²)										
Intervention condition	57	30.8	5.7	31.0	5.6	30.4	5.5	$R_{2,89} = 5.96$	1.00§	$R_{2,89} = 5.96$
Comparison condition	45	27.5	5.8	27.8	5.9	28.6	5.9	$P = 0.004$		$P = 0.004$
Waist-to-hip girth ratio (cm/cm)										
Intervention condition	58	0.913	0.098	0.895	0.085	0.895	0.090	$R_{2,88} = 0.38$	1.00§	$R_{2,88} = 0.38$
Comparison condition	43	0.914	0.092	0.904	0.081	0.905	0.086	$P = 0.687$		$P = 0.687$
Systolic blood pressure (mmHg)										
Intervention condition	57	121.5	20.1	115.5	16.3	115.5	14.3	$R_{2,87} = 7.21$	1.63	$R_{2,54} = 4.43$
Comparison condition	43	113.3	15.4	114.5	16.4	118.8	16.8	$P = 0.001$		$P = 0.017$
Diastolic blood pressure (mmHg)										
Intervention condition	57	74.5	12.8	72.6	10.8	70.7	10.2	$R_{2,87} = 4.03$	2.59	$R_{2,35} = 1.56$
Comparison condition	43	68.7	9.8	70.9	10.0	72.0	11.1	$P = 0.021$		$P = 0.224$

*Based on analysis of covariance models for unbalanced data, adjusting for age and glycaemic status (diabetes, impaired glucose tolerance, or normoglycaemia), with analyses weighted for sampling frequencies by community and condition. Two-tailed *P*-values indicate the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

†Unadjusted and ‡adjusted for clustering within communities, by way of variance inflation factors and reductions to degrees of freedom by the design effect.

§No adjustment on basis of negative intra-class correlations.

Behavioural Outcomes

Dietary Intake Over Three Days

There were no changes over time between conditions in three-day totals for caloric intake (total energy) or the masses (calorie-adjusted) of carbohydrate, protein, or lipid consumed (Table 16). For both conditions there were shifts in the amount of carbohydrate and protein consumed; levels dropped following baseline, but rose following mid-project such that values at the end of the project approximated those measured at baseline. Lipid consumption followed a similar pattern.

Physical Activity

For those individuals providing sufficient information to estimate metabolic equivalent hours of exercise per week ($n = 35$), there were no changes in this measure over time between conditions (Table 16). Within the comparison condition, there were no changes in the proportion of persons engaging at least once per week in sweat-producing physical activity ($n_c = 42$; $Q = 1.14$ with 2 d.f., $P = 0.56$); by testing occasion, proportions were 57.1, 66.7, and 61.9. There was a significant decrease in the proportion of individuals in the intervention condition reporting at least one sweat-producing episode per week ($n_i = 50$; $Q = 11.0$ with 2 d.f., $P = 0.004$); by testing occasion, proportions were 62.0, 74.0, and 48.0. Differences between conditions were not statistically significant at any testing occasion ($\chi^2_1 > 0.5$, $P > 0.48$).

Under both conditions the mean and average rank for episodes of sweat producing activity per week increased from baseline to mid-project, then decreased such that levels at the end of the project were lower than those at baseline. These changes were statistically significant within but not between conditions. Means (\pm SD), by testing occasion, are as follows: intervention condition, 1.64 (1.61), 1.94 (1.53), 1.32 (1.60) ($n_i = 50$; ANOVA $\chi^2 = 6.0$ with 2 d.f., $P = 0.049$); comparison condition, 1.68 (1.71), 2.12 (1.65), 1.56 (1.55) ($n_c = 41$; ANOVA $\chi^2 = 5.2$ with 2 d.f., $P = 0.040$). Differences between conditions were not significant at any testing occasion ($Z > -0.754$, $P > 0.36$).

Table 16. Physical Activity and Dietary Behaviour at Baseline, Mid-Project (8 Months) and End of Project (16 Months), and Tests of Differential Change Over Time Between Conditions: Cohort Surveys*

	<i>n</i>	Baseline		Mid-Project		End of Project		Unadjusted Test†	Inflation Factor	Adjusted Test‡
		Mean	SD	Mean	SD	Mean	SD			
Physical activity (MET-hrs/wk) [§]										
Intervention condition	20	10.1	7.3	11.1	10.8	8.7	6.3	$R_{2,23} = 0.079$	1.01	$R_{2,23} = 0.078$
Comparison condition	15	16.9	17.0	28.2	41.8	15.9	13.9	$P = 0.925$		$P = 0.925$
Carbohydrate intake (grams) [¶]										
Intervention condition	43	591	232	491	161	606	189	$R_{2,56} = 0.907$	1.08	$R_{2,52} = 0.842$
Comparison condition	23	483	224	474	229	578	302	$P = 0.410$		$P = 0.437$
Protein intake (grams) [¶]										
Intervention condition	43	222	83	169	60	190	66	$R_{2,56} = 2.44$	1.08	$R_{2,52} = 2.27$
Comparison condition	23	181	106	152	60	183	70	$P = 0.096$		$P = 0.113$
Lipid intake (grams) [¶]										
Intervention condition	43	165	76	151	69	176	69	$R_{2,56} = 2.54$	1.08	$R_{2,52} = 2.36$
Comparison condition	23	161	119	147	82	163	93	$P = 0.087$		$P = 0.104$
Energy intake (kcal)										
Intervention condition	43	4737	1790	3966	1277	4769	1348	$R_{2,56} = 1.10$	1.08	$R_{2,52} = 1.02$
Comparison condition	23	4106	2168	3949	2104	4468	2160	$P = 0.341$		$P = 0.368$

*Based on analysis of covariance models for unbalanced data, adjusting for age and glycaemic status (diabetes, impaired glucose tolerance, or normoglycaemia), with analyses weighted for sampling frequencies by community and condition. Two-tailed *P*-values indicate the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

†Unadjusted and ‡adjusted for clustering within communities, by way of variance inflation factors and reductions to degrees of freedom by the design effect.

§MET = metabolic equivalent; MET-hrs/wk = metabolic equivalent hours of physical activity per week. Small *n* reflects poor response rate to activity questions.

¶Total consumption over three days (one weekend day and two weekdays), adjusted for total caloric intake (kcal, or kilocalories) as a time-varying covariate.

Alcohol Consumption

There were no changes over time within either the intervention or comparison condition in the proportion of persons reporting alcohol consumption. Proportions, by testing occasion, are as follows: intervention condition, 62.7, 60.8, 60.8 ($n_i = 51$; $Q = 2.0$ with 2 d.f., $P = 0.367$); comparison condition, 47.5, 47.5, 47.5 ($n_c = 40$; $Q = 0.0$ with 2 d.f., $P = 1.0$). Differences between conditions were not significant at any testing occasion ($\chi^2_1 > 3.0$, $P > 0.08$).

Under both conditions there were no changes in the mean and average rank for the number of drinks consumed per week. Means (\pm SD), by testing occasion, are as follows: intervention condition, 1.91 (4.11), 2.17 (4.84), 2.50 (5.44) ($n_i = 50$; ANOVA $\chi^2 = 2.74$ with 2 d.f., $P = 0.254$); comparison condition, 3.97 (7.02), 3.42 (6.70), 2.19 (3.32) ($n_c = 31$; ANOVA $\chi^2 = 1.96$ with 2 d.f., $P = 0.375$). Differences between conditions were significant at the end of the project ($Z = 2.69$, $P = 0.007$), but not at baseline or mid-project ($Z > -0.51$, $P > 0.61$).

Smoking Status

There were no changes over time within either the intervention or comparison condition in the proportion of individuals classified as regular smokers. Proportions, by testing occasion, are as follows: intervention condition, 30.2, 23.3, 25.6 ($n_i = 43$; $Q = 2.8$ with 2 d.f., $P = 0.247$); comparison condition, 59.0, 59.0, 56.4 ($n_c = 39$; $Q = 0.5$ with 2 d.f., $P = 0.78$). Differences between conditions were significant at all testing occasions ($\chi^2_1 > 9.60$, $P = 0.002$).

Psychosocial Outcomes

There were no changes over time between conditions in any psychosocial variable: self-esteem, mastery, depression, affect balance, or social support (Table 17).

Diabetes Knowledge, Quality of Life and Health Beliefs

Among persons with diabetes and impaired glucose tolerance, there were no changes over time in knowledge of diabetes, quality of life, or diabetes health beliefs (Table 18). Neither global multivariate nor univariate analyses of domain scores showed any change over time.

Table 17. Psychosocial Measures at Baseline, Mid-Project (8 Months) and End of Project (16 Months), and Tests of Differential Change Over Time Between Conditions: Cohort Surveys*

	<i>n</i>	Baseline		Mid-Project		End of Project		Unadjusted Test [†]	Inflation Factor	Adjusted Test [‡]
		Mean	SD	Mean	SD	Mean	SD			
Self-esteem (6-point scale) [§]										
Intervention condition	45	5.0	1.1	5.2	1.0	5.2	0.9	$R_{2,73} = 1.69$	1.17	$R_{2,62} = 1.44$
Comparison condition	41	4.7	1.4	4.9	1.4	4.5	1.6	$P = 0.191$		$P = 0.245$
Mastery (5-point scale) [§]										
Intervention condition	46	3.9	0.6	3.9	0.6	3.8	0.7	$R_{2,74} = 2.74$	1.17	$R_{2,63} = 2.33$
Comparison condition	41	3.5	0.7	3.7	0.8	3.6	0.7	$P = 0.071$		$P = 0.106$
Depression (score) [§]										
Intervention condition	46	16.7	6.6	17.8	7.4	18.7	7.7	$R_{2,74} = 1.33$	1.17	$R_{2,63} = 1.13$
Comparison condition	41	20.6	8.8	19.5	8.3	20.5	8.5	$P = 0.272$		$P = 0.329$
Affect balance (10-point scale) [¶]										
Intervention condition	45	8.0	1.9	8.2	2.1	8.1	2.2	$R_{2,72} = 0.10$	1.17	$R_{2,62} = 0.09$
Comparison condition	40	7.4	2.3	7.7	2.2	7.2	2.9	$P = 0.902$		$P = 0.919$
Social support (score x 10) [§]										
Intervention condition	43	23.0	7.7	22.8	7.7	21.9	8.5	$R_{2,66} = 0.82$	1.15	$R_{2,57} = 0.71$
Comparison condition	35	20.0	8.0	21.1	8.7	20.9	8.2	$P = 0.450$		$P = 0.496$

*Based on analysis of covariance models for unbalanced data, adjusting for age and glycaemic status (diabetes, impaired glucose tolerance, or normoglycaemia), with analyses weighted for sampling frequencies by community and condition. Two-tailed *P*-values indicate the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

[†]Unadjusted and [‡]adjusted for clustering within communities, by way of variance inflation factors and reductions to degrees of freedom by the design effect.

[§]Low score = low affect; high score = high affect.

[¶]Low score = negative affect; high score = positive affect.

Table 18. Mean Diabetes Knowledge, Quality of Life and Health Beliefs, and Net Intervention – Comparison (I – C) Differences Over 16 Months from Baseline (B) to End (E) of Project: Cohort Surveys of Persons with Diabetes and Impaired Glucose Tolerance*

	<i>n</i>	Baseline		End of Project		Difference (E – B)	Net (I – C) Differences	Unadjusted Test†	Inflation Factor	Adjusted Test‡
		mean	SD	mean	SD					
Knowledge of diabetes (13-point score)										
Intervention condition	10	8.8	4.3	9.6	2.9	+0.7	-0.1	$F_{1,14} = 1.35$	1.03	$F_{1,14} = 1.31$
Comparison condition	9	7.7	2.0	8.5	3.0	+0.8		$P = 0.264$		$P = 0.272$
Diabetes quality-of-life (global multivariate test)								$R_{4,9} = 2.41$	1.03	$R_{4,9} = 2.33$
								$P = 0.126$		$P = 0.134$
Impact of diabetes (0 = low, 100 = high)										
Intervention condition	12	37.6	7.5	38.8	8.6	+1.2	+4.3	$F_{1,13} = 1.53$	1.03	$F_{1,13} = 1.48$
Comparison condition	6	41.3	4.7	38.2	4.8	-3.1		$P = 0.238$		$P = 0.245$
Worry: social-vocational (0 = low, 35 = high)										
Intervention condition	12	9.4	4.8	9.3	4.8	-0.1	-0.1	$F_{1,13} = 0.22$	1.03	$F_{1,13} = 0.21$
Comparison condition	6	9.2	3.9	9.2	1.9	0.0		$P = 0.649$		$P = 0.654$
Worry: diabetes-related (0 = low, 20 = high)										
Intervention condition	12	6.8	4.1	6.9	4.1	0.1	+3.3	$F_{1,13} = 3.04$	1.03	$F_{1,13} = 2.95$
Comparison condition	6	8.2	1.2	5.0	1.1	-3.2		$P = 0.105$		$P = 0.110$
Satisfaction (0 = low, 75 = high)										
Intervention condition	12	31.2	8.5	32.3	7.0	+1.1	-7.4	$F_{1,13} = 0.62$	1.03	$F_{1,13} = 0.60$
Comparison condition	6	38.0	7.7	29.5	8.3	-8.5		$P = 0.446$		$P = 0.452$

Diabetes Health Beliefs (global multivariate test)										$R_{4,9} = 0.47$ $P = 0.758$	1.03	$R_{4,9} = 0.45$ $P = 0.767$
Susceptibility to diabetes (20-point score) [§]												
Intervention condition	12	7.8	2.3	6.9	2.4	-0.9	0.4			$F_{1,13} = 0.84$	1.03	$F_{1,13} = 0.81$
Comparison condition	6	7.5	1.8	6.2	2.0	-1.3				$P = 0.377$		$P = 0.384$
Severity of diabetes (20-point score) [¶]												
Intervention condition	12	10.6	2.1	9.8	2.0	-0.8	-0.1			$F_{1,13} = 0.35$	1.03	$F_{1,13} = 0.34$
Comparison condition	6	11.0	3.0	10.3	2.3	-0.7				$P = 0.566$		$P = 0.570$
Benefits (20-point score) [§]												
Intervention condition	12	8.3	1.6	7.9	1.0	-0.4	-0.4			$F_{1,13} = 0.36$	1.03	$F_{1,13} = 0.35$
Comparison condition	6	8.8	1.8	8.8	1.8	0.0				$P = 0.557$		$P = 0.564$
Barriers (20-point score) [¶]												
Intervention condition	12	12.9	3.1	13.4	2.4	0.5	0.0			$F_{1,13} = 0.86$	1.03	$F_{1,13} = 0.83$
Comparison condition	6	12.2	2.9	12.7	2.4	0.5				$P = 0.371$		$P = 0.379$

*Based on analysis of covariance models for unbalanced data, adjusting for age and glycaemic status (diabetes or impaired glucose tolerance), with analyses weighted for sampling frequencies by community and condition. Two-tailed P -values indicate the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

†Unadjusted for clustering within communities.

‡Adjusted for clustering within communities, by way of variance inflation factors based on the design effect (inconsequential adjustment for degrees of freedom).

§Low scores suggest readiness to change.

¶High scores suggest readiness to change.

Cross-Sectional (Community Level) Surveys

Sampling Fractions and Response Rates

The probability of being selected for surveys (i.e., the sampling fraction) varied by community but was equivalent between the two conditions (Table 19). Differences in sampling fractions are accounted for in all analyses by weighting for community sampling frequencies.

Surveys were undertaken at baseline and 16 months later at the end of the project. Response rates did not differ significantly between the baseline and end-of-project surveys for communities or conditions, nor were there significant differences in response rates between communities or conditions for either of the two surveys. The average response rate across surveys was 80.1%, greater than that expected (70%). There were no significant differences between communities for either survey in the proportion of persons surveyed by telephone or home visit, nor did these proportions vary significantly between surveys. Approximately 74 persons were surveyed per condition for each survey. This number is greater than required as estimated by calculations of statistical power (65 persons) and for a minimum level of precision of ± 0.10 for estimates of population proportions at a 95% level of confidence (60 persons).

Descriptive Characteristics of Samples

Descriptive characteristics of the samples are presented in Table 20. Mean age was significantly greater by six years in the intervention community relative to the comparison communities, as for cohorts. There were no significant differences between communities or conditions in gender distributions or in the proportion of respondents self-reporting diabetes or first or second degree relatives with diabetes.* Five persons in the intervention community participated in each survey, and one person in each of the two comparison communities participated in each survey, but this difference was not significant (Fisher's exact test: $P = 0.44$). Across both surveys, five persons in the intervention community were participants in at least one cohort testing occasion, whereas six persons in the comparison communities were participants in at least one cohort testing occasion.

*Community Advisory Boards did not approve questions to distinguish between respondents who had diabetes and respondents who had first or second degree relatives with diabetes.

Table 19. Sampling Frames, Sample Sizes, and Response Rates by Condition and Community for Cross-Sectional Surveys at Baseline and End of Project (Random Selection)

	Intervention Condition		Comparison Condition	
	Okanagan	Spallumcheen	Penticton	Both Pooled
On-reserve population	707	331	380	711
Sampling frame: adults 18+ yrs (N)	475	212	238	450
Efficient sample size*	65	43	22	65
Adjusted for response rate (0.70)	93	61	32	93
Persons sampled per survey (n_s)	93	61	32	93
Sampling fraction (n_s/N)	0.196	0.288	0.134	0.206
<i>Baseline survey</i>				
Persons with phones†	85	44	30	74
Respondents	66	32	28	60
Refusals	13	9	2	11
Phone not in service	6	3	0	3
Persons without phones†	8	16	2	18
Respondents	8	14	2	16
Refusals	0	2	0	2
Total number of respondents (n_r)	74	46	30	76
Response rate (n_r/n_s)	0.796	0.754	0.938	0.817
<i>End of project survey</i>				
Persons with phones†	80	46	26	72
Respondents	59	36	20	56
Refusals	11	6	3	9
Phone not in service	10	4	3	7
Persons without phones†	13	15	6	21
Respondents	13	13	5	17
Refusals	0	3	1	4
Total number of respondents (n_r)	72	48	25	73
Response rate (n_r/n_s)	0.774	0.787	0.781	0.785

*Efficient sample sizes were based on minimum precision estimates and statistical power calculations for numbers per condition, adjusted for community clustering. Actual sizes reflect adjustments for estimated non-response. Within the comparison condition, numbers for Spallumcheen and Penticton were calculated by weighting the pooled size required by community cohort survey participation rates.

†Surveys were done by phone for individuals with phone service, and by home visit for those without service (using a standardised instrument).

Table 20. Characteristics of Simple Random Samples Surveyed at Baseline and 16 Months Later at End of Project, by Condition and Community

	Intervention Condition		Comparison Condition					
	Okanagan		Spallumcheen		Penticton		Both Pooled	
	mean	95% CI*	mean	95% CI*	mean	95% CI*	mean	95% CI*
<i>Baseline survey</i>	<i>n = 74</i>		<i>n = 46</i>		<i>n = 30</i>		<i>n = 76</i>	
Age (years) [†]	46.5	42.9 – 50.1	41.2	37.4 – 45.0	38.7	33.9 – 43.5	40.1	37.1 – 43.1
Male (%)	37.8	27.4 – 49.3	39.1	25.9 – 53.7	46.7	29.5 – 64.4	42.1	31.4 – 53.4
Female (%)	62.2	50.7 – 72.6	60.9	46.3 – 74.1	53.3	35.6 – 70.5	57.9	46.6 – 68.6
Participated in cohort testing at least once (%)	9.4	4.2 – 17.8	10.9	4.1 – 22.5	6.7	1.1 – 20.3	9.2	4.1 – 17.4
Sampled in baseline and final surveys (%)	6.7	2.5 – 14.3	2.2	0.1 – 10.3	3.3	1.7 – 15.4	2.6	0.4 – 8.4
Has diabetes or a relative with diabetes (%) [‡]	52.7	41.3 – 63.9	45.6	31.7 – 60.1	46.7	29.5 – 64.4	46.0	35.1 – 57.3
<i>End of project survey</i>	<i>n = 72</i>		<i>n = 48</i>		<i>n = 25</i>		<i>n = 73</i>	
Age (years) [†]	44.1	40.6 – 47.6	35.0	30.6 – 39.4	39.6	34.0 – 45.2	36.7	33.2 – 40.2
Male (%)	38.9	28.2 – 50.5	35.4	22.9 – 49.6	36.0	19.2 – 55.9	35.6	25.3 – 47.1
Female (%)	61.1	49.5 – 71.8	64.6	50.4 – 77.1	64.0	44.1 – 80.8	64.4	52.9 – 74.7
Participated in cohort testing at least once (%)	6.9	2.6 – 14.7	10.4	3.9 – 21.6	4.0	0.2 – 18.2	8.2	3.4 – 16.3
Sampled in baseline and final surveys (%)	6.9	2.6 – 14.7	2.1	0.1 – 9.8	4.0	0.2 – 18.2	2.7	0.5 – 8.7
Has diabetes or a relative with diabetes (%) [‡]	51.4	39.9 – 62.8	56.2	42.1 – 69.7	40.0	22.4 – 59.8	50.7	39.3 – 62.0

*Miettinen's mid-*P* exact 95% confidence interval (CI).

[†]Significantly different among communities ($P < 0.026$) and between conditions ($P < 0.010$) for baseline and end-of-project surveys.

[‡]First or second degree relative with diabetes; Advisory Committees did not approve of a question to distinguish between respondent's or relatives' diabetes.

Diabetes Knowledge and Awareness

After adjustment for clustering, the intervention community showed significantly greater net increases in actual knowledge of diabetes, relative to the comparison communities (Table 21). Net increases in the intervention community in self-perceived knowledge of diabetes were not statistically significant, however, after adjustment for clustering ($F_{1,199} = 3.01$, $P = 0.084$). Relative to the comparison communities, net increases in the intervention community in awareness of the project (0.9 points on a 10-point scale) and in participation in the project (1.3 points on a 10-point scale) were not statistically significant (not shown in Table 21).

Behavioural and Anthropometric Outcomes

Relative to the comparison communities, there were significant net increases in the intervention community in the prevalence of sweat-producing physical activity at least once per week (25.8%) and in the average number of episodes of sweat-producing activity per week (1.7 episodes) (Table 21). Net reductions in body mass index were not statistically significant. Net increases in the intervention community relative to the comparison communities in consumption of dietary fat (1.8 points on a 10-point scale) and complex carbohydrates (1.4 points on a 10-point scale) were not statistically significant (not shown in Table 21).

Co-Variation Between Changes in Knowledge and Risk Factors

There was no difference between conditions in variation over time between actual or perceived knowledge of diabetes or awareness of the project, and episodes of sweat-producing activity per week, body mass index, or consumption of fat or complex carbohydrates. None of the second order interaction terms were statistically significant. There was a marginal difference after adjustment for clustering between conditions in the relationship over time between awareness of the project and actual knowledge of diabetes ($F_{1,199} = 3.48$, $P = 0.063$). For any level of awareness, actual knowledge of diabetes was greater in the intervention community than in the comparison communities, and the magnitude of this difference increased between surveys.

Table 21. Diabetes Knowledge and Risk Factors, and Net Intervention – Comparison (I – C) Differences Over 16 Months from Baseline (B) to End (E) of Project: Cross-Sectional Surveys of Adults Ages 18–87*

	Baseline			End of Project			Difference (E – B)	Net (I – C) Differences	Unadjusted Test [†]	Inflation Factor	Adjusted Test [‡]
	<i>n</i>	mean	SD	<i>n</i>	mean	SD					
Perceived knowledge of diabetes (10-point rating)											
Intervention condition	70	4.6	2.7	71	5.1	3.0	+0.5	+1.2	$F_{1,275} = 4.18$ $P = 0.042$	1.39	$F_{1,199} = 3.01$ $P = 0.084$
Comparison condition	72	4.3	2.4	69	3.6	2.2	-0.7				
Actual knowledge of diabetes (13-point score)											
Intervention condition	70	9.4	3.3	71	9.4	2.8	0.0	+2.3	$F_{1,275} = 8.10$ $P = 0.004$	1.39	$F_{1,199} = 5.83$ $P = 0.017$
Comparison condition	72	7.8	3.6	69	5.5	4.1	-2.3				
Body mass index [weight (kg) + height (m) ²]											
Intervention condition	70	27.8	5.9	69	27.8	5.4	0.0	-1.4	$F_{1,269} = 1.23$ $P = 0.268$	1.00	$F_{1,269} = 1.23$ $P = 0.268$
Comparison condition	70	25.7	4.4	67	27.1	6.3	+1.4				
Sweat-producing activity at least once per week (%)											
Intervention condition	73	52.1	5.8	72	79.2	4.8	+27.1	+25.8	$\chi^2_1 = 5.91^{\S}$ $P = 0.015$	1.06	$\chi^2_1 = 5.59^{\S}$ $P = 0.018$
Comparison condition	75	48.0	5.7	71	49.3	5.9	+1.3				
Number of events of sweat-producing activity per week											
Intervention condition	36	3.9	2.0	55	4.4	2.5	+0.5	+1.7	$F_{1,149} = 4.15$ $P = 0.043$	1.02	$F_{1,146} = 4.07$ $P = 0.045$
Comparison condition	32	4.8	2.7	33	3.6	1.7	-1.2				

*Based on analysis of covariance models for unbalanced survey data, adjusting for age, with analyses weighted for sampling frequencies in each community to provide approximately unbiased population-level estimates of changes in means. Two-tailed *P*-values indicate the significance of orthogonal contrasts in the interaction effects of survey and condition, which assess differential change over time between intervention and comparison communities.

[†]Unadjusted and [‡]adjusted for clustering within communities, by way of variance inflation factors and reductions to degrees of freedom by the design effect.

[§]Breslow-Day homogeneity χ^2 testing interaction between surveys (two strata) and condition (dichotomous) in effects on activity (dichotomous).

Statistically Significant Results and Adjustments for Multiple Comparisons

Cohort Analyses

Of twenty outcomes evaluated for cohorts, tests of differential change over time between study conditions were statistically significant for just five variables. Changes in concentrations of HbA_{1c}, and proportions of individuals with hypertriglyceridaemia and those engaging at least once per week in sweat-producing activity, were *negative* for the intervention condition relative to the comparison condition. Changes in the remaining two variables, body mass index and systolic blood pressure, were *positive* for the intervention condition relative to the comparison condition. Means and 95% confidence intervals, adjusted for clustering, are presented for the five significant variables in Table 22. The sole apparent meaningful change is for body mass index.

Adjusting hypothesis tests for multiple comparisons aligns with interpretations of import of change based on 95% confidence intervals. Adjustments were made within classes of variables for which some cluster-adjusted *P*-values were significant. For blood measures, the unadjusted significance of change in HbA_{1c} (*P* = 0.017) (Table 13) was nullified (*P* = 0.102) by adjustment for the six tests conducted. The unadjusted significance of change in hypertriglyceridaemia (*P* = 0.033) (Table 14) was also annulled by adjustment for other tests. Thus, there were no statistically significant changes over time in any blood measure.

Anthropometric outcomes and systolic and diastolic blood pressure were grouped together for adjustments for multiple comparisons. Thus, there were four tests overall. Initial levels of significance for reductions in the intervention condition relative to the comparison condition in body mass index (*P* = 0.004) and systolic blood pressure (*P* = 0.017) (Table 15) remained statistically significant after adjustment for multiple comparisons. The adjusted levels of significance were 0.016 for body mass index, and 0.050 for systolic blood pressure. Review of means and 95% confidence intervals (Table 22) confirms tangible change for body mass index but change of borderline importance for systolic blood pressure.

For the ten tests performed for behavioural variables, the sole change in sweat-producing physical activity at least once per week (*P* = 0.004) (Table 16) was offset by adjustment for multiple comparisons. The resultant level of significance was 0.08. This effect, too, is in keeping with the means and 95% confidence intervals reported in Table 22.

Table 22. Cohort Survey Means and 95% Confidence Intervals (CI): Variables for Which Tests of Change Over Time Between Conditions Were Statistically Significant*

	<i>n</i>	Baseline		Mid-Project (8 Months)		End of Project (16 Months)	
		mean	95% CI	mean	95% CI	mean	95% CI
Glycosylated haemoglobin (%)							
Intervention condition	61	5.82	5.40 – 6.24	6.15	5.53 – 6.76	6.20	5.46 – 6.94
Comparison condition	43	5.93	5.01 – 6.85	5.85	5.21 – 6.49	5.47	4.86 – 6.08
Triglyceride > 2.45 mmol/L (%)[†]							
Intervention condition	62	38.7	21.2 – 56.2	32.3	15.6 – 48.9	56.5	38.7 – 74.3
Comparison condition	43	39.5	18.3 – 60.7	39.5	18.3 – 60.7	55.8	34.3 – 77.2
Body Mass Index (kg/m²)							
Intervention condition	57	30.8	29.3 – 32.3	31.0	29.5 – 32.5	30.4	28.9 – 31.8
Comparison condition	45	27.5	25.8 – 29.2	27.8	26.1 – 29.5	28.6	26.8 – 30.3
Systolic Blood Pressure (mmHg)							
Intervention condition	57	121.5	113.0 – 130.0	115.5	108.6 – 122.4	115.5	109.4 – 121.6
Comparison condition	43	113.3	105.8 – 120.8	114.5	106.5 – 122.5	118.8	110.6 – 127.0
Sweat-prod. activity ≥ 1/wk (%)[‡]							
Intervention condition	50	62.0	48.0 – 76.0	74.0	61.3 – 86.6	48.0	33.6 – 62.4
Comparison condition	42	57.1	41.5 – 72.7	66.7	51.9 – 81.5	61.9	46.6 – 77.2

*Confidence intervals adjusted for clustering by multiplying standard errors by variance inflation factors specified in previous tables with tests of significance.

[†]Proportion of individuals with hypertriglyceridaemia.

[‡]Proportion of individuals engaging at least once per week in sweat-producing physical activity.

Cross-Sectional Analyses

Adjustments for cross-sectional results were made for all variables together. Of the ten outcomes evaluated, tests of differential change between study conditions were statistically significant for just three variables. Unadjusted for multiple comparisons, positive changes were apparent for the intervention condition for knowledge of diabetes ($P = 0.016$), sweat-producing physical activity once per week ($P = 0.018$), and the number of events of sweat-producing activity per week ($P = 0.045$) (Table 21). None of these changes remained significant, however, after adjustment for multiple comparisons. Adjusted levels of significance were 0.160 for knowledge, 0.162 for sweat-producing activity at least once per week, and 0.360 for the number of events of sweat-producing activity per week. Analyses of co-variation between changes in knowledge and risk factors did not approach statistical significance for any variable after adjustment for multiple comparisons. Review of means and cluster-adjusted 95% confidence intervals for variables significant before adjusting for multiple comparisons (Table 23), suggests meaningful change in physical activity only.

Table 23. Cross-Sectional Survey Means and 95% Confidence Intervals (CI): Variables for Which Tests of Change Over Time Between Conditions Were Statistically Significant*

	Baseline			End of Project		
	<i>n</i>	mean	95% CI	<i>n</i>	mean	95% CI
Actual knowledge of diabetes (13-pt score)						
Intervention Condition	70	9.4	8.3 – 10.5	71	9.4	8.5 – 10.3
Comparison Condition	72	7.8	6.6 – 9.0	69	5.5	4.2 – 6.8
Sweat-producing activity at least once/week (%)						
Intervention Condition	73	52.1	40.0 – 64.2	72	79.2	69.2 – 89.2
Comparison Condition	75	48.0	36.1 – 59.8	71	49.3	37.0 – 61.6
Number events of sweat-producing activity/week						
Intervention Condition	36	3.9	3.2 – 4.6	55	4.4	3.7 – 5.1
Comparison Condition	32	4.8	3.8 – 5.8	33	3.6	3.0 – 4.2

*Confidence intervals adjusted for clustering by multiplying standard errors by variance inflation factors specified in previous tables with tests of significance.

Intervention Community Surveys of Systems

Community systems change is summarised by analytic level for the intervention condition in Table 24. Responses are cross-classified by survey, system component and the nature of the indicator and its focus. Salient issues are elaborated below.

Sub-System Actions Involving Community Groups

The Okanagan Band Council undertook two policy actions relevant to diabetes prevention and control: (a) sanctioning the weekly distribution of information about diabetes, by way of flyers placed for pick-up in central locations; and (b) hiring by mid-project, in response to organised lobbying by diabetes project workers, a Recreation Co-ordinator to promote physical activity and acceptable opportunities for exercise.

Support for the project through Band Council Resolutions was followed by a decision to allow use without charge of the local park for outdoor events. Three businesses (Nehoot Grocery, Little Kingdom Grocery and Gas Bar, and Moonie's Restaurant) allowed posting and distribution of information, and larger family clans promoted participation in project activities. Other indications of support included unlimited use without charge of the old Band Hall for project meetings, activities and screening initiatives, by the New Horizons group administering the building.

Indicators of the participation of community groups included *ad hoc* exercise and diabetes support groups and the participation of Band Council members, elders and leaders in events and demonstrations. These actions were slow to start, however, and the participation of influential persons did not generally extend to include participation in tests and measurements.

Other indicators of group involvement include the project Advisory Group, links made between alcohol/drug and recreation workers to merge diabetes education with their work, and parenting and church groups that requested diabetes information for discussion purposes.

Sub-System and Supra-System Relationships

This level of analysis concerns the extent to which groups within the community became involved with each other and external organisations. A coalition of sorts evolved from three workers hired on behalf of the project who, along with friends and family, developed connections with the Heart

and Stroke Foundation, the Canadian Diabetes Association, Vernon Jubilee Hospital and the Municipality of Vernon. The products of this involvement included the provision of resources and personnel for educational talks and demonstrations (e.g., food preparation by nutritionists).

In terms of participation in internal and external activities related to the project, workers made presentations on diabetes and project results to the Band Council, at a regional Aboriginal alcohol treatment centre, and at the 3rd International Conference on Diabetes and Indigenous Peoples. Nurses and community workers also made presentations on the project to the Canadian Diabetes Association. Awareness of the project was heavily promoted by workers: two major stories on the project were published in the Medical Services Branch, Pacific Region, "First Nations Health" newspaper (July 1995, Vol. 4, No. 1; and August 1996, Vol. 5, No. 3), and a television story on the project was aired by a local station (CHBC, November 21, 1995).

Whole System Norms and Values

At the outset of the project, health was perceived as the joint responsibility of the Band Council and the Federal government. Through the provision of Federal funds, Band policy supported a focus on a host of health issues. The form of this support, however, was such that many activities, workshops and programmes were imposed on the community through a "top-down" approach by the Band Council and other leaders. Participation in such initiatives was not widely valued, and people generally reacted by avoiding formal attempts imposed to address problems perceived by others. People were highly sensitive to co-optation and imposed strategies, to the extent that public pressure forced the replacement of the Band manager, social worker and programmes coordinator soon after the project began (for reasons unrelated to the project).

Besides internal community politics, prevailing external politics at the outset of the project had been generally paternalistic. Vernon Jubilee Hospital, the Medical Services Branch and the Federal government had all targeted a variety of Aboriginal health issues, yet strategies tended to be directive and non-supportive of holistic, community-based approaches. There was a prevailing perception that local physicians rarely provided adequate information for Aboriginal people. Further, the policy of the Diabetes Programme at Vernon Jubilee Hospital was to merge Aboriginal people into educational programmes developed for the non-Aboriginal population, without

provision for the different circumstances and needs of Aboriginal people, or conceptions of diabetes specifically or health generally.

As the project progressed, it became apparent that there was a growing awareness within the Band of the implications of the Aboriginal Health Transfer process imposed by the Federal government. The requirement that Bands assume direct responsibility for health was creating anxiety. People felt that their capacity for managing services needed to be developed before being given full responsibility. The Brighter Futures and Head Start initiatives were perceived as positive steps towards addressing Aboriginal health issues in meaningful ways. As favourably as these initiatives were perceived, there was little recognition by the Band Council of the fit of these initiatives with the diabetes project and the health transfer process. The Council did not appear to recognise that the community-based, "grass-roots" approach taken by the project could provide a process model if not a functional framework upon which to base developmental health efforts.

A variety of shifts in norms and values were associated with the diabetes project. From a baseline of general interest in health and awareness of a need to eat well and lose weight, there were apparent improvements in the strength of peoples' commitment to diabetes prevention and general health. Evidence of these shifts was suggested by the hiring of a new Recreation Co-ordinator, by greater interest and participation on local sports teams, and by an increase in discussions about diabetes and health matters at formal and informal gatherings. High profile individuals began to promote the project. Persons who had had difficulty adhering in the past to special diets because of social pressure, found others supporting their food choices and making similarly healthful decisions. Physical activity had never been of as much concern to people as weight loss and eating patterns, but there was a marked increase in awareness of the need for regular activity. Community workers received many calls and requests for information about diabetes, exercise and healthful eating. People with diabetes were sought out as sources of information for others, and complications suffered by two Band members (renal failure requiring long-term dialysis) received much attention. Despite widespread shifts in norms, some groups (certain family clans) were resistant to change, and were vocal in their opposition to the project. These negative reactions had little apparent effect, however, on generally positive shifts.

Table 24. Community Participation (Intervention Condition) By Analytic Level: Systems Evaluation

Analytic Level	Indicator and Focus	Intervention Planning Phase (0–7 months pre-intervention)	Early Intervention Phase (4 months intervention)	Mid-Project (12 months intervention)
<i>Sub-Systems</i>				
Community groups and organisations	• Policy: diabetes	• None	• Band Council allows weekly distribution of flyers	• Continued
	• Policy: dietary behaviours	• None	• Band Council allows weekly distribution of flyers	• Continued
	• Policy: weight control	• None	• Band Council allows weekly distribution of flyers	• Continued
	• Policy: physical activity/recreation	• None	• Band Council allows weekly distribution of flyers • Band Council considers funding activity co-ordinator	• Continued • Recreation Co-ordinator hired to promote activity
Community groups and organisations	• Support: project	• Band Council Resolutions and letters from Chiefs • Medical Services Branch sanctions staff support	• Use of old Band Hall granted for all project activities • Local stores allow posting/distributing information • Some family clans promote participation in project	• Continued • Band Council grants use of park for demonstrations
Community groups and organisations	• Participation: project	• None	• Several exercise groups started and led by residents	• Diabetic support group started by MSB nurses • Council members/leaders participate in demonstrations
Community groups and organisations	• Other indicators of involvement: project	• Community Advisory Group started, regular meetings	• Diabetes Project Newsletter started; focus on activities • Local newspaper, "Senk'l'iP," carries diabetes articles	• Local parent/church groups focus on diabetes issues • Local sports teams note increase in participation • Alcohol/recreation workers link up to address diabetes

Table 24. Community Participation (Intervention Condition) By Analytic Level: Systems Evaluation (continued)

Analytic Level	Indicator and Focus	Intervention Planning Phase (0–7 months pre-intervention)	Early Intervention Phase (4 months intervention)	Mid-Project (12 months intervention)
<i>System Relationships</i>				
Sub-system links to external groups	• Coalitions: chronic disease prevention	• None	• Connections to Municipality of Vernon re: diet/nutrition information/demonstrations by community nutritionists	• Connections to Canadian Diabetes Association • Connections to Heart and Stroke Foundation
Sub-system links: internal/external	• Participation: raising awareness of project	• None	• Baseline screening results presented to Band Council • Workers make presentations at Indigenous Diabetes Conf.	• Workers make presentation on diabetes at alcohol centre • MSB nurses present project to Canadian Diabetes Assoc.
Sub-system links: internal/external	• Involvement: project activities/initiatives	• None	• Workers lobby hospital for diabetes information/material	• Workers recruit speakers and organise forums on diabetes • Workers' promotion leads to media coverage of project
<i>Whole System</i>				
Internal community norms and values	• Policy: general health issues	• Policy supports focus on health issues, but process not "grass-roots" oriented • Health is joint responsibility of Band and Federal gov.	• "Top-down" personnel replaced: Manager, social worker and co-ordinator • Imposed health services not supported by community	• Growing awareness of health-lifestyle links results in hiring new Recreation Co-ordinator
Internal community norms and values	• Perceptions: level of the individual	• Interest in health and health issues; recognition of need to eat well and lose weight	• Increasing awareness of diabetes, heart disease, and general health issues • Broader awareness of risk factors for diabetes, heart disease, and complications	• Further increase in healthful norms, related to greater awareness of diabetes • Despite positive shifts, some social groups (family clans) are resistant to normative change

Table 24. Community Participation (Intervention Condition) By Analytic Level: Systems Evaluation (continued)

Analytic Level	Indicator and Focus	Intervention Planning Phase (0-7 months pre-intervention)	Early Intervention Phase (4 months intervention)	Mid-Project (12 months intervention)
Internal community norms and values	<ul style="list-style-type: none"> Perceptions: level of groups/organisations 	<ul style="list-style-type: none"> Health matters are discussed incidentally at gatherings Primary health concerns are weight loss/healthful eating Physical activity is of minor importance People desire to eat in culturally dominant ways and are resistant to "being different" Cultural eating patterns interfere with transition from contemplation to action 	<ul style="list-style-type: none"> Council and other groups are discussing diabetes and risk factors with regularity and interest Increasing perception of the value/benefit of the project Groups are asking for more information about diabetes and its community impact 	<ul style="list-style-type: none"> Council and other groups are increasingly interested in project; members participate actively in project activities Involvement of high-profile persons is fueling normative change and diffusion of healthful norms, even among resistant families
External community norms and values	<ul style="list-style-type: none"> Policy: issues related to diabetes 	<ul style="list-style-type: none"> Paternalistic strategies and efforts at Federal, provincial and local levels incompatible with desire for autonomy Physicians are perceived to provide inadequate followup information and explanations of tests and results Hospital-based diabetes programme does not respect different circumstances and needs of Aboriginal people None 	<ul style="list-style-type: none"> Growing anxiety within Band over implications of Federal Health Transfer process, on basis of responsibility for services without capacity or experience in developing supportive infrastructures 	<ul style="list-style-type: none"> Continued
Community activism on health issues	<ul style="list-style-type: none"> Actions: health and diabetes-related 	<ul style="list-style-type: none"> Federal <i>Brighter Futures</i> and <i>Head Start</i> initiatives seen as positive, yet their health links are not widely recognised 	<ul style="list-style-type: none"> Health education materials widely available in community 	<ul style="list-style-type: none"> Meetings with supermarket managers and restaurateurs to request to healthful fare

CHAPTER 8

DISCUSSION

This chapter casts the results in the broader context of community health research and considers the implications of the Okanagan Diabetes Project. The chapter is divided into five sections. In the first section, the findings of the project are summarised in relation to the research questions. The second section assesses implications in terms of (a) the adequacy of implementation and factors associated with implementation, (b) the basis of the programme and its underlying theoretical assumptions; (c) methodological challenges and limitations influencing conclusions about effectiveness (i.e., statistical conclusion validity and internal validity) and (d) generalisability of results (external validity). The third section synthesizes results in relation to other known diabetes interventions in Canadian Aboriginal populations, and reviews broader issues in community-based disease prevention and health promotion initiatives. The fourth section provides recommendations for further research on diabetes prevention and control in Aboriginal populations, and the last section summarises and concludes the dissertation.

Effects in Relation to Research Questions

The Okanagan Diabetes Project did not yield convincing evidence of effectiveness in terms of measurable changes related to diabetes prevention and control. Of a battery of quantitative outcomes evaluated, the intervention programme was associated with only two statistically significant changes. Among “high-risk” individuals with or at familial risk for diabetes, adjusted for multiple comparisons, reductions occurred in body mass index and systolic blood pressure. For the same individuals, there were no changes in fasting concentrations of glucose, glycosylated haemoglobin, cholesterol, triglycerides, or high- or low-density lipoprotein cholesterol. No changes were observed for body fat distribution, measures of physical activity, or intake of dietary protein, carbohydrate, lipid, or total energy consumed. There were no changes in alcohol consumption, in the prevalence of hypertension or cigarette smoking, or in psychosocial

constructs including self-esteem, mastery, depression, affect balance and social support. Against overwhelmingly limited change in physiological, anthropometric, behavioural and psychosocial outcomes, the two statistically significant changes associated with the intervention programme were well within chance levels. Neither was associated with necessary precursor changes in behaviour; for example, improved dietary behaviour or increased physical activity. Thus, the two changes should not be construed as caused by the programme. This is not to suggest that they did not occur, but rather, that other, unknown factors were involved in producing them.

Given the above summary, the answer to the first research question posed — whether the programme was effective among “high-risk” individuals in terms of achieving improvements in risk factors for diabetes and psychosocial constructs — is an unqualified “no.” The answer is the same for the second research question posed on the effectiveness of the programme on coping among individuals with diabetes or impaired glucose tolerance. For such persons there were no significant changes in quality of life, beliefs necessary for improvements in self-care behaviours, or knowledge of diabetes symptoms, risk factors and complications.

Beyond individuals with and at risk for diabetes, the intervention programme was not associated with any effect at the level of the community, adjusted for multiple comparisons, in terms of aggregate individual-level changes. Thus, the answer to the third research question posed, is also negative. There were no statistically significant community changes in diabetes knowledge, awareness of the project, or behavioural and anthropometric risk factors for diabetes. Review of means and cluster-adjusted 95% confidence intervals for the only three variables to be found statistically significant before adjustment for multiple comparisons (Table 23) suggests that changes in one, sweat-producing physical activity at least once per week, may have been meaningful. While useful, cluster-adjusted confidence intervals do not themselves account for the fact that ten hypothesis tests were made on cross-sectional outcomes. Therefore, the level of significance for sweat-producing physical activity after adjustment for multiple comparisons ($P = 0.162$) can be interpreted as a fair indication of the validity (as a programme effect) of a shift in levels of physical activity. As for the two significant cohort results, the change in levels of physical activity in the intervention condition were not accompanied by changes in other variables that would be expected to precede or co-vary with improvements in level of physical activity.

For the fourth (and final) research question, on the social environmental impact of the programme (assessed qualitatively), limited effects were apparent in support of diabetes prevention and control through sub-system actions by community groups. Interactions between sub-system groups and organisations outside the community were apparent as well. Moreover, perhaps most importantly of all environmental effects, the beginnings were apparent of whole-system shifts in community norms and values supporting healthful living. Such conclusions are subjective and speculative, however. Data on the social environmental impact of the programme must be interpreted with considerable caution. Given the lack of quantitative effects and major methodological limitations associated with surveys of community systems (bias and equivocal validity), limited positive shifts in the social environment provide little support by themselves for programme effectiveness. Environmental changes might nevertheless have yielded measurable changes in quantitative outcomes had the programme continued for longer than 16 months, or had further follow-up measurements been conducted after a post-intervention interval.

To summarise, the Okanagan Diabetes Project was not effective within the timeframe of this study in relation to the primary research questions concerning whether the community-directed diabetes prevention and control programme achieved positive changes in quantitative outcomes. No impact was observed among “high-risk” individuals or at the aggregate level of the community. Secondary research questions, contingent upon positive changes as assessed by the primary research questions, therefore could not be answered. These secondary questions sought to establish the nature of relationships among changes in psychosocial, behavioural, physiological and anthropometric variables. Secondary questions were also intended to determine whether changes observed were in keeping with the programme or “treatment” theory. The programme theory was that interventions developed, implemented, and controlled by community members would facilitate and promote gains in personal and collective efficacy, leading to improvements in knowledge and psychosocial status. Such changes, it was theorised, might predispose positive shifts in behaviour. Behavioural changes, in turn, were expected to predict positive changes in physiological and anthropometric variables. Positive shifts in psychosocial and behavioural variables were also expected to be associated with positive

environmental changes. Since necessary precursor changes did not occur in the aggregate to a statistically significant degree, the programme theory could not be evaluated.

Implications

The study was structured to test the effect of a community-directed diabetes prevention and control programme at the population level. The programme was not effective in accomplishing this within the timeframe of this analysis. The lack of positive results suggests three potential explanations reflecting practical difficulties and limitations specific to designing, implementing and analysing community-based trials. The first explanation is that the intervention community was not sufficiently activated to enable individual and collective change through the development and implementation of broad and meaningful diabetes prevention and control strategies. Inadequate implementation, low levels of penetration of interventions and factors associated with these provide strong reasons for the limited response to the programme. The appropriateness of the programme theory and foundational assumptions make up the second explanation for the few changes observed. The third explanation is that methodological challenges, including inadequate statistical power and analytic issues, preclude being able to document positive changes. A fourth issue is the generalisability of the results. Each of these considerations is reviewed below.

Inadequate Implementation

Theory and previous research suggested that a programme planned, implemented and controlled by community members can facilitate healthful behavioural and environmental change. It was hypothesized that community-directed, culturally appropriate strategies for diabetes prevention and control would not induce the negative conditioning and resistance that occurs when change initiatives are perceived to be imposed on Aboriginal people by those removed from, or without any appreciation for, the Aboriginal experience. A necessary assumption for this process is that the community is able to become sufficiently “activated” for people to work together individually and in groups, towards achieving increases in personal and collective efficacy that carry through to changes in behaviour and environment. Given negative evaluation results, the failure to achieve

proper implementation may reflect what has been described in the evaluation literature as a “Type III” error (Basch *et al.*, 1985). A “Type III” error occurs when a programme evaluated as ineffective was implemented inadequately. Thus, overall ineffectiveness relates not necessarily to a lack of effectiveness of the interventions attempted, which thus cannot be adequately assessed, but to a failure to implement them properly. Implementation failure differs from theory failure in that the former implies inadequate procedures, whereas the latter implies inappropriate conceptualising (Green & Lewis, 1986; Weiss, 1972).

Strong explanations for the lack of quantifiable success of the project concern: (a) the degree to which the community was activated in planning and implementing diabetes prevention and control strategies; (b) the amount of time available for, and responses to, initiatives actually implemented; and (c) the level of participation achieved by various interventions. These issues are not really independent, but it is helpful to consider each explanation separately.

Sufficiency of Community Activation

An activated community would be expected to develop and implement interventions sufficient to achieve large-scale penetration of substantial numbers in the community. An impressive array of interventions was indeed mounted, targeting behavioural change and environmental supports for behavioural interventions (see Intervention Implementation, Chapter 6), but the penetration of these interventions was low. As discussed, all strategies required time before even approaching their effective potential, and the actualisation of initiatives was variable and incomplete. Low levels of penetration and limited actualisation of interventions suggest insufficient community activation.

Review of the theoretical model on which the project was founded provides an indication as to why community activation may have been insufficient. As given in Figure 2 (Chapter 6, p. 167), the activation process consisted of two fundamental components: (a) input from external academic researchers; and (b) synergistic community processes involving sub-system mobilisation and dissemination of quality intervention components. The direct arrow from “external project input” to “community processes” indicates that synergistic sub-system mobilisation and intervention planning and dissemination were conceived as a function of contributions of technical expertise from external academic researchers. That is, beyond use of

skills in planning and obtaining grant funds, external researchers were required to contribute throughout the project by stimulating and promoting effective community change processes. Once grant funds were awarded, however, input from external researchers became limited for the most part to planning and orchestrating data collection procedures, and meeting periodically for reviews and updates with community workers in whose hands lay the primary responsibility for developing and implementing interventions and to activate and mobilise the community.

Community workers were capable, well-intentioned and hard-working lay persons. They were nevertheless relatively inexperienced and without a detailed understanding of principles of community organisation, as well as theory and previous research on the problem. There were just two community workers in the intervention community, each committing an average of 30 hours per week to the study. Paid from project funds, these individuals received assistance from the local community health representative paid by the Medical Services Branch. It may be unrealistic to have expected these three individuals, in the absence of expected contributions of expertise from external researchers, to develop and implement interventions sufficient to achieve large-scale penetration in the community. Indeed, a diverse array of interventions were developed and implemented. These were useful but impromptu reactions, with their origins in discussions with local public health practitioners, and related more to the health professional culture than to Aboriginal culture. Interventions did not unite formal theory or previous research with Aboriginal logic and concepts gleaned from qualitative analyses of diagnostic interviews. The programme reflects a disjunction between the interventions implemented and the needs suggested by diagnostic interviews. The failure to develop such links in the activation phase was a weakness of the study. Responsibility for this situation resides with researchers accountable for the study. It does not reside with community workers, whose efforts were energetic and exemplary.

Responsibility for sub-system mobilisation, and planning and implementing interventions, cannot reasonably be expected to reside with community workers alone. External researchers were required to provide input into these processes, to ensure that theory and previous research were brought to bear on the problem through systematic and organised responses with a strong basis for success (Murray, 1995). The lack of a direct link between the interventions mounted and qualitative findings from pre-intervention interviews was especially problematic. Qualitative

procedures were conceptualised and promoted from the start (both in the funding application and in responses to reviewer criticism) as enabling development of a local theory that emically frames the community situation and serves concomitantly as a template for the intervention planning process. The development of such a theory was not pursued. The high level of Aboriginal perspective and input through pre-intervention interviews had little bearing on sub-system mobilisation and intervention planning. Attention to integrating theory with Aboriginal logic and cultural concepts may have enabled greater activation (Boston *et al.*, 1997).

A section in Chapter 5 on organisational issues described actions by which external researchers might stimulate community initiative and promote change processes and penetration of various interventions across the community. To recapitulate, these actions were to: (a) facilitate the establishment of co-operative working relationships among community groups; (b) encourage the creation of self-maintaining community problem solving structures; (c) stimulate efforts to promote interest and participation in community affairs; (d) foster collaborative attitudes and practices; and (e) encourage and facilitate the development of indigenous leadership. Of these five process actions, it is fair to say that just two, (d) and (e), received adequate attention.

Through a commitment to principles of participatory research, attempts were made to foster collaborative attitudes and practices. Further, the nature of relationships with community workers and community representatives encouraged the development of indigenous leadership. These actions alone, however, were not sufficient for adequate activation, because efforts were not directed towards other process needs. The restricted nature of sub-system actions and changes as given in Table 24 (Chapter 7), though positive and encouraging, is testimony to limited mobilisation and community activation. This may reflect a lack of emphasis in pre-intervention interviews on elucidating indigenous ways of mobilising and activating the community. It may also reflect a failure to establish a community consensus on priorities, setting goals and outlining a division of responsibility. Coalitions might have served a role in facilitating change, but minimal effort was directed at promoting and maintaining coalitions. Nevertheless, when imposed or poorly used at the local level (e.g., as a management tool for the implementation of interventions), coalitions are subject to caveats and may even be dysfunctional (Green &

Frankish, 1996). Finding the right mix of personal, organisational, community and centralised control in disease prevention and health promotion initiatives continues to be difficult to attain.

A process evaluation could have helped in an understanding of why activation was inadequate and how it could have been improved. Although committed to in the planning stage, a process evaluation was not actually conducted, mainly because of a limited focus by external researchers on project management. Attention to process could also have contributed to understanding how Aboriginal beliefs about inner strength and its cultural basis can be integrated with western theories of self-efficacy and reciprocal determinism to promote positive behaviours and supportive environments. In addition, process evaluation could have provided feedback and guidance to the community workers on how to facilitate greater levels of community mobilisation. On-going evolution and iterative revision of the programme through process evaluation could have enabled a proper assessment of the programme theory through adequate implementation, possibly increasing the likelihood of a positive summative evaluation (Patton, 1997).

The fact that the actions of community workers were not guided or supported effectively by researchers ostensibly serving as facilitators and advocates for community change processes is a strong explanation for limited community activation and low penetration of interventions. Researchers might question whether it is realistic to expect to uphold a role that requires active involvement in community organisation and efforts to monitor and respond to process needs, as well as responsibility for data collection, analysis and the logistical aspects of community-based research. The research team involved just three individuals with research training. One of these (the author) was located in Vancouver. The other two individuals had teaching responsibilities at Okanagan University College (88 km from the intervention community) and limited time to commit to the project. Monthly and sometimes bi-weekly meetings brought together the entire research team, but community workers received little continuing guidance or systematic monitoring from external researchers. It is an accurate and fair conclusion that external researchers were unable to commit to the project the time and effort necessary to achieve adequate community activation. A relevant issue, then, is whether it is reasonable to expect community workers to be supported by researchers located outside the community, and how knowledge of theory and previous research

can be brought to bear on the problem, when technical resources are not readily accessible in the community.

It may not be feasible for researchers with academic positions to be able to provide input into community change processes beyond that achieved in this project. The apparent disjunction between the guidance and support achieved and that apparently required for greater activation suggests the need to have provided a bridge linking (a) academic researchers responsible and accountable for the study with (b) community workers and others involved in conducting the day-to-day aspects of the study, including implementation activities. As implementation will not occur all at once for a social intervention, an important planning step could have been to hire and enable the presence in the intervention community of a co-ordinator with a Master's degree or equivalent training in areas involving scientific research and community development. This individual would preferably have been of Aboriginal descent or have had experience working with Aboriginal populations, able to reside in the community or maintain a strong presence on a daily basis. An understanding of research would ensure adherence to the knowledge development component of the project (contributing to the goals of evaluation). Skills and knowledge of community organising would be of value in mobilising individuals and groups to stimulate penetration and uptake of interventions (contributing to the goals of intervention). The presence and efforts of such an individual would also provide for greater attention to process. Skilled local co-ordination has been used to good effect in the Kahnawake Schools Diabetes Prevention Project, in a Mohawk community near Montréal (Macaulay *et al.*, 1995).

Adequate Time for Implementation

Lest the process of a social intervention become primarily an exercise in data gathering for the purpose of evaluating change with little theoretical basis, a consideration beyond making available skilled human support is allowing sufficient time for implementation. The seven month pre-intervention training and programme development phase of the project was of a duration scarcely sufficient to obtain the minimum ground-swell of community support necessary to undertake baseline screening and to begin implementation processes. It is possible that the presence of an on-site co-ordinator might have moved this phase along more quickly. Another issue is that

programme implementation is iterative and on-going throughout the duration of a social intervention; it does not happen all at once. The project was wrapping up just as residents were beginning to appreciate the nature, importance and potential impact of the undertaking.

Recognising that there exists a lengthy lag between the start of implementation and the point at which residents become familiar with the issues addressed, the forces at work and the nature of new opportunities, it is appropriate (and may be absolutely necessary) to consider undertaking — and funding — social interventions of durations greater than 24 months. A broad portion of the community was not ready for action at any given point during the project, as evidenced by low participation scores (reviewed in the next section). More time for diffusion of interventions, with interventions tailored to specific stages in the psychological process of change (Graham-Clarke & Oldenburg, 1994; Green & McAlister, 1984), may have been associated with greater uptake and adoption of healthful behaviours (Rogers, 1983). Time is required for effective integration of programme components, towards achieving synergy among them and increasing the potential for broad diffusion throughout the community (Schooler *et al.*, 1993). Sufficient time is also necessary for feedback on the comprehensiveness of information diffusion channels, to ensure that a knowledge-behaviour gap is not created or exacerbated among separate sub-groups within a community (Fortmann *et al.*, 1995).

Though speculative, members of the research team in this project believe that ten, rather than seven, months of pre-intervention work would have assisted in strengthening the basis for adequate programme implementation. This period should begin at the time the funding award is announced, preferably not longer than six months following submission of the research proposal. Over 12 months elapsed in this project between the time the proposal was submitted and the time the funding award was announced. During this period much community support dissipated, and extensive efforts were required to re-establish support within the seven month pre-intervention period following notification of the award. It might also be necessary to build in some provision for maintaining cohesion of the planning group between writing the grant application and activating the funded project, towards making use of the lag period between submission of the research proposal and notification of its status. As a blueprint for an intervention research study with ten months of pre-intervention work from time of notification of a funding award, given the collection

of baseline data and 18 months of active intervention (i.e., on-going implementation), mid-project measures might then be collected (i.e., 28 months from start, or 18 months from baseline measurements). Twelve more months could then be allocated to intervention saturation and normative change, followed by final testing and project evaluation. With time for data analysis and report writing, the total duration of such an undertaking would be 42-48 months.

It is possible that in combination with systematic, theoretically-guided efforts to activate the intervention community, an additional 18-24 months beyond the 24 months allocated for this project would have yielded behavioural, physiological and anthropometric changes of clinical as well as statistical significance. For the community-based approach applied, there was insufficient time in which to influence substantially risk factors associated with the prevention and control of diabetes. This is not to say that adequate time was not available to achieve reductions in risk factors at the level of individuals, had an individual-based approach been used. Long-term glucose status, for example, as given by the concentration of glycosylated haemoglobin, can improve after as few as 6 weeks on an exercise regimen (Ruderman *et al.*, 1990). The time required for community-level changes is greater, however, than the time required for changes for sub-groups of motivated persons for whom interventions can be individually tailored. The time discrepancy arises because entire *distributions* of risk factors must change in order for community means to be reduced, whereas changes among sub-groups involve shifts in only part of the overall distribution (Blackburn, 1983; Kottke *et al.*, 1985; Rose, 1982). The difficulty of shifting means for entire distributions of outcomes in community-level analyses is a challenge inherent in evaluations of community trials (Green, 1997).

Participation

Participation in intervention initiatives can be conceived as a function of implementation, as well as a factor contributing to it. As a function of insufficient activation, low participation nevertheless mediates at least in part the impact of inadequate implementation on programme effectiveness. The mean participation score (\pm standard deviation) for individuals in the "high-risk" cohort in the intervention community was 4.02 (\pm 2.1) on a 10-point scale. The 50th percentile was 4.25, and the 75th percentile was 5.25. Thus, participation was typically low among members of cohorts in

the intervention community. Perceived (self-rated) participation was also low for the intervention community as a whole, on the basis of aggregated data from a random sample of individuals ($n = 70$). The mean level (\pm standard deviation) of perceived participation assessed at the end of the project, relative to participation 18 months earlier at the start of implementation, was just 3.0 (± 3.1) on a 10-point scale. These data support the conclusion that implementation and penetration were less than adequate. The project achieved little in the way of predisposing, enabling or reinforcing substantial participation in intervention initiatives.

Positive changes in body mass index and triglyceride concentration associated with high participation suggest some utility of the interventions initiated. Nevertheless, despite high levels of participation, mean concentrations of fasting glucose and HbA_{1c} actually worsened over time among individuals with diabetes. Had interventions achieved penetration of greater numbers in the community and broader response, and had more time been available for implementation, then it is possible that the programme might have yielded at least some quantifiable indications of effectiveness. That perceptions of health risk could have influenced participation is suggested by the finding that a majority of people with diabetes and impaired glucose tolerance fell into the high participation category. Smoking status was the strongest predictor of participation, however, with non-smokers participating more than smokers. Other studies have indicated that smokers and persons with poor health status are less likely to participate in health surveys (Cottler *et al.*, 1987) and in the early stages of prevention initiatives (Criqui *et al.*, 1978). Beyond those factors related to high participation in specific sub-groups, low participation overall, as a function of inadequate mobilisation, appears to have mediated the lack of community programme effectiveness.

Insufficient activation and inadequate time for penetration and uptake of interventions are the implementation issues most clearly related to the lack of quantifiable success of the project, as determined by a review of the theoretical model on which the project was founded. These effects appear to be mediated through low participation, for the community as a whole and for "high-risk" cohorts. That implementation was insufficient precludes conclusions about the utility of the programme theory and the interventions mounted, although analyses of participation status suggest some level of usefulness of the interventions generally. Contrasts between study

conditions attest to the ineffectiveness of the project, rather than that of the interventions *per se*. To infer that interventions and the programme theory were ineffective would be to commit a Type III error (Basch *et al.*, 1985), since conclusions about the effectiveness of interventions and the theory behind them require knowledge of adequate implementation. It may be concluded only that the project as a whole was ineffective in bringing about substantive change. Nevertheless, it is useful to review factors influencing the appropriateness of the programme theory, and whether foundational assumptions were justified.

Appropriateness of Programme Theory

The intervention programme was conceived as an emergent “treatment package” based on community needs and community-directed solutions rather than the well-established efficacy of theoretically pure components each implemented in accordance with a preconceived change model. Conceding a complex social system of diagnosis and delivery in the context of social interventions (Campbell, 1987), the main aim of the evaluation was summative: to ascertain the effectiveness of the project in its entirety as a social action. Had some level of effectiveness been apparent, the programme theory would have provided a basis for exploring how and why particular changes occurred. Had implementation been adequate and the project still ineffective, then revision of the programme theory would have been warranted. Given inadequate implementation, the impact of inadequate procedures cannot be assessed independently of inappropriate conceptualising; it is possible that implementation failure and theory failure together influenced the results observed (Green & Lewis, 1986; Weiss, 1972).

As discussed, the programme theory was that interventions developed, implemented, and controlled by community members would facilitate gains in personal and collective efficacy, leading to improvements in diabetes knowledge, psychosocial status, and levels of behavioural, physiological and anthropometric risk factors for diabetes. Such shifts were also expected to be associated with positive environmental changes. The weakest link in this pathway might be the presupposed connection between behavioural change and precursor changes in knowledge and psychosocial status. This model derives, however, from that employed in the Stanford Three-Community Study (Farquhar, 1978), where it was associated with some level of success. One

might wonder, therefore, whether foundational issues influencing predisposition to behavioural change differ between Aboriginal communities and other communities neither marginalised nor subject to rapid acculturation.

Granting at least the possibility that participatory approaches and community control for intervention processes may yield improvements in knowledge and psychosocial status, is it a tenable assumption that in marginalised Aboriginal communities such actions alone will facilitate achievement of behavioural changes influencing health status? Can participatory approaches and community control in the context of externally driven disease prevention and health promotion initiatives enable the empowerment of a disenfranchised people into a politically aware society? If regaining control over their lives is indeed the most basic quality-of-life issue for Aboriginal people (as suggested by this study and the available literature), then how much control over the lives of Aboriginal people can health initiatives ever really provide for? It seems doubtful that any such initiatives will, in the space of a fraction of 150 years of oppression, subjugation and relegation to low status identity, provide for an informed, motivated electorate sufficient to overcome poverty, limited education, cultural barriers and jurisdictional problems reflecting long-standing social and historical precedents. It is probable that to achieve substantial improvements in health status, the aspirations of Aboriginal people for self-determination must be broadly supported concomitant with attempts to influence behaviour at the individual level and through environmental support for behavioural interventions.

A broader ecological perspective illustrates how targeting environmental change is distinct from environmental support for behavioural interventions (Richard *et al.*, 1996). Hawe (1994) argued that structural modification of the social environment was necessary to support empowerment as an outcome for community interventions, noting that achieving empowerment at the individual level may not translate into empowerment at the community level unless more sweeping social achievements were accomplished. This project did not target structural change of the social environment, possibly contributing to its limited impact in effecting activation of the intervention community, widespread penetration and uptake of interventions, and meaningful levels of participation. Realistically, however, structural modification of the greater society will not be achieved by one particular study, and providing for improvements in political and economic

power to enable Aboriginal people to gain greater control and resources consistent with self-determination was never a goal of this study. Nevertheless, such efforts at other levels might be necessary to enable successful interventions among Aboriginal populations.

From an ecological perspective, empowerment can exist at three levels: (a) the personal level, by gaining control and influence in daily life and in community participation; (b) the small group level, through the shared experience, analysis and influence of small groups on their own efforts; and (c) the community level, through achieving and utilising resources and strategies to enhance community control (Lord & Hutchison, 1993). Wallerstein (1992) defined empowerment as “a social-action process that promotes participation of people, organizations, and communities towards the goals of increased individual and community control, political efficacy, improved quality of community life, and social justice” (p. 198). Conceived as a process and an outcome, empowerment is a multi-dimensional construct implying individual change as well as change in the social setting itself. The implication is that disease prevention and health promotion initiatives may be more effective if undertaken in combination with, or in the context of, broader social actions supporting self-determination. This is not to suggest that health initiatives need be secondary to community development, capacity-building efforts, or policy actions targeting change in the social conditions that predispose health problems. Rather, the potential effectiveness of community-level health initiatives is inexorably tied to social realities influencing self-determination. These need to be addressed simultaneously, preferably by way of multisectoral, co-ordinated actions.

Understanding empowerment requires clarifying the counterpoint from which it evolves, widely conceived as a sense of powerlessness. Kieffer (1984) summarised this as “an attitude of self-blame, a sense of generalized distrust, a feeling of alienation from resources for social influence, an experience of disenfranchisement and economic vulnerability, and a sense of hopelessness in socio-political struggle” (p. 16). As a perceived or subjective phenomenon, powerlessness concerns the expectancy that one cannot determine the occurrence of the outcomes that one seeks (Seeman, 1959). Similar conceptions of powerlessness are passive acceptance of oppressive cultural “givens,” where one becomes powerless in assuming the role of “object” acted on by the environment, rather than “subject” acting in and on the world (Friere, 1970), and loss of sense of control over one’s place in a system of social relations (Gaventa,

1980). Powerlessness can also be conceived as an objective as well as subjective phenomenon (Albee, 1981). Lerner (1986) distinguished “real” powerlessness from “surplus” powerlessness. “Real” powerlessness, he argued, reflects economic, political and social arrangements that prevent people from actualising their human capacities. In contrast, “surplus” powerlessness reflects the contribution of people to “real” powerlessness to the extent that they do not believe they are capable of actualising possibilities that exist within the context of “real” powerlessness.

Although some authors tend to distinguish the concept of personal empowerment from community empowerment (e.g., Labonté, 1989; Wallerstein, 1992), movement from a position of powerlessness always occurs in the context of community (Lord & Hutchison, 1993). Such interdependence is consistent with Bandura’s (1982) conceptions of individual and collective efficacy, where increases in self-belief and self-esteem enable people, individually and collectively, to take control of their environment. Cultural norms concerning collective control are perhaps the most powerful determinant of personal control, and thus also of empowerment (Peterson & Stunkard, 1989). *A deeply rooted state of powerlessness in Aboriginal communities, ingrained in culture, may therefore relate to the limited effectiveness of this and other disease prevention and health promotion initiatives, where such actions do not occur in the context of social policy changes and other actions to address the root causes of powerlessness.* Put another way, a failure to facilitate the self-determination of Aboriginal peoples across all levels of Canadian society may inherently limit and compromise attempts to improve health status at the community level.

The Okanagan Diabetes Project attempted to facilitate the empowerment of an Aboriginal community towards action on diabetes prevention and control, without simultaneous efforts to change the context of the prevailing social environment. It is possible that such actions, limited as they are, can lead to greater perceived powerlessness and ill-health (Hagey, 1997; Wallerstein, 1992). This may occur because Aboriginal people may perceive accurately the extent of their control over their environment, and resist, passively or actively, attempts to promote voluntary modifications of lifestyle. In particular, individuals may perceive participation in such activities as irrelevant where they offer little, if any, potential for real control or power over destiny (Boston *et al.*, 1997). Low sociopolitical control, even among those who perceive high levels of control in other dimensions, may limit the effectiveness of public health interventions (Zimmerman, 1990;

Zimmerman & Zahniser, 1991). Individualistic approaches providing information without broader and more meaningful opportunities to support new habits, yield few changes (Milio, 1986). A systems approach focusing on “the social, economic, political, institutional, cultural, legislative, industrial and physical environments in which behavior takes place” (Green & Raeburn, 1988, p. 153), together with community actions that assist individuals to engage in healthful behaviour, may offer the most promising strategy for empowerment in health promotion (Yeo, 1993).

According to Milio (1986), a combination strategy providing for emphasis on the greater social system is not likely to prevail for public health interventions in the near future. The reason behind this assertion is that a more individualistic emphasis, whether community-based or not, is less costly politically and for economies, as well as for programme budgets, if only in the short term. Another factor potentially inhibiting a systems emphasis is the benefits involved for those with vested interests in maintaining the *status quo*, through shifting responsibility for health from government to those individuals or groups suffering particular health problems (e.g., diabetes in Aboriginal populations), thus distracting attention from systemic determinants of lifestyles (Evans & Stoddart, 1990). In this way, diabetes becomes a problem of Aboriginal people, rather than of the social determinants of poverty, marginalisation and alienation. Reflection on the theory behind the Okanagan Diabetes Project suggests a certain naïvety in the notion that health professionals can facilitate through internal actions the empowerment of a disenfranchised community towards improving health status. As comprehensive, well-guided and participatory as such actions might be, there is no escaping the massive role and impact of social determinants of health that must also be addressed.

If it is the case that powerlessness is embedded in Aboriginal culture, then it is necessary that co-ordinated, multisectoral empowerment strategies target fundamental change in the larger Canadian society. Though some individuals may be motivated to engage in healthful behaviour without broader actions, others will enter the “at risk” population because no action has been taken to change those forces in society that created the problem in the first place (Syme, 1986). A true programme for addressing health needs in the Canadian Aboriginal population, including diabetes or any other issue, must address the re-ordering of society and the need to create a social reality in which Aboriginal people can achieve self-determination. The phenomenon of

powerlessness requires that programme theories address the need for interventions aimed at enhancing control, not only at the individual level but also at the community and environmental levels. Failing to promote control across all three dimensions is implicated in a variety of negative intervention efforts, including the Multiple Risk Factor Intervention Trial (Syme, 1991). Most interventions in Aboriginal populations, including the Okanagan Diabetes Project, have focused attention on individuals, with little attention to the social environment in which communities and residents are located (Lamarine, 1987). It is not possible to assess whether the more limited strategies of the project inhibited its success, but broader actions were not feasible within the research framework. Funders might acknowledge in future competitions and research initiatives, however, the need to link community interventions to complementary health and social policy.

Methodological Challenges and Limitations

Beyond implementation and theoretical issues, methodological challenges may relate also to the lack of success of the project, by obscuring or hindering documentation of truly positive changes. This explanation concerns issues inherent in evaluations of small-scale disease prevention and health promotion projects, though responses to common challenges vary considerably in their manner and effectiveness (Cook & Shadish, 1994).

The Okanagan Diabetes Project was structured as a quasi-experiment. Measures before, during and at the end of the study in communities in which conditions to enable a community-directed diabetes intervention programme were either present or absent enables some measure of change in outcomes to be associated with the project. Methodological rigour was held to be important for discerning causality. The appropriateness of evaluation as applied research (relative to other paradigms) is assumed and will not be debated. The focus in this section is the adequacy and sensitivity of the methodology used in relation to the results observed.

A critic might argue, even given compromised implementation, that the project yielded positive effects that insensitive procedures cannot confirm. Thus, to conclude that the project was ineffective might be to commit a Type II (or β) error. Discussion of the notion that positive changes were obscured by insensitive analytic methods should be kept separate, however, from discussion of the validity of conclusions on effectiveness. The first issue requires an assessment

of statistical conclusion validity in relation to the results observed. The latter issue requires an appraisal of the internal validity of results in terms of bias and confounding.

Validity of Statistical Conclusions

Statistical conclusion validity is a requirement for causal inference, assuming internal validity and temporal antecedence (where a cause precedes an effect) (Cook & Campbell, 1979). It is a function of two factors: (a) statistical power; and (b) appropriate statistical procedures. Low statistical power or inappropriate statistical procedures can result in false conclusions about co-variation between a treatment and the outcomes observed. Threats posed by these factors are discussed below.

Statistical Power

The power of an analysis is influenced by the level of probability (α) beyond which any co-variation is considered to reflect chance variation, as well as the sample size and the true treatment effect (Hassard, 1991). In this study, the null model projected no difference over time between intervention and comparison conditions, given no programme effect. That differences were not observed could reflect a small treatment effect at the level of the population and the small sizes of cohorts and cross-sectional samples. Given the low initial sample sizes and moderately high levels of attrition from cohorts, statistical power was clearly less than adequate. Power was also compromised by the need encountered following baseline testing to add a second comparison community, because of the additional variability introduced into the comparison condition.

Lipsey (1990) commented on the low levels of statistical power in community-based intervention studies, in relation to the need for outcome measures that reflect the true effect size associated with effective treatments. Sensitive measures are more easily recommended than obtained, however, for community interventions. The results of even large-scale intervention efforts have indicated only small gains actually attributable to the intervention programme (Gyarfas, 1992). Thus the true effect size for small-scale intervention projects, including the present study, is probably even lower. Rooney and Murray (1996) suggested on the basis of a meta-analysis of smoking prevention programmes, adjusted for clustering, that the average effect size for social

interventions may be only 0.10 standard deviation units, or perhaps 5%. The same authors noted that even under optimal conditions the effect size may be only 0.50 to 0.75 standard deviation units, or perhaps 20%-30%. Therefore, accepting a realistic estimate of a small treatment effect, the primary and most practically modifiable determinant of statistical power, is sample size.

Sample size and power calculations in this study were necessarily based on individuals rather than communities. *A priori* calculations used a multiplier ($\sqrt{2}$) by which the variance among individuals was inflated to adjust for clustering. This increased the number of persons required to achieve statistical significance. Calculations unfortunately assumed a moderate rather than small treatment effect (0.50 rather than 0.10 standard deviation units), on the basis of the results of meta-analyses of studies involving high-risk and usually highly motivated persons in more intensive, individual-level behaviour change programmes (Brown, 1990, 1992). This was clearly too optimistic for a community trial. Funding constraints, logistical and administrative issues, and limited numbers of individuals with or at familial risk for diabetes did not support sampling and testing sufficient numbers to detect a small effect with a high level of power. The sampling pool might have been broadened to include others not at familial risk for diabetes, controlling in analyses for differences in familial risk and glucose status, but funding and administrative issues would have remained. Budgeting for ample funds at the outset of a project may help to alleviate logistical and administrative problems. The essential issue, then, is funding sufficient to allow managing, sampling and testing greater numbers of individuals to enable demonstration of small effects. Such effects may be meaningful and of public health importance, because small changes among a majority of individuals can shift entire distributions of risk factors (Rose, 1992).

Low statistical power can sometimes be improved by increasing the α level from 0.05 to 0.10. This may be acceptable where the risk of missing a real effect outweighs a corresponding increase in the risk of Type I error. Together with statistical procedures that do not elevate further the risk of Type I error, this strategy can extend the power of a study and reduce the chance of failing to detect real effects. Increasing α will not be particularly helpful when a large number of outcomes are assessed, as in the present study, since probability values must still be adjusted to account for multiple comparisons. The sheer number of such comparisons, more than relatively minor (and arbitrary) distinctions as to an acceptable level of risk of an α error, will drive conclusions

about the statistical importance of effects. Reducing the number of hypotheses tested could be worthwhile in some instances, yet a variety of theory-driven, distinct measures is necessary for assessing the programme theory on which community change mechanisms are based.

Another approach for improving power is one-tailed statistical tests as used in analyses of some community interventions (Williams *et al.*, 1981) and interventions in communities (Multiple Risk Factor Intervention Trial Research Group, 1982). One-tailed tests may be justifiable when directional hypotheses are reasonable, but the decision on one- versus two-tailed tests must be made *a priori*. In this study, α was set at 0.05 and a decision was made to use two-tailed tests for analyses. Such decisions reduced the risk of Type I error, as did adjustments to error variances and degrees of freedom (to account for clustering) and adjustments for multiple comparisons. The decision to use two-tailed rather than one-tailed tests took into account literature indicating that community trials can yield negative as well as positive effects, if any at all. One cannot alter after collecting and viewing the data the decision rule on analytic power. Nevertheless, analytic power was constrained by conservative procedures, and future efforts might consider seriously the use of one tailed tests, where appropriate.

It is possible that rigorously protecting against the risk of Type I error may have reduced power and inflated the chance of Type II error. As evident from a review of Tables 22 and 23 (Chapter 7), however, the means and cluster-adjusted 95% confidence intervals for differences statistically significant before adjustment for multiple tests as well as those still significant after adjustment attest to minor differences between conditions. Therefore, it is reassuring that adjustments for multiple comparisons negated most unadjusted indications of significance. Lack of congruence between statistical significance and the practical meaning of such determinations can be difficult to explain, because statistical significance is not synonymous with practical relevance. On the basis of means and their variability, it does not appear that the ineffectiveness of the project as assessed can be attributed to Type II error associated with conservative procedures taxing already low levels of statistical power. For the effects observed, even if larger numbers had been sampled and statistical significance achieved on the basis of greater power, the magnitude of differences would still provide limited evidence of practical effectiveness.

Appropriateness of Statistical Procedures

Given the analytic challenges reviewed in Chapter 5 and the nature of the solutions implemented, statistical procedures were as sensitive as could be expected while still remaining valid. This is not the place for a detailed rationale for the procedures used, as background material was reviewed in Chapter 5, and the implications considered for analyses of small-scale quasi-experiments. Salient issues are discussed below.

The quasi-mixed model analysis strategy used in this project approximated a multi-level analysis approach suitable for trials involving several communities per study condition. A quasi-mixed model strategy is the only approach suitable for studies involving one or two communities nested within study conditions. It provides a way to account for clustering, or non-independence of observations within intact social units. Given just one or two social units per study condition, the community factor cannot be treated statistically as a random effect nested within study conditions specified as fixed effects in order to account for clustering through explicit modelling of community-level variance. A quasi-mixed model approach mimics a multi-level mixed (fixed and random) effects analysis. Since the community factor must be presumed to be a fixed effect, the residual variance of statistical tests is inflated by a factor calculated from external estimates of the intra-class correlation describing the level of non-independence of observations for particular classes of variables. The magnitude of the inflation factor calculated depends on the harmonic mean group size sampled across communities and the size of the estimated intra-class correlation for a particular variable. Degrees of freedom for the re-calculated test statistic are also adjusted (reduced) by division by the same factor used to inflate the residual variance.

Use of a quasi-mixed model analysis approach in this study might be criticised as overly conservative, because test statistics based on uncorrected fixed effects analyses were invariably diminished, sometimes substantially, by adjustments for clustering. Such a criticism implies that less conservative options exist for analysis, perhaps by making no correction at all. Such options, however, would fail to incorporate into statistical tests an important estimate of the magnitude of the clustering. Yet few studies actually account for clustering. For example, a follow-up of the long-term effects of the Stanford Five-City Project, published recently in the *American Journal of Public Health* (Winkleby *et al.*, 1996), based all tests on fixed effects analyses that did not account

in any way for clustering (or for multiple comparisons). Improvements maintained over the follow-up period, described as “modest,” were relatively minor. Review of means and standard deviations suggests that the statistical significance of those effects for which differences existed might well have been nullified had corrections for clustering and multiple comparisons been performed. No comment was made on the limitations of the analytic procedures used.

Accepting a quasi-mixed model analysis approach as appropriate is to accept that greater “sensitivity” in analyses that do not account for clustering is illusory and an invalid ideal. Similarly, use of weighted marginal means in analyses provides unbiased population-level estimates of changes between study conditions, and is the only acceptable strategy under challenging field conditions. Weighting is inefficient when the distribution of outcome variables does not depend on variables used in the sampling design or to adjust for non-response. Such ideal conditions do not apply to quasi-experimental community-based intervention studies, where weighted marginal means provide a necessary group-level adjustment potentially attenuating the impact of ecological bias between groups. Moreover, population-weighted analyses are necessary for analysis of unbalanced survey-type data. Therefore, the efficiency argument against weighting is moot. Many of the differences in outcomes between conditions here were highly significant when unweighted analyses were performed, but the magnitude of these effects decreased substantially once weighting was incorporated into analyses.

As final points about the appropriateness of statistical procedures, the use of planned orthogonal contrasts to test differences between the single intervention community and the two comparison communities permitted more powerful and focused tests of effects than the usual omnibus test for any difference, which requires post-hoc tests to define the nature of any general difference identified. Use of the cell means model for analysis of variance procedures enabled straightforward tests of effects as well as the benefit of estimating any contrast or set of multiple contrasts between the means of communities and sub-groups nested within study conditions. Thus, use of the cell means model for analysis of the “messy” (unbalanced and incomplete) data collected in this study worked well in conjunction with planned orthogonal contrasts. For small community-based intervention studies, these strategies have much to recommend them. On the

other hand, regression analysis based on the effects model is a viable and flexible alternative strategy, particularly for larger studies involving several communities per study condition.

Internal Validity of Conclusions

Internal validity is considered to exist when accurate conclusions are made about co-variation between variables (Campbell, 1969). The conclusion has been made that the provision of conditions to enable a community-directed diabetes intervention programme was not effective in terms of yielding measurable changes in outcome variables. The question, then, is the level of accuracy of this conclusion. Issues associated with statistical conclusion validity were discussed in the preceding section. It may be surmised that statistical procedures were appropriate but that statistical power was less than sufficient, at least in terms of detecting small differences between study conditions that might be of public health importance. Review of means and confidence intervals (Tables 22 and 23) suggests that statistical conclusions are accurate, however. Attention is therefore directed to other threats to validity and plausible rival hypotheses that might account for the results (lack of effect) observed.

Selection Bias and Allocation Bias

Bias is any systematic deviation between the true characteristics of the population involved in this project and the measured attributes of samples representing this population. Allocation bias is related to selection bias and concerns inequalities in the manner by which individuals were assigned to study conditions, by use of communities as the unit of allocation. Selection bias concerns the non-random selection of individuals from the population of which they are ostensibly representative (Sheps & Birnbaum, 1992). Random selection and random allocation grant each member of the population involved an equal chance of being selected and allocated to a particular study condition, and is the only way to reduce the possibility of bias.

Randomisation is not necessarily essential, however, for unbiased estimates of treatment effects, so long as the process by which individuals were selected can be modelled as realistically as possible at the analytic stage (Muthén & Jöreskog, 1983). Such attempts were made in this project. Cain (1975) put the issue succinctly, noting that “the critical difference for avoiding bias is

not whether the assignments are random or nonrandom, but whether the investigator has knowledge of and can model the selection process" (p. 304). It is largely moot whether communities were allocated randomly to study conditions, because too few communities were involved to reduce by randomisation the possibility of bias from differences between communities. All that random assignment achieves is some assurance that the investigators did not bias the results by picking the more predisposed and enabled community for intervention. Randomisation of individuals was incompatible with the process of community-based intervention, but the selection of individuals as members of communities could be, and was, modelled analytically.

The first defense taken against bias was at the design stage, through use of matching. The communities chosen for participation were in the same geographic region and similar in terms of demographic characteristics including lifestyle, socio-economic status and education (Statistics Canada, 1993b, 1993c). Baseline screening confirmed that the three communities involved were also similar in terms of the percentage distribution of high blood pressure and out-of-range (clinically elevated) metabolic parameters, mean levels of most behavioural variables and psychosocial constructs, and the prevalence of diabetes (Daniel *et al.*, 1995). Matching was not used in analyses due to the low statistical power of analyses of few matched units.

Given matched communities, the selection process was modelled in analyses to help to attenuate bias from selectivity problems (Muthén & Jöreskog, 1983). Community was modelled as a proxy for the reasons that sort people into different communities, to control for ecological bias and for confounding that operates through the unknown "assignment rule" distinguishing the intervention community from the comparison communities (Graubard & Korn, 1994; Judd & Kenny, 1981a; Rosenbaum, 1984). Other analyses modelled differences among communities in the underlying distributions of individuals in various sub-categories (e.g., glucose status, participation status, etc.). Individual-level confounders including age and time-varying covariates were modelled as well, secondary to group-level variables. Individual-level covariates were not used to control for group-level differences, since this practice does not attenuate bias at the group level and can actually worsen it (Greenland & Morgenstern, 1989).

In terms of widely-acknowledged threats to internal validity (Campbell & Stanley, 1966), the primary disadvantage of the quasi-experimental design used is the potential for selection-allocation interactions with history, maturation, testing, instrumentation, regression and mortality. Such threats of interaction raise the possibility that the results observed may have been caused by inherent, pre-existing differences between the intervention and comparison communities. Matching and statistical modelling may attenuate but not negate the impact of such bias. Differences were not apparent at baseline between conditions in counts for clinically elevated values for physiological variables, but differences between means were observed for cholesterol, low-density lipoprotein cholesterol, body mass index, systolic blood pressure, depression, physical activity and protein consumption. With the exception of depression, means for the intervention community were at more unhealthful levels than those of the comparison communities. Thus, it is possible that the less favourable profile of the intervention community at the outset of the project inhibited rapid healthful change or that the less favourable profile gave them more room for change and therefore greater propensity to change (regression to the mean). Baseline differences are nevertheless to be expected in quasi-experiments, requiring that conclusions must be based on relative, not absolute, changes over time (Kenny, 1975).

Beyond the limitation of selection-allocation interactions, it is possible that unmeasured differences at the individual or aggregate level may have predisposed statistical regression. This threat was addressed, however, by ensuring that selection at the individual and community level was not on the basis of extreme scores, and that differential recruitment did not occur. Further, given the more unhealthful status of the intervention community at baseline, regression might have been expected to promote strong and more positive net changes for the intervention community, and this was not the case. In general, bias affecting both study conditions equally will not cause biased effects, but differential responses to bias between conditions *will* cause bias in the estimated effects. Bias that may have negated a measurable impact of the project on the intervention community through selection-allocation interactions is possible though unlikely.

Sampling Bias

Both longitudinal and repeated cross-sectional samples were used in this study. Bias can affect these sampling strategies in different ways. In terms of Campbell and Stanley's (1966) typology of threats to internal validity, Koepsell *et al.* (1992) have shown that longitudinal samples are more susceptible than cross-sectional samples to bias. The potential impact of the bias associated with longitudinal and cross-sectional samples does not differ, however, between fully randomised and quasi-experimental designs. Given the short follow-up period for cohorts in this study and the fact that two comparison cohorts were tracked in addition to that in the intervention community, it is unlikely that biases specific to longitudinal samples were sufficient to compromise internal validity.

Roe and Korn (1993) have shown mathematically that in the presence of a concurrent control group a class of biases unique to longitudinal studies, known as time-period effects, do not distort the estimated difference between group means, the variability of this difference, or its distribution. Random time-period effects are unexplained increases or decreases in the observed value for all (or most) individuals measured at a particular time point. These effects may be predisposed by changes in study procedures, equipment, personnel and participant co-operation. While known factors can be modelled, many time-period effects occur because of some common unmeasurable or omitted factor and cannot be modelled explicitly. In combination with age-adjustment, a concurrent control group can "cancel out" period effects and aid the separation and interpretation of cohort-specific treatment effects independent of confounding by age and period (Wolinsky, 1993). Thus, use in this study of comparison cohorts suggests that the threat of bias related to secular and time-period trends was minor.

Validity of Self-Reported Data

Information on health behaviours and psychosocial status was appraised by self-report, through self-administered questionnaires. Self-reports were the only feasible means for collecting such information, primarily for logistical and cost reasons. As "blinding" was not possible, people may have been inclined to over-report desirable health behaviours and under-report undesirable health behaviours. Equally troublesome is the possibility of differential tendencies in the direction and magnitude of false reporting for different subgroups (Green & Krotki, 1968). Differential

tendencies in reporting could have occurred, for example, between persons with diabetes, impaired glucose tolerance or those who were normoglycaemic. Normative changes in socially desirable forms of behaviour could have predisposed persons who engage in unhealthful activities to make false reports of their behaviours, to be perceived more favourably by others. Thus, subjective bias is a threat to the validity of self-reported data (Kriegsman *et al.*, 1996).

The possibility of bias in self-reported data is a limitation of this study only in terms of generalising status at a given time point. Use of comparison samples for longitudinal and cross-sectional measures suggests that biased self-reports would not cause the estimated differences between conditions to be biased. This notion assumes no systematic bias between conditions, with inaccuracies distributed randomly and equally under both conditions, and in both directions, thus cancelling themselves out (Feinstein, 1977). This assumption would not hold, however, if one considers the greater likelihood of a social demand bias in the intervention community pushing (or pulling) respondents toward a more exaggerated positive bias in their post-test responses than in their pre-test or in the pre-test and post-test responses in the comparison communities.

Observation Bias and Misclassification Bias

Observation bias results from systematic differences or inaccuracies in the way data are gathered, recorded and analysed. In this study, it is possible that observation bias is a threat to the validity of the results of cross-sectional surveys conducted by telephone and home interview. Such bias could have occurred if differential tendencies were exhibited by interviewers asking questions and recording responses. Interviewers may by their prejudices have given the benefit of any doubts to individuals in the intervention community rather than to those in the comparison communities, to more articulate participants, or to male or female participants (Green & Krotki, 1968). Such bias might also threaten the validity of anthropometric measurements for members of cohorts, through differential tendencies in measurement protocol and in recording data, whether for a particular study condition or for specific sub-groups of individuals. Checks were not built in to the project to assess the possibility of such bias, and this is a limitation of the study.

Misclassification bias, a form of observation bias, could have resulted from low validity in classifying individuals on their clinical status for blood measures, or in classifications of behaviours including smoking and alcohol consumption. For such measures, if the validity of the observation is differential, then the consequent misclassification will also be differential (Abramson, 1988). Misclassification bias can influence analyses and lead to spurious conclusions about relationships at a given time point (e.g., analyses of smoking and alcohol consumption could be biased by over or under-reporting these behaviours). It is unlikely, however, that there were differences between conditions in the extent of misclassification bias. Laboratory tests may have yielded inaccurate results too high or too low, leading to misclassification of glucose or lipid status, yet it is reasonable to assume such errors were distributed equally between study conditions. Bias in self-reports of smoking and alcohol consumption would be expected to be equally distributed also. Thus, the differences estimated between study conditions should be valid despite any misclassification bias.

Missing Data and Attrition from Cohorts

The impact of missing data through attrition or loss to follow-up is a form of observation bias that warrants consideration independent of more general issues. It affects cohorts but not repeated cross-sectional samples. In this study, only 57% of individuals measured at baseline completed two follow-up surveys over 16 months of intervention. Moderately high attrition was to be expected, however. In the Stanford Five-City Project 39% of the baseline cohort completed three follow-up surveys over a five-year period (Farquhar *et al.*, 1990). Koepsell *et al.* (1992) reviewed several community studies suggesting that losses from a cohort occur mostly among individuals with the least healthful lifestyles. Assessing differences between respondents and non-respondents as well as identifying or determining whether the non-response mechanism is important or not are important steps in appraising the impact of bias caused by attrition (Jackson *et al.*, 1996).

That non-response was greater for the comparison condition made critical the approach taken to model the selection process and use weighted marginal means. That is, to fulfill the condition of ignorable non-response, it was necessary to model the community factor and test

data-dependent (i.e., population-weighted within intervention conditions) hypotheses (Gibbons *et al.*, 1993). This is an acceptable approach to reducing bias when missing data are related to the nature of a treatment (Little & Rubin, 1987), provided that data are missing at random in the sense that missing values depend not on any unobserved value, but only on observed values. Low intercorrelations between dichotomous dummy variables coded for missing values were sufficiently low (less than 0.21) to suggest that data were missing at random. Thus, although the probability of non-response was not equal across time and differed by study condition, the non-response mechanism was considered to be ignorable.

Analyses were conducted to test whether differences between drop-outs and finishers varied by study condition. Drop-outs (non-respondents) were individuals enrolled in cohorts and measured at baseline, but who did not participate in the second or third waves of data collection. Finishers participated in all three waves of data collection. In essence, these analyses assessed whether bias operating through differentials in the characteristics of drop-outs was a threat to the internal validity of conclusions about programme effectiveness. Differentials were not observed for any descriptive or outcome variable, supporting the conclusion that missing observations were not in themselves informative and that the non-response mechanism was ignorable. It can be concluded that attrition and missing data are not a threat to the internal validity of conclusions about the effectiveness of the project. Such effects, however, did compromise the anticipated power of statistical analyses.

Cross-Contamination and Secular Trends

Cross-contamination of the comparison communities through uptake of information or behaviours promoted in the intervention community does not appear likely because, in general, changes in outcomes were minor and inconsequential under both study conditions. Cross-contamination is a possibility when communities are located within the same geographic region, and depends on the extent to which residents travel between communities or experience similar exposures through media or other channels. The lack of patterns or directional change within conditions suggests that cross-contamination is not a threat to the validity of conclusions about the ineffectiveness of the project.

In a like manner, it does not appear probable that programme changes were eclipsed or out-paced by favourable secular trends over the course of the study in health promotion activities or in diabetes risk factors, as has proved a problem for evaluating cardiovascular disease prevention initiatives (Cutler *et al.*, 1985; Murray, 1995). When secular trends exist, the challenge is to out-pace or to modify the secular trend in order to achieve a programme effect (Green, 1997). Even if this cannot be done, there will be clear patterns in the data in terms of improvements in levels of risk factors or disease rates (Fortmann *et al.*, 1995). Such patterns were not apparent in the data obtained in this study.

In summary, a review of potential biases supports the conclusion that the provision of conditions enabling a community-directed diabetes intervention programme was not effective in causing quantifiable changes in outcome variables. Few plausible rival hypotheses might account for the lack of effect of the project. The primary threat to validity is selection-allocation interactions between the intervention programme and characteristics of individuals in communities assigned to different study conditions. A secondary threat is observation bias that might have influenced the results of repeated cross-sectional surveys and anthropometric measurements for cohorts.

Selection-allocation interactions are a limitation of the quasi-experimental design, for which there was no realistic alternative. If operative, selection-allocation interactions imply that estimates of effectiveness will be biased if interactions existed between conditions, communities and time in relation to the outcomes observed. Such interactions cannot be tested empirically for a nested (incomplete factorial) design, and it is difficult to assess the seriousness of this threat to validity. A sensible interpretation, however, supports the conclusion of a lack of effectiveness.

The secondary threat of observation bias is a limitation of the way the study was planned and conducted. Checks were not incorporated to assess whether differential tendencies were exhibited by interviewers asking questions and recording responses or by observers performing anthropometric measurements. While a limitation to interpreting particular measurements, this threat to validity is not in itself sufficient to cast doubt on the overall conclusion of ineffectiveness.

In combination with the preceding appraisal of statistical conclusion validity, this review of threats to internal validity supports the conclusion that methodological challenges and limitations

were not responsible for a failure to document ostensibly positive changes. The main explanation for the lack of effect of the project remains insufficient activation of the intervention community and inadequate implementation of interventions for diabetes prevention and control.

External Validity (Generalisability)

Though some assert that quasi-experimentation has nothing intrinsically to do with generalising descriptive results to a larger population (Mohr, 1995), the analytic procedures used in this study attempted to account explicitly for the additional variance attributable to communities, thus providing a basis for the results to be generalised at the population level. That is, the communities involved were not considered themselves to be the population of interest, but instead, as forming a sample from a hypothetically infinite population of such communities. Through concern with the robustness of results, analytic procedures thus addressed the need for relevance of conclusions about effectiveness.

Analytic procedures cannot overcome the fact that the choice of communities was far from random, being heavily influenced by feasibility and cost considerations. Beyond the population that was the focus of the study — on-reserve residents of Aboriginal communities in British Columbia's Okanagan region — it is difficult to define other populations to which results can be extrapolated in a formal, statistical way. Generalisation is a more judgmental process for this study than for fully randomised designs because of the potential limitation of two particular threats to external validity: selection-allocation bias and interaction effects of selection-allocation biases and the intervention programme (cf. Mohr, 1995).

Interactions between the intervention programme and selection-allocation biases cannot be assessed empirically. The potential for such interactions, however, suggests that the results of the project may have limited generalisability, and may hold only for the Okanagan Aboriginal population from which individuals were selected or admitted as members of specific communities. Limited generalisability is a common concern for community-based intervention projects, in terms of the specificity of the populations involved and factors influencing specificity. One may ask, for example, whether the North Karelia residents who invited the study in Finland (Puska *et al.*, 1985) were more keen to respond than would be the residents of such regions where cardiovascular

death rates were not so high. One could simultaneously ask whether the California samples in the Stanford studies (Farquhar *et al.*, 1990) would be more predisposed to respond than other U.S. populations less preoccupied with lifestyle issues. Further, as discussed, it is an open question whether marginalised Aboriginal communities are less able to respond to attempts to modify lifestyle in the absence of attention to root environmental conditions affecting power and control.

Bias associated with differential attrition between study conditions is related tangentially to interactions between an intervention programme and selection-allocation biases, but is more correctly the product of a programme than interactive with it (Campbell & Stanley, 1966). Given differential attrition from cohorts, the possibility of bias threatening external validity was assessed empirically by way of condition-by-participation interaction terms for descriptive and outcome variables, none of which were statistically significant. The main effects of participation were then assessed. Across conditions, age was the only variable for which a difference existed between drop-outs and finishers. Finishers were in their mid-to-late 40s, whereas drops-outs were in their late 30s to mid-40s (Table 11). Thus, although differential attrition was not associated with bias threatening external validity, the generalisability of the results of cohort analyses may be limited to individuals 40 years and older (since 39.7 years is the lower end of the 95% confidence interval for the age of finishers).

Three additional threats to external validity may limit generalisability. The first is interaction effects of testing and the intervention programme, which may influence responsiveness and make the results obtained for pre-tested individuals unrepresentative of the effects for the untested population from which individuals were selected. The threat of a sensitising effect of the pre-test was originally described by Solomon (1949); it influences longitudinal but not repeated cross-sectional samples. Pre-testing may affect outcomes either by enhancing or reducing the effectiveness of an intervention. The fact that relative differences over time were contrasted between study conditions suggests that this bias is not a major threat, although a differential response in the intervention community (which cannot be tested) could have reduced the potential effectiveness of the programme. Nevertheless, the overall results of cohort analyses were in the same direction (no effect) as the results of cross-sectional analyses.

The second additional threat to external validity is reactive effects not to the intervention programme *per se*, but to the fact that it was conducted as a research study. Such effects would preclude generalising about the lack of effectiveness of the project to other communities in which similar conditions might be made available to enable a diabetes intervention programme not part of a research study. Thus, it is possible that the lack of effectiveness of the project is related to the fact that it was mounted as an externally driven research project. This possibility may reflect some level of resistance, as discussed, to attempts to promote voluntary modifications of lifestyle, where participation in such activities offers little potential for greater power or control over destiny.

The third potential threat to external validity is a possibly biased history of relationship between the communities involved, and the academic institution responsible for the study or the funding agency. This threat can be ruled out, however, as good relations prevailed between the communities and Okanagan University College; a negative bias did not exist. Further, none of the communities had had any previous involvement with Health Canada's National Health Research and Development Program, the agency funding the project.

The generalisability of this and other community-based studies is a matter of degree and is not appropriately assessed as a dichotomy (Altman, 1986). Contextual factors must be considered in weighing the generalisability of the results of the overall programme. Nevertheless, given documentation of the limitations of this project, results may be generalised in terms of the specific problems and limitations identified.

Synthesis

The Okanagan Diabetes Project was based on the extensive theoretical and methodological underpinnings of the heavily funded "first generation" cardiovascular disease prevention projects conducted in the United States and elsewhere (Mittelmark *et al.*, 1993). It may be more appropriately considered a "second generation" project, however, insofar as it was a collaborative initiative implemented by community members and public health stakeholders, relying on a relatively small intervention and evaluation budget (\$182,124 over two years). Large cardiovascular disease prevention projects in the United States have had annual budgets of \$1

million to \$1.5 million for 10 years or more (Goodman *et al.*, 1995), but none of these trials was concerned with a rural population in communities as small as those involved in this project.*

The case has been made for smaller, more focused community-based chronic disease prevention studies with high-risk individuals in minority populations (Winkleby, 1994). Where implemented, such studies have had limited budgets and short durations. Relatively little information exists on the effectiveness of small-scale projects, perhaps because funds for such projects have been directed mainly into intervention efforts rather than comprehensive evaluation and dissemination activities. Nevertheless, the data available from small-scale cardiovascular disease prevention projects in the United States suggest that favourable health changes can be demonstrated after only a few years of intervention exposure (Brownson *et al.*, 1996; Croft *et al.*, 1994; Goodman *et al.*, 1995). The Okanagan Diabetes Project, with an intervention exposure duration of just 16 months, contrasts sharply against typical intervention exposure durations of three years or more for successful small-scale cardiovascular disease prevention initiatives. The lack of quantifiable effect of the Okanagan Diabetes Project is thus not altogether surprising given the limited time available for community change processes, as well as inadequate implementation.

Of three major community-based NIDDM prevention and control projects mounted in Canadian Aboriginal populations, the Okanagan Diabetes Project is the first to have undergone a systematic summative evaluation. The results of the other two projects, the Kahnawake Schools Diabetes Prevention Project in Québec (Macaulay *et al.*, 1995) and the Sioux Valley Diabetes Prevention Project (Mustard *et al.*, 1995) in Manitoba, have not been disseminated.† As these projects involved intervention exposure durations of up to three years, their evaluation results are awaited with great interest. Whether longer exposure durations will yield more positive changes is not the only question, because differences in implementation and programme theories, and methods of evaluation, will also relate to the outcomes observed. None of these projects,

*One might argue that the communities involved in the Stanford Three-Community Study were rural small towns. Watsonville, Gilroy and Tracy, however, were semi-rural, with substantially more residents than the Aboriginal communities in the Okanagan Diabetes Project. The total on-reserve population for the largest of the three Okanagan communities was just 707 individuals.

†Another major project is the Sandy Lake Health and Diabetes Project in Sioux Lookout Zone in Ontario (Hanley *et al.*, 1995), currently focused on gathering epidemiological field data and planning interventions for implementation at a later point (Gittelsohn *et al.*, 1996).

however, have targeted or been linked directly to structural modification of the larger society through policy or environmental actions.

Small secondary diabetes prevention projects ($n \leq 52$) for which evaluation data are available have observed either no change in quantitative outcomes, or changes well within chance levels given the numbers of outcomes analysed. A study in the Nuu-chah-nulth community on Vancouver Island (two years duration) (King-Hooper *et al.*, 1995) falls into the first category, whereas intervention programmes among the Haida Gwaii in British Columbia's Queen Charlotte Islands (three years duration) (Heffernan *et al.*, 1996) and the James Bay Cree in Québec (three months duration) (Robinson *et al.*, 1995) fall into the latter category. The limited impact of these projects did not vary with intervention exposure duration, but a broader issue is the penetration of various interventions mounted. Intervention exposure duration can be theorised to interact with the degree of penetration of substantial numbers of various activities in communities, as well as the level of participation achieved within communities and among high-risk sub-groups.

The primary focus on the lack of measurable effect on quantitative outcomes in the Okanagan Diabetes Project should not negate the importance of positive environmental changes as determined by qualitative surveys of community systems. Actions by community sub-systems and whole system changes in norms and values would carry more weight, however, if they had been associated with changes among individuals in "high-risk" cohorts or with shifts in community-level results aggregated from cross-sectional surveys of individuals. That changes in individual-level and community-level variables did not occur constrains considerably the basis for inference about environmental changes. A cautious interpretation nonetheless supports the conclusion of meaningful achievements in *some* intermediate processes of the theoretical framework linking the intervention programme to individual change in behaviour through the environment. Thus, the project was successful in generating some community support and the co-operation of some sectors necessary for eventual changes in health status. These achievements may reflect the commitment of the research team to principles of participatory research, capacity-building and development of indigenous leadership (Hagey, 1997), and an emphasis on environmental as well as direct behavioural changes.

Positive achievements in intermediate processes support the conclusion that community control and responsibility for the intervention process can be facilitated to provide at least the basis for healthful change. Perceptions of relevance and appropriateness among those who are the intended recipients of a programme are critical to the eventual effectiveness of attempts to influence lifestyles. Use of community workers to conduct diagnostic baseline interviews ($n = 59$) in the intervention community was in keeping with the need to ground intervention strategies to an understanding of how illness generally, and diabetes specifically, are interpreted and managed in the community. Thus, the opportunity provided for integrating cultural values, attitudes and beliefs into strategies predisposing, enabling and reinforcing lifestyle change may be in large part responsible for the beginnings observed of normative change and healthful shifts in values. The limited nature of community changes, however, may reflect a disjunction between opportunity and effective action in that Aboriginal concepts were not integrated with interventions through complementary linkages with theories of behavioural and environmental change. It is unfortunate and a major limitation of the project that intervention development and the community activation process cannot be reviewed in detail, because a process evaluation was not conducted.

On evaluating community trials, Fortmann *et al.* (1995) have argued for shifting research foci to "address how communities change and how interventions can be designed to enhance ... changes in healthful directions" (p. 582). Little is known about community change processes, and detailed analyses are needed (Altman, 1986). The experience of this project is that process evaluation and feedback on interventions are critical to provide a basis for summative evaluation and testing programme theory. There is also a need for understanding how to achieve healthful local policies and how to advance major policy initiatives at regional, provincial and federal levels (Heller, 1990). Surveys of community systems have merit in this regard, because multiple levels of focus are necessary for incorporating and assessing a systems approach in health promotion efforts (Green *et al.*, 1996). For example, a multiple level process evaluation could be used to assess the utility of individually targeted interventions (e.g., weight loss and exercise classes) relative to media campaigns (e.g., newspaper articles and "fact sheets") and policy initiatives (e.g., locally, including promotion of leisure-time physical activity, and nationally, including attention to land claims or self-government). Given difficulties in recruiting substantial numbers to participate

in individually targeted interventions, programme emphasis might shift towards approaches that reach more people with the potential for greater total community-level impact, even if most individuals experience less change (Koepsell *et al.*, 1995).

Recommendations for Future Initiatives

The foregoing sections broach several issues that can be summarised as recommendations for future research on diabetes prevention and control, or chronic disease prevention and health promotion more generally, in Canadian Aboriginal populations. Accepting the challenges and limitations of community studies, the identification of factors promoting effectiveness at a level sufficient to survive summative evaluation is necessary if researchers are to advise responsibly those funding agencies, public health stakeholders and community representatives whose concerns they attempt to address. That is, if community-based research on chronic disease prevention in the Canadian Aboriginal population is to be conducted under conditions that predict failure or limited benefits, then all should be aware of this, and the issues should be made explicit.

One-shot programmes, such as the Okanagan Diabetes Project, are usually found to be less than effective when subjected to a systematic and reasonably rigorous summative evaluation (Sechrest & Figueredo, 1993). Breaking the cycle of spirited beginnings and discouraging endings that characterises a great many social interventions requires an honest and forthright appraisal of errors and problems encountered in mounting projects. Community-based research is a messy and untidy undertaking that falls far short of conforming to the models codified in methodology textbooks (Bynner, 1980). Whether this reflects the unrealistic expectations of textbook “models” or their sloppy execution is not the point. Theoretical and methodological issues require as much attention as factors associated with programme implementation and project management. Future efforts and advancement of the field depend on avoiding mistakes made by others, and applying details of effective concepts (Altman, 1986). Recommendations follow below. These recommendations are more than methodological ideals; they arise directly from experience gained in planning, implementing and evaluating the study reported here.

(i) *The research and the programme of interventions to be evaluated should be predicated on an explicit theoretical framework.* An intervention programme is a representation of a theoretical link between the known or perceived determinants of a problem, the problem itself, and predicted changes in the problem situation (Cronbach *et al.*, 1980). Theory-driven research is critical under conditions that preclude true experiments, to help to attenuate threats to validity and strengthen a basis for inference (Lipsey, 1990). Theory should guide decisions on methodology, causal attributions of effects, and prediction and interpretation of results. Socio-behavioural theory should guide strategies for individual and community change processes (Glanz *et al.*, 1990). Specification of a programme or “treatment” theory is necessary to make explicit the pathways by which a project is to achieve its objectives. Through specification of the theoretical model guiding this project, it was possible to discriminate between theory failure and implementation failure, thus avoiding a “Type III” evaluation error. Theoretical frameworks in future studies should address the need for facilitating empowerment at the individual, community and social environmental levels.

(ii) *Theory should be integrated with Aboriginal logic and cultural concepts.* Cultural values, beliefs and attitudes are the basis of Aboriginal responses to diabetes as an environmental and social phenomenon (Garro, 1995). Integrating theories of behavioural and environmental change with Aboriginal logic and belief systems can enable the development of culturally rational and acceptable intervention strategies combining scientific knowledge and evidence-based practices (Hagey, 1984). Promoting cultural integrity through a negotiated understanding of illness process and control requires understanding how illness is interpreted and managed locally (Garro, 1987). Pre-intervention interviews and qualitative analyses in this project addressed this need, but inadequate implementation precluded development of strong linkages integrating theory with Aboriginal logic and cultural concepts.

(iii) *The research process should embrace the active involvement of Aboriginal people.* Only by involving Aboriginal community members in all aspects of the research process can relevant questions and sensitive procedures achieve the delicate balance sought between knowledge

development and meaningful community benefit (Green L.W. *et al.*, 1995). Perceptions of cultural relevance affect the acceptance and viability of lifestyle interventions in Aboriginal communities, thus conditioning community activation (Webster & Nabigon, 1993). Community control and responsibility for the intervention process can facilitate personal and collective efficacy to empower individuals and groups to take control of their lives and environment (Bandura, 1982; Rappaport, 1984). The moderate success of this project in generating community support and organisational co-operation may relate to the commitment made to principles of participatory research, capacity-building and development of indigenous leadership.

(iv) *Intervention programmes should be of an adequate duration.* Community interventions are likely to require exposure durations of at least three years to achieve changes in outcomes (Brownson *et al.*, 1996). With time for planning, four-year programmes should be considered minimal to achieve measurable health outcomes. In this project, the 16-month intervention phase and the eight-month planning phase were far too short. Allowing for diffusion and uptake of interventions sufficient to change the risk profiles of entire communities necessitates longer intervention durations than for projects targeting change in high-risk groups (Rogers, 1983). The potential for measuring the public health benefit of community projects depends on time for interventions to take hold and garner momentum sufficient to outpace favourable secular trends in diffusion of knowledge and behaviour (Green, 1997). The time required for shifting entire distributions of risk factors should not be equated with the time required to change mean levels of risk factors among particular groups of high-risk individuals (Rose, 1992).

(v) *Interventions should vary across different levels of implementation.* Programmes should make use of individual-level strategies (e.g., exercise classes) as well as community-level actions (e.g., media campaigns) and environmental initiatives (e.g., policy actions) (Fortmann *et al.*, 1995). The blend of strategies should be theory-driven but in keeping with community needs, priorities, opportunities and constraints (Koepsell *et al.*, 1995). As in this project, "high-risk" groups might be targeted to receive greater levels of exposure than the community in general. More intensive outreach strategies are required to reach the last cohorts in the knowledge and risk-reduction

diffusion-adoption curve (Green, 1997). Nevertheless, attention to factors predisposing, enabling and reinforcing behavioural and environmental change requires that population-level interventions be mounted as well as specific individual-level strategies (Green & Kreuter, 1991). Beyond theoretical reasons for this assertion is the practical fact that high levels of participation in individually tailored interventions may be difficult to achieve (Green, 1986). Thus, a primary focus on individual-level interventions can compromise the population-level impact of a programme. This project attempted implementation at several levels.

(vi) *Project management should ensure intensity of effort combined with appropriate adaptation at all phases of the programme and research process.* Rigour in the usual processes of planning, data collection and evaluation is necessary but not sufficient to draw meaning from a social intervention. Rigour in implementation is also required. This is not to suggest that rigid adherence to a preconceived plan of action is desirable (Ottoson & Green, 1987), especially for the emergent and needs-based processes characteristic of community-based research. Mindful attention to theoretical foundations, evidence-based practices and previous research on the problem, however, can prevent the research process from going awry (Ratcliffe & Gonzalez-del-Valle, 1988). Consistency of effort may require involvement of an on-site project co-ordinator with graduate-level training in research and knowledge of theory and community development. As in this project, such an option may be particularly important when project investigators are unable to provide on-going attention to all phases of research, particularly implementation, because community workers cannot reasonably be expected to bear this task. Maintaining scientific rigour in community-based research requires a high level of commitment and effort among all partners in the research process (Allison & Rootman, 1996).

(vii) *Programme quality and implementation should be assessed by process evaluation.* The failure to conduct a process evaluation of the intervention development and implementation phases of this project led to a disjunction between the programme theory and the interventions implemented. Process evaluation provides diagnostic information about programme quality and intervention delivery methods, and is necessary to ensure the sufficiency and integrity of the

implemented programme (Green & Lewis, 1986). Appraising the processes and characteristics of the programme environment can enable the development of effective interventions and advance knowledge of how context influences outcomes (Moos, 1988). Iterative use of process and impact evaluation procedures in the development of programme processes can yield more effective models for social programmes (e.g., Tharp & Gallimore, 1979). An iterative model of testing, feedback and revision helps solve complex problems, and generates more knowledge than successive summative evaluations of one-shot programmes (Sechrest & Figueredo, 1993).

(viii) *Sample size and power should be sufficient to assess research questions.* Small-scale community trials involving few communities must necessarily base statistical power and sample size calculations on numbers of individuals required to achieve a given effect size, rather than on numbers of communities. The variance of the estimated effect should be inflated to account for the lack of independence among individuals within communities. An inflation factor of $\sqrt{2}$ may be a reasonable approximation for such purposes (Salonen *et al.*, 1986). Sample size and power calculations should be realistic in expecting no more than a small effect size; the average effect size for social programmes, corrected for clustering, may be only 0.10 standard deviation units, or 5% (Rooney & Murray, 1996). Even under optimal conditions, effect sizes may be only 0.50 to 0.75 standard deviation units, or 20%-30% (Rooney & Murray, 1996). Anticipating small effect sizes and obtaining adequate sample sizes can circumvent many evaluation problems by enabling reasonable statistical power for testing research questions (Sechrest & Figueredo, 1993). If many outcomes are to be evaluated even greater statistical power may be necessary, given adjustments for multiple comparisons. As in this study, moderate levels of attrition can compromise already low levels of statistical power, and this should be anticipated in the project planning phase.

(ix) *Design and analysis issues unique to community trials should be addressed.* Community-based intervention studies, especially those involving few numbers of communities, face a host of unique methodological challenges (Murray *et al.*, 1994b). These include unit of analysis issues involving correlated data and problems with analytic efficiency, unbalanced data, hierarchical and multi-level designs, longitudinal and cross-sectional samples, random effects, sampling of and in

communities, ecological and individual-level bias, and validity of self-reported data and measures of the community environment, to name just a few pressing concerns (Koepsell *et al.*, 1992). There is no single “best” way of designing, conducting and analysing a community-based trial. Care must be taken to balance against contextual realities the need for scientifically sound information and appropriate techniques for obtaining such information. Balance may be difficult to achieve, but challenges need not prevent valid conclusions. This study incorporated a variety of strategies to attenuate design and analysis difficulties and bias associated with threats to validity.

(x) *Funding should be consistent with requirements for demonstrating positive effects.* The results of separate, well-executed evaluations contribute to a cumulative understanding of the theory, process and effectiveness of community-based intervention programmes (Bloom *et al.*, 1988). Ensuring the utility and social relevance of community trials requires adequate levels of funding consistent with sampling and measuring large numbers of individuals, lengthy exposure durations and adequate staffing to ensure high quality project management. The methodological challenges of such research drives its relatively high cost (Potvin, 1996). On the other hand, the social benefit of well executed community-based research, directly to the communities involved and indirectly through the generation of new and relevant knowledge on pressing needs in at-risk populations, is substantial and of major importance (Altman, 1986). Relative to the United States, Canada has a long history of strong research evaluation processes for federal initiatives (Melkers & Roessner, 1997). This lead reflects strong political support for evaluation activities. As other nations re-orient to emulate Canada's example, it is important that political support continues and funding reductions do not compromise evaluation efforts. Planning grants and lead funding to help with the diagnostic-planning phase before full funding for programmes is decided is also necessary. This need is especially relevant to initiatives emphasising participation, local and personal control over the determinants of health, and intersectoral action involving coalitions and other forms of alliance, co-operation and partnership (Green & Frankish, 1996).

Summary and Conclusion

This dissertation undertook an in-depth appraisal of the issues associated with diabetes and its prevention and control in the Canadian Aboriginal population. It reported on and evaluated the effectiveness in a rural Aboriginal population of a community-directed diabetes prevention and control project. Methodological issues relevant to undertaking and evaluating community-based research were reviewed, and ten recommendations were made for future community-based research on chronic disease prevention in Aboriginal populations.

The research responded to three problems: (a) the high prevalence of diabetes and the impact of the disease among the Canadian Aboriginal population; (b) the limited effectiveness of traditional health care approaches as applied to meet the needs of Aboriginal populations; and (c) the need to address through prevention the role of behavioural and environmental factors. It also addressed a need to plan and implement, in collaboration with Aboriginal people, a community-based, culturally sensitive diabetes prevention and control programme.

The project applied principles of participatory research in the context of a 24-month community-directed initiative in a rural Aboriginal population in the Okanagan region of British Columbia. The intent was to develop and implement interventions by which diabetes could be addressed in ways acceptable and meaningful to the intervention community, focusing on changing behaviours in combination with changing environments. Community workers and participants, guided by a community advisory committee, developed programme strategies and implemented a variety of interventions. The expectation of external researchers and health professionals was to serve as facilitators and advocates for community change processes, contributing technical expertise through knowledge of theory and previous research on the problem, and overseeing implementation, data collection and evaluation procedures.

The programme theory was that interventions developed, implemented, and controlled by community members would facilitate gains in personal and collective efficacy, resources and social support, leading to improvements in knowledge, skills, and psychosocial status. It was theorised that such changes would predispose, enable and reinforce positive shifts in behaviour. Behavioural changes, in turn, were expected to predict positive changes in physiological and

anthropometric variables. Positive shifts in psychosocial and behavioural variables were also expected to be associated with environmental changes.

The project was quasi-experimental, structured to enable causal inference about the effect of the intervention. The single intervention community was matched on demographic variables and pre-intervention levels of diabetes risk factors to two comparison communities. Project workers in the intervention community conducted interviews of individuals with or at risk for diabetes during a seven-month pre-intervention phase. Interviews were transcribed and qualitative analyses undertaken to elucidate themes and strategies for intervention. Baseline measures were obtained in each community, and programme implementation began in the eighth month of the project. A population approach was taken to diabetes prevention and control, but “high-risk” individuals were targeted to receive additional support.

Trend measurements of diabetes knowledge and risk factors (behavioural, physiological, and anthropometric) and psychosocial variables associated with self-efficacy and well-being were obtained for “high-risk” cohorts (individuals with or at familial risk for diabetes) in each community. Cohorts were tracked over the 16-month intervention phase, with measurements at baseline, the midpoint and completion of the study. Cross-sectional community-wide surveys were conducted in each community by telephone and home interviews at baseline and the end of the intervention phase. Cross-sectional surveys assessed the impact of the project at the community level in terms of diabetes knowledge, participation, and behavioural and anthropometric risk factors. Environmental surveys of systems in the intervention community were conducted during the pre-intervention phase and the early and late intervention phases. The focus was on the actions of community sub-systems and groups, and their interaction with each other and with organisations outside the community, as well as whole-system changes in norms and values.

The project was evaluated in terms of its impact on health outcomes, broadly defined to include psychosocial constructs and indicators of well-being, and on behavioural, environmental, physiological and metabolic risk factors for diabetes. The primary research questions sought to determine whether the community-directed diabetes prevention and control programme was associated with positive changes over time in quantitative outcomes. No impact was observed among “high-risk” individuals or at the aggregate level of the community. Secondary research

questions, contingent on positive changes as assessed by the primary research questions, therefore could not be answered. These had sought to establish the nature of relationships between changes in psychosocial, behavioural, physiological and anthropometric variables; specifically, whether changes were in keeping with the programme theory.

Unfortunately, the project was not effective. At the population level, the provision of conditions for development of a community-directed diabetes prevention and control programme did not yield measurable changes in health outcomes. This conclusion appears warranted regardless of low statistical power and biases threatening internal validity. Partially explaining the lack of quantifiable change in outcomes and low levels of participation, analysis of the conditions of the project — especially implementation — suggests insufficient activation of the intervention community. Activation processes did not address the mobilisation of community groups and organisations in a manner sufficient to enable or reinforce individual and collective change through development and dissemination of quality interventions for diabetes prevention and control. Appraising the project in relation to the theoretical model serving as its basis suggests inadequate attention to process and technical input too limited to have achieved community activation sufficient to change social norms reinforcing behavioural change. Theory and previous research on the problem were not integrated with qualitative information from pre-intervention diagnostic community interviews, nor were qualitative results brought to bear on sub-system mobilisation and intervention planning. Interacting with these limitations were the short intervention planning and active intervention phases of the project, just eight and sixteen months, respectively. Thus, the breadth and level of penetration of the interventions implemented were insufficient.

Granting the importance of diabetes in the Canadian Aboriginal population and the potential offered by community-based, culturally sensitive programmes for prevention and control of the disease, it is important to learn from the mistakes and problems encountered in this project. The lack of quantifiable effectiveness of the Okanagan Diabetes Project is not an indictment of the concept of community-based solutions for chronic disease prevention and control. Rather, the results of the project point to problems in the application of the concept. The conditions associated with the failure of this project may also predict failure or limited benefits for similar

projects in other Aboriginal populations. A broader issue is the need to link community interventions to structural and normative modification of the larger social environment through health and social policy initiatives.

Ten recommendations were suggested for future research on disease prevention and health promotion in Aboriginal populations. These can be ordered into three categories, none less important than others. The first set consists of recommendations with a focus on methodology, such as theory, design and analysis issues, and sample size and statistical power. The second set reflects social needs and the realities of applied social research, such as the active involvement of Aboriginal people in the research process, integrating western theory with Aboriginal logic and cultural concepts, targeting interventions at multiple levels, and the basic necessity of process evaluation. The third set consists of recommendations for those who would fund and conduct community-based research for prevention of diabetes and other chronic diseases. Funders must acknowledge that establishing the effectiveness of social interventions requires adequate levels of support over durations of three to four years and the possible need for planning grants in advance of programme funding decisions. Researchers must acknowledge the greater level of involvement demanded by collaborative social research, and be prepared to maintain or enable the maintenance of collaboration, rigour and commitment to the research process in all phases of a project.

In conclusion, this project did not achieve successful control and reduction of diabetes risk factors, but the theoretical model providing the foundation for the study essentially remains untested and may yet serve as a useful guide for other projects able to avoid the pitfalls encountered here. Rather than discard this model and proceed onward to test further one-shot programmes based on other, perhaps less systematically developed theoretical and empirical foundations, it may be worthwhile to implement this model in other settings, to be subjected to process and outcome evaluation at multiple stages. Understanding why the Okanagan Diabetes Project was not successful is a step towards developing and achieving more effective solutions to the growing problem of diabetes in Aboriginal populations. Commensurately strong efforts are required to deal with the problem. Systematic and thorough evaluation research is needed to understand not only whether a project was effective, but how and why it was effective or

ineffective, how it can be improved upon, and how it might need to be adapted for specific sub-populations.

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APPENDIX A

Calculations of Sample Size and Statistical Power

APPENDIX A

Calculations of Sample Size and Statistical Power

I. Cohort Surveys Involving Continuous Variables

Sample size estimates were undertaken by adapting classic experimental procedures for the calculation of statistical power. For continuous measures and cohort sample sizes, for two sample means, statistical power is given by (Hassard, 1991):

$$\text{Power Index (PI)} = z_{\alpha} + z_{\beta} = \left(\frac{\sqrt{n}}{\sqrt{2}} \right) \left(\frac{\mu_1 - \mu_2}{\sigma} \right), \text{ and } n = 2 \left\{ \text{PI} \left(\frac{\sigma}{\mu_1 - \mu_2} \right) \right\}^2$$

where n is the number of subjects required for each of two groups whose means (μ) are being contrasted and σ is the true or population standard deviation of the response being measured.

Given the absence of NIDDM intervention studies involving Aboriginal Canadians, it was difficult to estimate the parameters necessary to calculate the sample sizes required to find the true treatment effect for the various outcomes to be studied. Methods exist to calculate sample size and power from estimated relative treatment effects and estimates of community-level variance and the over-time variance of estimated community parameters (Koopsell *et al.*, 1991). Appropriate estimates of these parameters are rarely available, however, for behavioural and lifestyle variables. The lack of NIDDM intervention data on indigenous peoples in other parts of the world and the likelihood that other peoples are not directly comparable — genetically or environmentally — with Aboriginal Canadians increases the difficulty of parameter estimation.

Educational lifestyle intervention programmes typically have moderate effects (Brown, 1990; Brown, 1992). In lieu of knowing the true treatment effect ($\sigma/(\mu_1 - \mu_2)$), Cohen (1977) defines a moderate effect as that in which the difference is half the standard deviation; $\sigma/(\mu_1 - \mu_2)$ is therefore given by 1/0.50. These calculations, however, make two crucial assumptions: (a) no clustering of individuals from community to community or from survey to survey; and (b) no community-by-survey component of variation. As such clustering will occur for many variables in community-based studies, Salonen *et al.* (1986) suggest increasing σ by a factor of $\sqrt{2}$. Sample size was calculated based on the conventions of Cohen (1977) and Salonen (1986), defining a moderate effect as ($\sqrt{2} / [0.50]$).

Defining levels of α and β

The allowable risk of Type I error was set at 5%; thus, $\alpha = 0.05$. The allowable risk of Type II error was set at 5% for preliminary calculations, where $\beta = 0.05$ and power = 0.95. Given at least a moderate treatment effect, these specifications provide a low risk of Type I and Type II errors.

Preliminary calculations of the optimal number of individuals for each of the two conditions

$\alpha = 0.05$, $z_{\alpha} = 1.64$ (one-tailed, given uni-directional risk factor hypotheses); $\beta = 0.05$, $z_{\beta} = 1.64$

$$n = 2 \left\{ (1.64 + 1.64) \left(\frac{\sqrt{2}}{0.50} \right) \right\}^2 = 2(86.1) = 172$$

A minimum of 172 subjects per condition (344 overall) were optimally required based on an estimated moderate treatment effect, and Type I and Type II error risks of 0.05 each. These figures were discordant with the number of individuals estimated at the outset of the project to

have or be at familial risk for diabetes (approximately 90, or 180 overall) in the two communities initially involved. Statistical power was therefore calculated for 90 persons per condition:

$$z_{\beta} = \left(\frac{\sqrt{n}}{\sqrt{2}} \right) \left(\frac{(\mu_1 - \mu_2)}{\sqrt{2}} \right) - z_{\alpha} = \left(\frac{\sqrt{90}}{\sqrt{2}} \right) \left(\frac{(0.50)}{\sqrt{2}} \right) - 1.64 = 2.37 - 1.64 = 0.73$$

$$\beta = 0.23 \text{ and power} = 0.77.$$

Power of 0.77 is less than optimal but greater than that for many community-based studies, which are often less than 0.50 (Koepsell *et al.*, 1991).

II. Separate Samples (Cross-Sectional) Surveys Involving Prevalence Measures

For prevalence measures and the separate samples design for cross-sectional community-level surveys, the estimated size of the samples required was calculated by adapting classical procedures. For two proportions (Hassard, 1991):

$$N = 2(P1)^2 \frac{p_o (1 - p_o)}{(p_1 - p_2)^2}$$

where p_1 and p_2 are two proportions being compared, p_o is the average of p_1 and p_2 , and p_o defines directly the variance, $p_o (1 - p_o)$.

As with calculations for continuous variables, it was difficult to estimate parameters, but a reasonable estimate of the proportion of persons who are motivated to engage in regular, low-level physical activity (e.g., walking) would appear to be approximately 40% (Jacobs *et al.*, 1986; Stephens *et al.*, 1985). Because physical activity is both a preventive and treatment factor for obesity, and because the strength of the evidence supporting a relationship between physical inactivity and diabetes is stronger for Aboriginal populations than the evidence for dietary behaviours, the sample size needed to detect change in the prevalence of behaviours across the two conditions was based on increasing the prevalence of physical activity from 40% to 80%. To account for additional variance due to clustering within communities (Donner, 1982), the variance of the estimate was multiplied by a factor of 2 in a manner analogous to increasing σ by a factor of $\sqrt{2}$ (Salonen *et al.*, 1986).

Defining levels of α and β

The risk of Type I error was set at 5%; thus, $\alpha = 0.05$. The risk of Type II error was set at 5%; thus $\beta = 0.05$ and power = 0.95. These specifications provide a low risk of Type I and Type II errors.

Calculating the optimal number of subjects for separate samples

$\alpha = 0.05$, $z_{\alpha} = 1.64$ (one-tailed, given uni-directional risk factor hypotheses); $\beta = 0.05$, $z_{\beta} = 1.64$; $p_1 = 0.40$, $p_2 = 0.80$, and $p_o = (p_1 + p_2)/2 = (0.40 + 0.80)/2 = 0.60$; and the variance, $p_o (1 - p_o)$, is doubled to account for clustering.

$$N = 2(P1)^2 \frac{2 \{p_o (1 - p_o)\}}{(p_1 - p_2)^2} = 2(1.64 + 1.64)^2 \frac{2 \{0.60 (1 - 0.60)\}}{(0.40 - 0.80)^2} = 64.6 = 65$$

A minimum of 65 subjects per separate sample were required based Type I and Type II error risks of 0.05 each, accounting for community clustering.

APPENDIX B

Demographic Questionnaire

- (h) chronic bronchitis or emphysema? Yes / No
- (i) sinusitis? Yes / No
- (j) diabetes? Yes / No
- (k) epilepsy? Yes / No
- (l) heart disease? Yes / No
- (m) cancer? Yes / No
- (n) stomach or intestinal ulcers? Yes / No
- (o) effects of stroke? Yes / No
- (p) urinary incontinence? Yes / No
- (q) acne requiring prescription medication? Yes / No
- (r) Alzheimer's disease or other dementia? Yes / No
- (s) cataracts? Yes / No
- (t) glaucoma? Yes / No
- (u) any other long term condition? Yes / No

If you answered Yes to (u), please specify:

HLTH-Q4 Are you taking any prescription or non-prescription medication? Yes / No
(circle one)

HLTH-Q5 If you are taking medication, please provide the name of this medication, and indicate the purpose for which you take it: (prescription and non-prescription)

medication: _____ purpose: _____

medication: _____ purpose: _____

medication: _____ purpose: _____

medication: _____ purpose: _____

medication: _____ purpose: _____

medication: _____ purpose: _____

(use back of page if more space needed)

SECTION III: EDUCATION

EDUC-Q1 Excluding kindergarten, how many years of elementary and high school have you successfully completed? (circle one)

none 1-5 years six seven eight nine ten eleven twelve thirteen

EDUC-Q2 Have you graduated from high school? Yes / No
(circle one)

EDUC-Q3 Have you ever attended any other kind of school such as university, community college, business, trade/vocational school, or other post-secondary institution?
 Yes / No
 (circle one)

EDUC-Q4 What is the highest level of education you have attained? (circle one only)

- | | | | | | | | | |
|---|--|-----------------|---|---|--|--------------------------------|--|----------------------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| some trade, technical, vocational or business college | some community college or nursing school | some university | diploma or certificate from trade, technical, vocational or business school | diploma or certificate from community college or nursing school | bachelor's degree, or teacher's college (BSc, BA, LLB) | Master's degree (MA, MSc, MEd) | degree in medicine, veterinary medicine or optometry (MD, DDS, DMD, DVM) | earned doctorate (PhD, DSc, EdD) |

SECTION IV: INCOME

INC-Q1 For your household, please indicate whether you are the primary wage-earner, whether your partner or spouse is the primary wage-earner, or whether the earnings of you and your partner or spouse are approximately equivalent.

(place an "X" in the most appropriate box)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
you are the primary wage-earner	partner/spouse is primary wage-earner	equivalent earnings between you and your partner/spouse

INC-Q2 Please indicate how your income affects the type of food you buy and eat. Do you feel that you have enough money to buy nutritious foods?
 Yes / No
 (circle one)

INC-Q3 Please indicate how your income affects your opportunities to engage in leisure-time physical activity and other forms of recreation. Do you feel that you have enough money to engage in leisure-time physical activity?
 Yes / No
 (circle one)

INC-Q4 Please indicate the number of persons residing in your household, according to their age:

number of infants up to 5 years old.....	_____
number of children aged 6 to 12 years.....	_____
number of teenagers aged 13–18.....	_____
number of adults aged 19–65.....	_____
number of adults aged 66 and older	_____

You have come to the end of the questionnaire! Thank-you for taking the time to complete it. We repeat that your answers are entirely confidential. Please place the questionnaire in the envelope provided, seal it, and return it to one of the research team members.

APPENDIX C

Anthropometric Proforma

APPENDIX C

Anthropometric Proforma

Okanagan Diabetes Project

Name _____ M/F ID# _____
(last) (first & initial) (circle one)

Birth Date ____/____/____ Measurement Date ____/____/____
month / day / year month / day / year

Measured by _____ Smoker / Nonsmoker
(circle one)

Body Size:

height [stature] (cm) | ____ . ____ . ____ . || ____ . ____ .
weight (kg)..... | ____ . ____ . ____ . || ____ . ____ .

Skinfolds (mm):

biceps..... | ____ . ____ . ____ . || ____ . ____ .
triceps..... | ____ . ____ . ____ . || ____ . ____ .
subscapular..... | ____ . ____ . ____ . || ____ . ____ .
iliac crest..... | ____ . ____ . ____ . || ____ . ____ .
medial calf..... | ____ . ____ . ____ . || ____ . ____ .

Girths (cm):

waist..... | ____ . ____ . ____ . || ____ . ____ .
gluteal..... | ____ . ____ . ____ . || ____ . ____ .
mid thigh | ____ . ____ . ____ . || ____ . ____ .

Blood Pressure (mmHg):

Check #1..... _____
Check #2..... _____

APPENDIX D

Lifestyle Questionnaire

SWAC-Q1 (d) What is the average length of time that you spend doing the activity (or activities) that make you sweat?

(average length of time per session; e.g., if walking, then average time per walk)

SECTION II: LEISURE-TIME PHYSICAL ACTIVITY

The questions in this section ask about leisure-time physical activity. This may or may not make you sweat. We are interested in the time you spend on leisure-time activity and in what you do.

LTPA-Q1 Instructions:

- (a) Please read over the following list of typical leisure-time activities. If we have missed any activities you do for recreation or leisure, please write them down at the bottom of the list.
- (b) In the appropriate box, answer *Yes* or *No* for any activities you did over *the last month*.
- (c) For each activity to which you answered *Yes*:
 - (i) Indicate the number of times you did it *over the last month*, and
 - (ii) Indicate the *average* length of time you spent doing it each time (please indicate hours and minutes)

Leisure-time activities	Engaged in? Yes or No	Number of times per last month	Average length of time per session
Hiking through mountains			
Walking for exercise			
Gardening or yard-work			
Hunting			
Fishing			
Horseback riding			
Rodeo			
Softball/baseball			
Football/soccer			
Skating (roller or ice)			
Volleyball			
Basketball			
Bowling			
Bicycling			
Running/jogging			
Swimming			
Racquetball/handball			
Weight-lifting			
Dancing			
Calisthenics			

SECTION IV: SMOKING

The questions in this section ask about cigarette smoking.

SMOK-Q1 Do you currently smoke cigarettes daily, occasionally, or not at all?

(place an "X" in the most appropriate box)

daily

occasionally

not at all

If you answered "not at all" please go to SMOK-4

SMOK-Q2 At what age did you begin to smoke cigarettes? years old

SMOK-Q3 How many cigarettes do you currently smoke daily? cigarettes/day
(now go to next section)

SMOK-Q4 Have you ever smoked cigarettes? Yes / No
(circle one)

If you answered "No" please go to the next section
If you answered "Yes" please answer the next question

SMOK-Q5 How long has it been since you quit smoking cigarettes? .. years

SECTION V: ALCOHOL CONSUMPTION

The questions in this section ask about alcohol consumption. As used here, the word *drink* means any of the following: one bottle or can of beer or wine cooler; one glass of draft; or one straight or mixed drink with 1.5 ounces of hard liquor.

ALCO-Q1 Do you drink alcohol? Yes / No
(circle one)

If you answered "No" please go to the next section
If you answered "Yes" please answer the following questions

ALCO-Q2 Over the last four weeks, what is the average number of drinks you have had per week? drinks per week

ALCO-Q3 Over the last four weeks, what is the average number of drinks you have had per occasion? (e.g., over the course of an evening) drinks per occasion

ALCO-Q4 Over the last four weeks, what is the greatest number of drinks you have had on one occasion? drinks

You have come to the end of the questionnaire! Thank-you for taking the time to complete it. We repeat that your answers are entirely confidential. Please place the questionnaire in the envelope provided, seal it, and return it to one of the research team members.

APPENDIX E

Social Environment Questionnaire

SEST-13 All in all, I feel good about myself.

strongly agree agree disagree strongly disagree

SEST-14 On the whole, I am satisfied with myself.

strongly agree agree disagree strongly disagree

SEST-15 I wish I could have more respect for myself.

strongly agree agree disagree strongly disagree

SEST-16 (a) I certainly feel useless at times.

strongly agree agree disagree strongly disagree

SEST-16 (b) At times I think I am no good at all.

strongly agree agree disagree strongly disagree

SECTION II: MASTERY

Please indicate, by placing an "X" in the box that most accurately represents your feelings, how strongly you agree or disagree with the following statements: (make only one "X" per statement)

MAST-Q1 There is really no way I can solve some of the problems I have.

strongly agree agree neutral disagree strongly disagree

MAST-Q2 Sometimes I feel that I'm being pushed around in life.

strongly agree agree neutral disagree strongly disagree

MAST-Q3 I have little control over the things that happen to me.

strongly agree agree neutral disagree strongly disagree

MAST-Q4 I can do just about anything I really set my mind to.

strongly agree agree neutral disagree strongly disagree

MAST-Q5 I often feel helpless in dealing with the problems of life.

strongly agree agree neutral disagree strongly disagree

MAST-Q6 What happens to me in the future mostly depends on me.

strongly agree agree neutral disagree strongly disagree

MAST-Q7 There is little I can do to change many of the important things in my life.

strongly agree agree neutral disagree strongly disagree

SECTION III: DEPRESSION

Please circle the number representing the best answer to each of the following questions.

BSD-Q1 During the last two days, how many times have you experienced thoughts of hopelessness, helplessness, intense worry, unhappiness, and so on?

1 not at all 2 rarely 3 frequently 4 most of the time 5 all of the time

BSD-Q2 Over the last two days, how relaxed have you been compared to how you normally feel? (circle any number between 1 and 10)

1 physically calm and relaxed 2 3 4 5 6 7 8 9 10 tense; wringing hands, trembling

BSD-Q3 During the last week, have you had difficulty starting and finishing ordinary tasks and jobs compared to when things really go well for you? (circle any number between 1 and 10)

1 no problem starting and finishing jobs 2 3 4 5 6 7 8 9 10 put things off; start but do not follow through

BSD-Q4 How satisfied are you with your ability to perform usual household duties such as shopping, meals, home repair, cleaning up, child care and so on? (circle any number between 1 and 10)

1 very satisfied 2 3 4 5 6 7 8 9 10 very dissatisfied

SECTION IV: AFFECT BALANCE

During the past few weeks, did you ever feel: (circle Yes or No)

ABS-Q1 Particularly excited or interested in something? Yes / No

ABS-Q2 So restless that you couldn't sit long in a chair? Yes / No

ABS-Q3 Proud because someone complimented you on something you had done? Yes / No

- ABS-Q4 Very lonely or remote from other people? Yes / No
- ABS-Q5 Pleased about having accomplished something? Yes / No
- ABS-Q6 Bored? Yes / No
- ABS-Q7 On top of the world? Yes / No
- ABS-Q8 Depressed or very unhappy? Yes / No
- ABS-Q9 That things were going your way? Yes / No
- ABS-Q10 Upset because someone criticized you? Yes / No

SECTION V: SOCIAL SUPPORT

Please answer the following questions as honestly as you can.

SOCS-Q1 (a) Are you married or do live with a partner in a long-term relationship? Yes / No
(circle one)

SOCS-Q1 (b) If you answered *No* to part (a) above, please proceed to the next question. If you answered *Yes* to part (a) above, please indicate whether you agree or disagree with the following statement:

My spouse (or partner) is someone who I can really talk with about things that are important to me.

..... Agree / Disagree
(circle one)

SOCS-Q2 Among your friends and relatives, *excluding* your partner if you're married or in a long-term relationship, please indicate the number of people you feel you can tell just about anything to, people you can count on for understanding and advice?

(place an "X" in the most appropriate box. Do not include spouse or partner in long-term relationship)

none at all

one person

two or more people

You have come to the end of the questionnaire! Thank-you for taking the time to complete it. We repeat that your answers are entirely confidential. Please place the questionnaire in the envelope provided, seal it, and return it to one of the research team members.

APPENDIX F

Diabetes Quality-of-Life Questionnaire

APPENDIX F

OKANAGAN DIABETES PROJECT — QUALITY-OF-LIFE QUESTIONNAIRE

This survey asks how you feel about having diabetes or impaired glucose tolerance (IGT), and about satisfaction with your treatment and management of diabetes/IGT. Because the focus is on the *quality* of your life, some of the questions are quite personal. We are committed to maintaining the confidentiality of your responses. No one will ever know your name. No one will ever learn what your responses were, unless you tell them yourself. Please answer these questions to the best of your ability — the only “right” answers are those that reflect the way you feel.

If any of the following questions are unclear or if you need any help, please ask one of the research team members.

DEMO-Q1 Participant Code Number _____

DEMO-Q2 How long has it been since you were diagnosed with diabetes or IGT? _____

Persons with diabetes should answer Q-3 and Q4, then proceed to Section I below. Persons with IGT should skip Q-3 and Q-4, and proceed directly to Section I below.

DEMO-Q3 If you have diabetes, do you use insulin for control? yes / no
(circle one)

DEMO-Q4 If you have diabetes, do you take oral (hypoglycemic) pills for control? yes / no
(circle one)

SECTION I: IMPACT OF DIABETES

Please circle the number representing the best answer to each of the following questions.

IMPAC-Q1 How often do you feel pain in relation to treatment of your diabetes/IGT?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

IMPAC-Q2 How often are you embarrassed by having to deal with your diabetes/IGT in public?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

IMPAC-Q3 How often do you have low blood sugar?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

IMPAC-Q4 How often do you feel physically ill?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

IMPAC-Q5	How often does your diabetes/IGT interfere with your family life?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q6	How often do you have a bad night's sleep?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q7	How often do you find your diabetes/IGT limiting your social relationships?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q8	How often do you feel good about yourself?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q9	How often do you feel restricted by your diet?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q10	How often does your diabetes/IGT interfere with your sex life?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q11	How often does your diabetes/IGT keep you from driving a car or using a machine?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q12	How often does your diabetes/IGT interfere with your exercising?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q13	How often do you miss school, work, or other duties because of diabetes/IGT?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q14	How often do you find yourself explaining what it means to have diabetes/IGT?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	
IMPAC-Q15	How often do you find that diabetes/IGT interrupts your leisure-time activities?				
1	2	3	4	5	
never	very seldom	sometimes	often	all of the time	

- IMPAC-Q16** How often do you tell others about your diabetes/IGT?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- IMPAC-Q17** How often are you teased because you have diabetes/IGT?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- IMPAC-Q18** How often do you feel that because of your diabetes/IGT you go to the bathroom more than others?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- IMPAC-Q19** How often do you find that you eat something you shouldn't, rather than tell someone you have diabetes/IGT?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- IMPAC-Q20** How often do you hide from others the fact that you are having an insulin reaction?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |

SECTION II: WORRY — SOCIAL/VOCATIONAL

Please circle the number representing the best answer to each of the following questions.

- WRSV-Q1** How often do you worry about whether you will get married?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- WRSV-Q2** How often do you worry about whether you will have children?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- WRSV-Q3** How often do you worry about whether you will not get a job you want?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- WRSV-Q4** How often do you worry about whether you will be denied insurance?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |
- WRSV-Q5** How often do you worry about whether you will be able to obtain an education?
- | | | | | |
|-------|-------------|-----------|-------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| never | very seldom | sometimes | often | all of the time |

WRSV-Q6 How often do you worry about whether you will not be able to do your usual work?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

WRSV-Q7 How often do you worry about whether you are able to take a vacation or a trip?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

SECTION III: WORRY — DIABETES RELATED

Please circle the number representing the best answer to each of the following questions.

WRDR-Q1 How often do you worry about whether you will pass out because of diabetes/IGT?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

WRDR-Q2 How often do you worry that your body looks different because of diabetes/IGT?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

WRDR-Q3 How often do you worry that you will get complications from your diabetes/IGT?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

WRDR-Q4 How often do you worry that friends, relatives or new people in your life will (or do) treat you differently because you have diabetes/IGT?

1	2	3	4	5
never	very seldom	sometimes	often	all of the time

SECTION IV: SATISFACTION

Please circle the number representing the best answer to each of the following questions.

SATI-Q1 How satisfied are you with the time it takes to manage your diabetes/IGT?

1	2	3	4	5
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied

SATI-Q2 How satisfied are you with the amount of time you spend getting check-ups?

1	2	3	4	5
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied

SATI-Q3 How satisfied are you with the time it takes to determine your blood sugar level?

1	2	3	4	5
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied

SATI-Q4 How satisfied are you with your current treatment for diabetes/IGT?

1	2	3	4	5
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied

SATI-Q5	How satisfied are you with the flexibility you have in your diet for diabetes/IGT?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q6	How satisfied are you with the burden diabetes/IGT is placing on your family?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q7	How satisfied are you with your knowledge about diabetes/IGT?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q8	How satisfied are you with your sleep, as influenced by diabetes/IGT?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q9	How satisfied are you with your social relationships and friendships?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q10	How satisfied are you with your sex life, as influenced by diabetes/IGT?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q11	How satisfied are you with your work, school and household activities?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q12	How satisfied are you with the appearance of your body?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q13	How satisfied are you with the time you spend exercising?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q14	How satisfied are you with your leisure time?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	
SATI-Q15	How satisfied are you with your life in general?				
1	2	3	4	5	
very satisfied	somewhat satisfied	neutral	somewhat dissatisfied	very dissatisfied	

You have come to the end of the questionnaire! Thank-you for taking the time to complete it. We repeat that your answers are entirely confidential. Please place the questionnaire in the envelope provided, seal it, and turn it in to one of the research team members.

APPENDIX G

Diabetes Health Beliefs and Knowledge Questionnaire

APPENDIX G

Diabetes Health Beliefs and Knowledge Questionnaire

OKANAGAN DIABETES PROJECT — HEALTH BELIEFS AND KNOWLEDGE

This survey asks what you know and what you believe about having diabetes or impaired glucose tolerance (IGT). Please answer these questions to the best of your ability — the only “right” answers are those that reflect the way you feel. The confidentiality of your responses is assured. No one will ever know your name. No one will ever learn what your responses were, unless you tell them yourself.

If any of the following questions are unclear or if you need any help, please ask one of the research team members.

.....
DEMO-Q1 Participant Code Number _____

DEMO-Q2 How long has it been since you were diagnosed with diabetes or IGT? _____

Persons with diabetes should answer Q-3 and Q4, then proceed to Section 1 below. Persons with IGT should skip Q-3 and Q-4, and proceed directly to Section 1 below.

DEMO-Q3 If you have diabetes, do you use insulin for control?yes / no
(circle one)

DEMO-Q4 If you have diabetes, do you take oral (hypoglycemic) pills for control? yes / no
(circle one)

.....
SECTION I: SUSCEPTIBILITY TO DIABETES

Please circle the number representing the way you feel about each of the following statements.

SUSC-Q1 My diabetes/IGT is well-controlled.

1 2 3 4 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

SUSC-Q2 My diabetes/IGT would be worse if I did nothing about it.

1 2 3 4 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

SUSC-Q3 I believe that my diet, exercise and medications will prevent diabetes complications, or the progression of IGT to diabetes.

1 2 3 4 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

SUSC-Q4 Diabetes/IGT can be a serious disease if you don't control it.

1 2 3 4 5
Strongly Agree Agree Undecided Disagree Strongly Disagree

SECTION II: SEVERITY OF DIABETES

Please circle the number representing the way you feel about each of the following statements.

SEV-Q1 My diabetes/IGT is no problem to me as long as I feel all right.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SEV-Q2 My diabetes/IGT will have a bad effect on my future health.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SEV-Q3 My diabetes/IGT will cause me to be sick a lot.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SEV-Q4 I believe I will always need my diabetes/IGT diet, exercise and medications.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SECTION III: BENEFITS

Please circle the number representing the way you feel about each of the following statements.

BEN-Q1 I believe I can control my diabetes/IGT.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BEN-Q2 I believe that my diet, exercise and medications will control my diabetes/IGT.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BEN-Q3 If I change my eating and exercise habits it will probably help me.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BEN-Q4 My diabetes/IGT medication makes me feel better. *(Please choose "undecided" if you do not take medication).*

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SECTION IV: BARRIERS

Please circle the number representing the way you feel about each of the following statements.

BAR-Q1 I would have to change too many habits to follow my prescribed diet, exercise and medication regime.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BAR-Q2 It has been difficult following the diet prescribed for me.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BAR-Q3 I cannot understand what I've been told about my diet.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

BAR-Q4 Taking my medication and/or exercising interferes with my normal daily activities.

1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

SECTION V: KNOWLEDGE OF DIABETES

Please circle either "Y" (yes) or "N" (no), in response to each of the following questions.

KNOW-Q1	Does eating too much fat contribute to diabetes?	<i>risk factor</i>	Y / N
KNOW-Q2	Does not enough physical activity contribute to diabetes?	<i>risk factor</i>	Y / N
KNOW-Q3	Does being overweight contribute to diabetes?	<i>risk factor</i>	Y / N
KNOW-Q4	Are excessive thirst and hunger signs of diabetes?	<i>symptom</i>	Y / N
KNOW-Q5	Is frequent urination a sign of diabetes?	<i>symptom</i>	Y / N
KNOW-Q6	Is weight loss a sign of diabetes?	<i>symptom</i>	Y / N
KNOW-Q7	Is blurred vision a sign of diabetes?	<i>symptom</i>	Y / N
KNOW-Q8	Are recurring or slow-to-heal infections a sign of diabetes?	<i>symptom</i>	Y / N
KNOW-Q9	Can diabetes result in damage to nerves?	<i>complication</i>	Y / N
KNOW-Q10	Can diabetes result in cardiovascular disease?	<i>complication</i>	Y / N
KNOW-Q11	Can diabetes result in damage to the eyes?	<i>complication</i>	Y / N
KNOW-Q12	Can diabetes result in damage to the kidneys?	<i>complication</i>	Y / N
KNOW-Q13	Can diabetes cause other diseases or health problems?	<i>complication</i>	Y / N

APPENDIX H

Cross-Sectional Community Survey for Interviews

APPENDIX I

Community Systems Surveys by Analytic Level

APPENDIX I

Community Systems Surveys by Analytic Level

Testing session no.: _____

Date: _____

Section I: Subsystem Level

Appraise prevalence of subsystem indicators in *community groups and organisations*

List and describe . . .

(a) Policies that specifically address . . .

(i) *diabetes*: _____

(ii) *dietary behaviour*: _____

(iii) *physical activity*: _____

(iv) *weight control*: _____

(b) Indicators of group and organisational support for the diabetes project:

(c) Indicators of group and organisational participation in the diabetes project:

(d) Any other indicators of the active involvement of groups and organisations in the diabetes project:

Community Systems Surveys by Analytic Level

Testing session no.: _____

Date: _____

Section II: Inter-Relationships Among Sub-Systems and Supra-Systems

("social connectedness;" the extent to which groups and organisations within the community are involved with each other and with outside groups and groups and organisations; e.g. physician groups, Vernon Jubilee Hospital, Medical Services Branch, town of Vernon, other Native Groups)

List and describe . . .

- (a) Coalitions that have developed, the processes of their development, and their connections to other groups and organisations both internal *and* external to the community:

- (b) Subsystem (i.e., community group and organisational) participation in internal *and* external community boards and task forces related to the diabetes project:

- (c) Subsystem (i.e., community group and organisational) involvement in community-wide *and* external activities related to the diabetes project:

Community Systems Surveys by Analytic Level

Testing session no.: _____

Date: _____

Section III: Whole System (internal and external community) Norms and Values

List and describe . . .

(a) Community (internal) policy on health and health issues related to the diabetes project:

(b) External policy on native health and health issues related to the diabetes project (hospital, Medical Services Branch, physicians, municipal, provincial, federal):

(c) Community enforcement or activism on health issues related to the diabetes project:

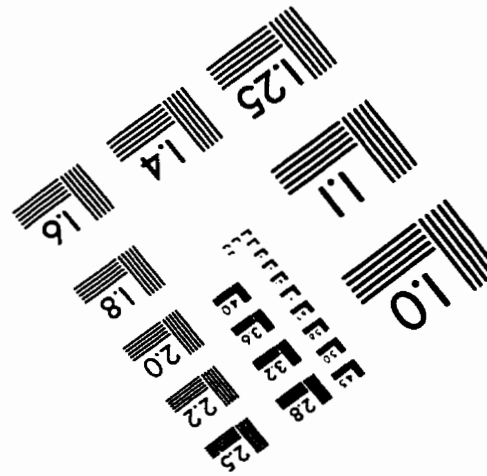
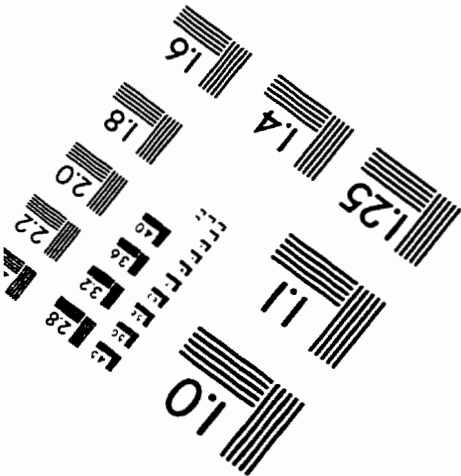
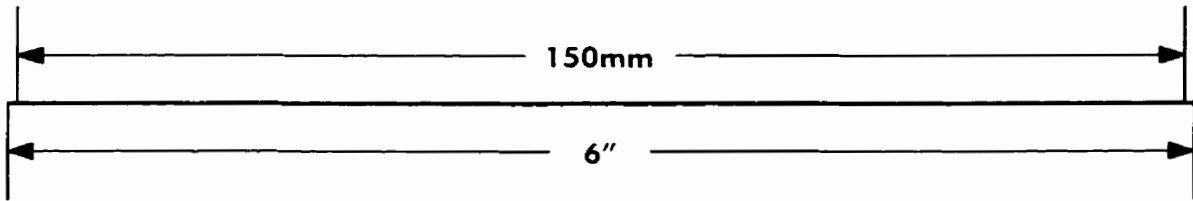
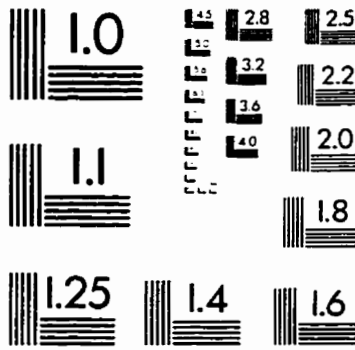
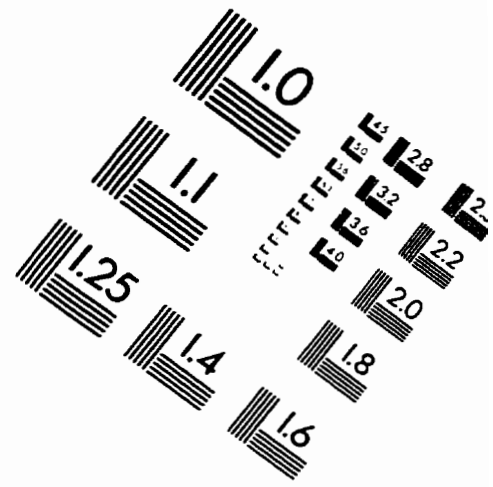
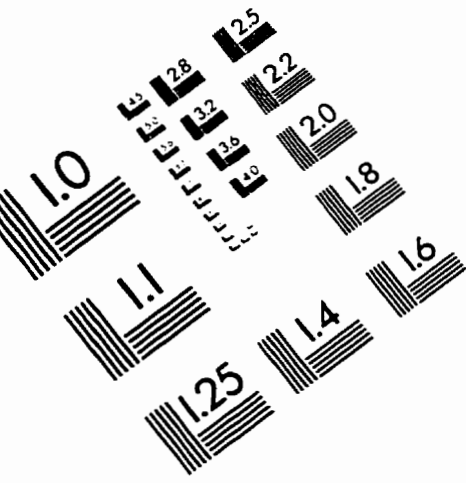
(d) Community perceptions of norms and values related to diabetes and health in general . . .

(i) at the level of the individual: _____

(ii) at the level of community groups and organisations: _____

(iii) outside the community at municipal, provincial and federal levels: _____

IMAGE EVALUATION TEST TARGET (QA-3)



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