GUIDELINES
FOR THE
DEVELOPMENT
OF A
NATIONAL PROGRAMME
FOR
DIABETES MELLITUS

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Foreword

There is no doubt that diabetes mellitus is becoming an increasingly important public health problem in all countries. For this reason, a resolution on prevention and control of diabetes mellitus, adopted by the World Health Assembly in 1989 (WHA 42.36), invited all WHO Member States:

1) to assess the national importance of diabetes;
2) to implement population-based measures, appropriate to the local situation, to prevent and control diabetes;
3) to share with other Member States opportunities for training and further education in the clinical and public health aspects of diabetes;
4) to establish a model for the integrated approach to the prevention and control of diabetes at community level.

According to the 8th General Programme of Work for 1990–1995, the World Health Organization should develop and apply national programmes on diabetes mellitus in selected Member States from all WHO regions. These programmes could cover the whole country or especially for those countries with a decentralized health care system, could be limited to the local level (district, community, etc.).

In order to develop national/local disease prevention and control programmes, the following conditions are necessary:

a) the understanding and support of national/local policy makers, and national and international organizations;
b) resources;
c) multidisciplinary and multisectoral teams responsible for national/local programme development;
d) guidelines for the development of programmes for diabetes mellitus.

Together with its Regional Offices, the International Diabetes Federation and 28 WHO collaborating centres in the field of diabetes, the Division of Noncommunicable Diseases and Health Technology of WHO Headquarters is developing components of diabetes prevention and control programmes – research, education, experimental testing and evaluation. These global guidelines have been prepared by Dr. G. Reiber (University of North Carolina Charlotte, USA), and Dr. H. King (Division of
Noncommunicable Diseases and Health Technology, WHO, Geneva). They will be used for developing regional, national and local programmes in response to the aforementioned resolution.

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The primary aim of these guidelines is to outline steps which may be taken to determine the national importance of diabetes and to assist health officials, health planners, health service administrators and diabetes professionals develop diabetes policies and programmes. Though this document emphasizes national diabetes programme development, the principles and strategies outlined can be applied similarly in provincial and local settings. Also, the general principles described may be applied to health programme development for other diseases. These guidelines may be too complex for some circumstances whilst too simple for others. Therefore, this document should serve only as a guide to planning and evaluating diabetes programmes, from which individual planners can abstract material relevant to their unique health situation and cultural, political, and economic environment.

Each section concludes with a synopsis of the content. The reader may find it helpful to work through these summaries first, in order to become familiar with the general planning concepts, before attempting detailed study of the main text. Terms are defined in the glossary and a programme outline is provided in conclusion. Regardless of the extent of a national, provincial or local diabetes problem, a careful review of the status of diabetes in the current health plan may permit diabetes to be accorded appropriate emphasis and resource allocation.

A further edition of the guidelines may appear at a later date. The authors invite comments and suggestions from readers whose experience developing programmes for diabetes mellitus may benefit others.

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1. Introduction

Diabetes mellitus is a cause for growing public health concern in both developed and developing countries. In many countries, it is now a leading cause of death, disability and high health care cost. The World Health Organization (WHO) estimates that diabetes affects millions of people worldwide. However, for many of these people efficacious diabetes care is not available. In 1989, recognizing diabetes as an increasing international public health problem, the 42nd World Health Assembly unanimously adopted a resolution calling on all Member States to assess the national importance of diabetes, implement population-based measures for prevention and control, and share with other nations opportunities for training and education (Annex 1). Developing nations, comprising the majority of the world's population, may find responding to this resolution particularly challenging since many are now facing the "double burden" of both infectious and chronic, noncommunicable diseases.

Diabetes mellitus is a complex, heterogeneous metabolic disease characterized by high blood glucose concentrations. It is associated with impaired insulin production and/or action, resulting in the body's inability to utilize nutrients properly. Various genetic and environmental/lifestyle factors influence diabetes etiology and prognosis. Important differences in the frequency of diabetes and its complications have been reported between countries, ethnic and cultural groups.

The major clinical classes of glucose intolerance include insulin-dependent diabetes mellitus (IDDM or Type 1), noninsulin-dependent diabetes mellitus (NIDDM or Type 2), malnutrition-related diabetes mellitus (MRDM), impaired glucose tolerance (IGT), and gestational diabetes (GDM). Terms and definitions used to describe and diagnose diabetes were unified and adopted in 1979–1980, updated in 1985 (Annex 2) and are reflected in the forthcoming Tenth Revision of the International Statistical Classification of Diseases and Related Problems (Annex 3). The standardization of the glucose tolerance test for the diagnosis of diabetes continues to be debated, though agreement has been reached on most aspects.

NIDDM, the most common form of diabetes, increases in prevalence from the third decade of life. By the seventh decade, the age-specific prevalence is usually three to four times higher than the overall prevalence in adults. Undiagnosed diabetes, almost exclusively NIDDM, has been reported in nearly equal proportions to diagnosed diabetes in many societies. In developing countries, undiagnosed cases may considerably outnumber diagnosed cases.
Prevalence of NIDDM is estimated at 2–5% of adult European and North American communities. In developing countries, NIDDM is rare in the traditional setting, but has become very common, exceeding 1% in adults, in many urbanized communities. It is thought that several ethnic groups, including Asian Indians, indigenous North Americans and Pacific Islanders have a greater genetic predisposition to NIDDM than do Caucasians. In the absence of effective interventions, the prevalence of NIDDM in all populations is likely to rise, due to aging, a fall in infectious disease mortality and increases in the prevalence of putative risk factors such as obesity, lack of regular physical exercise and inappropriate diet. To date, research has failed to demonstrate an association between NIDDM and specific genetic markers even though it is a highly familial disease.8,9

Prevalence of IDDM is approximately one-tenth that of NIDDM in Western communities. Clinical onset is most common during childhood, with the peak incidence generally corresponding with puberty. However, onset of IDDM is not confined to childhood and it now appears there may be secondary peaks in incidence in both early and late adulthood. The highest incidence of IDDM is reported from Northern Europe while very low rates are reported in developing countries. Most epidemiological studies of IDDM show higher incidence in autumn and winter. In Europe, an increasing gradient in IDDM incidence has been reported from south to north10 but this remains to be confirmed. Increases in incidence have been reported in several European populations over the past two decades, but such trends have not been observed in North America. A worldwide network of registries of childhood diabetes, the WHO DIAMOND (DIAbetes MONDiale) Project is rapidly improving knowledge of the epidemiology of this disease.11

Susceptibility to IDDM has been shown to be strongly associated with certain genetic markers. The factor(s) triggering the disease in susceptible subjects remain unknown, but viral infections and toxins are likely candidates. Although less common than NIDDM, IDDM is also of considerable public health importance because of its generally longer course, and high morbidity and mortality.

A third form of diabetes, malnutrition-related diabetes mellitus (MRDM) has been described in some tropical and developing countries. It is reported to occur in young, underweight individuals and although it generally requires insulin to maintain adequate metabolic control, it is not prone to ketosis. The nature, epidemiology and public health impact of MRDM is not well understood.12

Gestational diabetes, defined as glucose intolerance detected during pregnancy, occurs in approximately 2–5% of pregnancies and is considered the most common medical complication of pregnancy. It is thought to result from the metabolic stress of pregnancy and requires reclassification post-partum. Gestational diabetes imparts a risk of neonatal complications exceeding those observed in nondiabetic women. Women with gestational diabetes are at increased risk of developing subsequent NIDDM and their offspring may be at increased risk for developing obesity.13 The diabetic woman requires monitoring and
regulation throughout the pregnancy if she is to avoid the risk of adverse outcomes.

Diabetes has both acute and chronic complications. They are of variable speed of onset and severity, often adversely affect the individuals’ quality of life and they result in considerable premature disability and death. Acute metabolic complications include diabetic ketoacidosis, hypoglycemia and hyperosmolar coma. The major chronic complications are nephropathy, retinopathy, neuropathy and cardiovascular, cerebrovascular and peripheral vascular diseases.

Direct and indirect health care costs for diabetes are known to be high in many developed and developing countries, though formal evaluation of diabetes health economics is lacking in most settings. In the United Kingdom, an estimated 4–5% of the health care budget was spent on diabetes in 1986–7. The percentage of total diabetes costs attributable to direct health care costs was estimated at 43% in Sweden in 1978, 58% in Great Britain in 1981, and 42% in the United States in 1987. Hospitals among diabetic subjects tend to be longer and require more intensive treatment of associated conditions than those for subjects with normal glucose tolerance. Outpatient diabetes care also consumes a disproportionate share of health care manpower and resources with reports from developed countries indicating up to 8% of the total outpatient visits for those above age 55 are for diabetes. A recent WHO investigation in a Middle Eastern country showed even higher figures for hospitalization and outpatient visits.

The purpose of this document is to outline measures which may be taken to determine the national or local importance of diabetes and to develop appropriate policies and programmes. It is intended to assist multidisciplinary and intersectoral professionals to formulate diabetes programmes at the national and local level. It should serve only as a guide to planning and evaluating diabetes programmes, from which individual planners can abstract material relevant to their country’s unique health situation and cultural, political and economic environment. Regardless of the extent of a nation’s diabetes problem, a careful review of the status of diabetes in the current health plan may permit diabetes to be accorded appropriate emphasis and resource allocation. The ultimate goal of diabetes prevention and control programmes is to improve the health of individuals who suffer from diabetes or are predisposed to it.
Diabetes overview summary

- In 1989 the 42nd World Health Assembly invited Member States:
  - to assess their diabetes problem,
  - to implement population based diabetes control measures, and
  - to share with other nations opportunities for professional
    training and education.

- Major clinical classes of glucose intolerance include insulin-
  dependent diabetes mellitus (IDDM), noninsulin-dependent
  diabetes mellitus (NIDDM), malnutrition-related diabetes
  mellitus (MRDM), impaired glucose tolerance (IGT) and
  gestational diabetes (GDM).

- Diabetes may lead to both acute and chronic complications.

- Diabetes care costs have been estimated as high as 4–5% of a
  national health care budget.

- This guide is intended to provide general guidelines for planning
  which are adaptable for each country's unique situation.

- The ultimate goal of a diabetes prevention and control
  programme is to improve the health of individuals who suffer
  from diabetes or are predisposed to it.
2. General considerations for national programme development

In response to the disparity in health and health care between developed and developing countries, the symbolic goal of the World Health Organization, “Health for all by the year 2000” was articulated in 1978, stating that all peoples of the world should attain a level of health allowing them to lead socially and economically productive lives. The thrust of this declaration was that primary health care is the key to attaining health for all, since it addresses the main health problems in the community by providing promotive, preventive, curative and rehabilitative services. Primary health care also includes education, promotion of food supplies, safe and potable water, maternal and child health care, immunizations, essential drugs and prevention, treatment and control of common and locally endemic diseases. These considerations are compatible with diabetes mellitus prevention and control activities falling largely under the umbrella of the “health for all” strategy and its focus on primary health care.

Although diabetes control activities are being provided to some degree in most countries, objectives and strategies differ considerably, as do the outcomes of these control efforts. Countries will naturally differ in their approach to organizing, administering and financing health care. However, there are certain universal considerations in the provision of patient care and education. The following six assumptions are suggested as the foundation for diabetes programme development at the local, national and global level:

1. Diabetes is a heterogeneous disease requiring detection, prevention, and control measures in individuals and communities which are tailored to local cultural and practical considerations.
2. A substantial part of diabetes care is patient self care. Thus, patients must be educated before being delegated the responsibility for daily management of their condition.
3. Optimal diabetes care by the patient and provider can prevent or delay the development of complications.
4. Properly designed and integrated diabetes care programmes may result in sizable reductions in morbidity, disability, and mortality.
5. Diabetes health care costs may be reduced using a variety of cost-containment strategies.
6. Diabetes control programmes do not work in isolation. Their function is enhanced with intersectoral training/planning and integration of services at all levels in the health care system. Close linkage is encouraged with other chronic disease prevention and treatment programmes.
National health care may incorporate both preventive and curative medicine in a single agency or represent an intermingling of public and private systems with variable coordination between the preventive and curative segments. In many countries, there is need to remove barriers between public health and therapeutic medicine. Patient care should include health promotion, case-finding and treatment.

It appears that several chronic diseases share common risk factors. For example, both diabetes and hypertension are associated with obesity. Therefore, it has been thought useful to develop an integrated approach to the primary prevention of these and other chronic diseases. At the level of the community, the basis for such programmes is risk factor reduction by the modification of voluntary behaviours such as diet, cigarette smoking and habitual physical exercise. At the clinical level, many of these programmes serve the same patients so that integrated community care delivery systems may benefit patients and providers with economies of scale and some common strategies for long-term treatment.

The WHO Integrated Programme for Community Health in Noncommunicable Diseases (INTERHEALTH) is an example of internationally coordinated community interventions aimed at reducing common risk factors to prevent and treat several chronic diseases, including diabetes. This approach is to be recommended to both developing and developed countries, particularly in the area of primary prevention. Guidelines for the development of INTERHEALTH demonstration projects have recently been issued by WHO. WHO is currently exploring the use of intersectoral team training as an aide to diabetes programme development.

However, additional challenges posed by diabetes necessitate some vertical planning and programme development as well as formal linkage with the country’s primary health care system. Specifically, diabetic individuals require considerable knowledge for daily self-care and disease management (e.g., adapting prescribed dietary, therapeutic and lifestyle actions) whilst their health care provider is required to apply complex cognitive and medical management skills, which may also require involvement of multiple professionals for extended periods of time.

**General considerations section summary**

- Diabetes programme development is consistent with the WHO goal of health for all.
- Diabetes may be one of many competing national or local health, social and economic priorities.
- Integrated approaches to reducing risk factors for diabetes and other chronic diseases are recommended.
- Diabetes management and education services require both a vertical programme configuration and horizontal linkage with or within the country’s primary health care system.
3. Goals for national diabetes programmes

3.1 As far as possible, to prevent the development of diabetes in susceptible individuals and communities.

3.2 To maintain the health and quality of life of individuals with diabetes through effective patient care and education.

3.3 To provide diabetes education to health care professionals.

3.4 To prevent diabetes complications and thereby decrease morbidity, mortality and cost of diabetes.

3.5 To support research to prevent and control diabetes mellitus.
4. Preparing a medium and long-term programme for diabetes mellitus

The purpose of the medium and long-term programmes is to guide organizational activities within the framework of the WHO resolution on diabetes. It is convenient to set medium and long-term objectives, for example, for periods of five and ten years. To begin the diabetes programme planning process, a skilled planner or planning group(s) dedicated to this task is essential. For example, at the national level this group might include full time professional health planners, diabetes professionals, and others cognizant of economic, political and consumer needs. This group may be coordinated conveniently within the Ministry of Health and serve under the direction of the Ministry of Health until the diabetes programme director is employed. Although there may be some overlap between membership on the planning group and diabetes advisory group, the work of the planning group is concentrated, technical and involves gathering and synthesizing data to formulate options for the decision makers. The major priority of the intersectoral advisory group is to advise on programme priorities and directions as described in section 4.2.1.

Temporary placement of planners within the agency administration should maximize their authority and insure cooperation. These planners need access to professional practitioners, fieldworkers, consumers and personnel from academic, nongovernmental and allied agencies. Both central and decentralized participation will contribute to programme development and subsequent acceptance. Access to vital statistics, health care indices, administrative and fiscal data will facilitate realism in planning and budgeting. It is important to recruit a director for the diabetes programme as early as possible in order that he/she may contribute to the planning process.

Activities of the planning group can proceed simultaneously with the formation of a formal diabetes advisory committee described in 4.2.1. At the outset, the approach to planning and the duration of the planning period should be determined. While it is desirable to be as thorough and complete as possible, extending the planning period beyond twelve months is likely to make the effort difficult to sustain and may contribute to bureaucratic stasis. Moreover, it should be recognized that the subsequent interval from completion of the plan to delivery of patient services could require as much as 12–24 months for formal government review, acceptance and phased implementation.
Programme preparation section summary

- A skilled planner or planning group is needed for diabetes programme development.
- A programme director should be recruited early in the planning process.
- The duration of the planning period, stated at the outset, should not exceed one year.

4.1 Situational analysis

The information gathering and assessment phase or situational analysis involves determining the current status of the following nine areas as a basis for setting objectives and defining programme methods:

4.1.1. Demographic data on the national, provincial and/or local population and the epidemiology of the major health problems
4.1.2. Epidemiological data on diabetes
4.1.3. Diabetes education facilities and services for patients and the general public
4.1.4. Health care delivery programmes, facilities, personnel and allied agencies
4.1.5. Availability of insulin, oral agents, supplies and patient equipment for diabetes management
4.1.6. Current diabetes policies
4.1.7. Diabetes-related fiscal resources and health care costs
4.1.8. Agreement on the minimal acceptable guidelines/standards for delivery of diabetes health care
4.1.9. Comparison of diabetes state-of-the-art practices and resources with estimates for future needs and resources based on minimum acceptable standards.

Assessments described in sections 4.1.1 to 4.1.8 can occur concurrently. The specific types of data and information necessary for strategic planning and likely data sources are described in the following sections.

4.1.1 Demographic data on the national, provincial and/or local population and the epidemiology of the major health problems

The initial data collection should focus on describing the population by age, sex, ethnic group(s) and geographic location. This can be augmented with other variables such as education, income or occupation if they are available from a recent national census. Summary data on health problems are needed in order to compare the diabetes situation with other health problems and establish priorities for resource distribution.

*Sources of information that may be available are census data, the national, provincial or local office for health statistics, hospital admission/discharge and outpatient data, health care planning documents, registries and surveys.*
Demographic data section summary

- Data on the population, the health status and rates of specific diseases within the country are needed for comparisons and priority setting.

4.1.2 Epidemiological data on diabetes

The lack of extensive epidemiological data need not paralyze programme planning efforts. Planners should make maximal use of available data and document additional requirements together with proposed strategies for data collection and utilization for a more complete problem description (4.2.4).

Frequency:

The prevalence and distribution of diabetes should be described by age, sex, ethnic group(s) and geographic location. Diabetes registries, available only in select countries or communities, may catalog incident cases of diabetes (Annex 3). Should data on the prevalence and distribution of risk factors associated with development of diabetes be available, inclusion is desirable as a basis for preventive action.

Sources of information are national hospital and outpatient data, extant diabetes registries or survey data. If data are not available, hypothetical estimates might be computed by applying rates from similar communities to the national or local population structure. Descriptions of suitable survey methods are available in several recent articles^88–81 and in the WHO monograph Cardiovascular Survey Methods.57

Morbidity and disability:

The planning group should describe the distribution, extent, and impact of diabetes morbidity and disability using commonly accepted definitions. Minimally, this includes diabetic ketoacidosis, major infections, adverse outcomes of pregnancy, blindness, end stage renal disease, lower extremity amputation and cardiovascular events. Data on the prevalence of risk factors which are associated with development of diabetes complications would also be beneficial. Specification of age, sex, ethnic group(s), residence and diabetes type may help target high risk groups.

Potential sources of information include routine hospital admission/discharge and outpatient data, rates of specific complications, surveillance or national registry data, routine data from the national office of health statistics and data from special studies and surveys on admissions and bed occupancy. Surveys or hypothetical estimates may approximate the magnitude of the problem. Ad hoc surveys may yield useful information on admissions, bed occupancy and manpower.
Mortality:

Coding mortality data according to the International Classification of Disease (ICD) system allows within and between country comparisons. The tenth revision of ICD, now adopted by WHO, will be introduced in 1991, with both general and diabetes-specific changes from ICD-9. The section devoted to diabetes is summarized in Annex 4. However, under reporting of diabetes-related death is a serious surveillance problem since coding the immediate cause of death alone may miss the majority of the deaths in individuals with diabetes. In developed countries it is estimated that only 5% of the deaths in individuals with diabetes have the disease recorded on the death certificate. Ideally, trends for all forms of diabetes-related mortality should be projected forward five and ten years to facilitate strategic planning and clarify programme objectives.

Mortality data, when available, are usually maintained by national, regional and local vital statistics registrars. Prehospital mortality may be available from hospital discharge data or medical examination records. In some situations, hospital-based data may be the best available source. Extrapolation to the country's population should be done with caution as mortality data are often unreliable in both developed and developing countries.

Epidemiological data section summary

- Data are needed to describe the extent of the diabetes problem and the population affected.
- Data are needed to describe the extent of diabetes complications and associated disability.
- Data are needed on deaths occurring in individuals with diabetes.

4.1.3 Diabetes education facilities and services for patients and the general public

Guidelines and criteria desirable for patient education programmes have been published, but largely for developed countries. Since patient education is the strategy to equip diabetic individuals with the skills for daily self management, organized programmes with structured goals for operation and patient outcomes are suggested. Optimally, a structured education programme would define patient goals, monitor progress and formally evaluate achievement. Individual patient goals are suggested which consider health status, medical history, diabetes knowledge and skills, support systems, barriers to learning and resources. These goals, however, need to be realistic within the framework of local facilities for ongoing health care. Established inpatient and outpatient education programmes and community awareness programmes may be reported by geographic region.
Sources of information include national, provincial and local planning and programme documents, survey or administrative information and information from nongovernmental organizations.

Diabetes education section summary

- Guidelines for diabetes patient education programmes are available.
- Patient education and individual goals clarify expectations and responsibilities.
- Diabetes patient education programmes should be identified.
- The content of these programmes should be considered relative to identified health needs and priorities.

4.1.4 Health care delivery programmes, facilities, personnel and allied agencies

Programmes:

Background information on existing health care delivery programmes should include:

a) the national, provincial and local diabetes programme structure and its integration in the national health care delivery system;

b) administrative, communication and patient tracking systems;

c) programme components, patients served and documented unmet needs by geographic area;

d) programme capabilities for patient education, diabetes detection, diagnosis and treatment and prior assessments of programme effectiveness;

e) patterns of patient referral and coordination among services and providers;

f) five and ten year diabetes patient projections estimating patient-programme service needs for the country and major geographic areas.

Sources of information include national, provincial and local health plans, diabetes programme plans, service delivery reports, administrative and interview data.

Health care delivery programmes section summary

- Describe the primary health care delivery mechanisms.
- Explain how diabetes control services are coordinated with or within this structure.
- Estimate the population now receiving diabetes detection, diagnosis, treatment and education services and project these service needs forward five and ten years.
- Estimate existing and projected unmet needs assuming no changes in resources.
Facilities:

Current and planned primary (local office, clinic or health department), secondary (general hospitals) or tertiary (specialist hospitals) diabetes care facilities should be identified by type and location. Planners will want to know the scope of services provided by each facility. The location and type of any special diagnostic, treatment and/or laboratory equipment used in diabetes care should be specified, (e.g., laser photocoagulation or renal dialysis equipment). For budgetary purposes, whether facilities are leased or owned is important. Planners also need to address whether existing operations can be made more efficient or whether new facilities or major capital equipment will be required based upon five and ten year patient and service projections.

Sources of information include national, provincial and local planning documents, administrative data and current and future facility plans.

Health care facilities section summary

- Describe the current diabetes treatment facilities.
- Indicate whether these facilities will be adequate given the future projected service needs.
- Identify special equipment available and needed for service delivery.

Personnel:

Many providers are involved in diabetes patient care. In developing countries, primary care may be provided by paramedical staff, lay health workers or traditional healers. In developed countries, diabetes primary care providers are usually trained in general medicine and family practice. Diabetologists and endocrinologists, or internists with special diabetes training, may be required to manage patients with complex disease. Professional diabetes educators are an integral part of quality diabetes care regardless of their professional discipline. However, these educators are in very short supply in many countries. The complete range of specialists important to diabetes care also includes ophthalmologists, optometrists, nephrologists, neurologists, obstetricians, podiatrists, vascular and orthopaedic surgeons, physical and occupational therapists, mental health workers, social workers, and home health personnel. To augment clinical care, diabetes programme administrators, managers and support staff are recommended for efficient operation of programmes and services. These programme managers may perform management tasks, assist in community organization, oversee data collection and work with diabetes centres, units, teams and health workers.

Manpower planning includes identifying all such specialists, as well as other health professionals with special diabetes training, technical, laboratory, research or programme management skills. Data from operational registries or patient monitoring systems may help estimate the
volume of patients served by these professionals. Computing ratios of patients to specific providers for defined geographic areas will highlight inequities. In projecting personnel need and availability, coordination with the nation's primary care system, professional schools, diabetes training and certification programmes (if any) and professional societies is desirable. Anticipated shifts in population, disease patterns, professional relocation or retirement should be noted. Intersectoral personnel are also needed by diabetes programmes, particularly individuals with expertise in public information, law, insurance, economics, communication, information transfer, finance and marketing. Issues of salary, recruitment and retention should be addressed.

A second level of diabetes manpower planning involves specifics of academic preparation, continuing education and training courses for providers. The diabetes portion of professional education programmes should be reviewed for current content and relevance to the national diabetes focus.

Sources of information include national, provincial and local planning documents; licensing and certifying agencies; membership of professional associations; administrative data on health care personnel; enrolments, projections and course syllabi from professional schools.

Personnel section summary

- Describe the current distribution of diabetes health care providers by discipline, specialty and geographic location.
- Given the patient projections (e.g., 5 and 10 years) describe anticipated personnel needs.
- Suggest mechanisms to ensure the desired level of academic preparation, diabetes training and continuing education.

Allied Agencies:

Private, voluntary, business and industrial concerns with an interest in diabetes may be identified and their activities described. The current and proposed role for each agency together with the planned linkage with the existing national, provincial and/or local programmes can be specified. A number of philanthropic agencies augment limited diabetes resources nationally and internationally. Agency representatives should be invited to assist in planning and finding solutions to gaps between available and required resources.

A lay organization representing the interests of diabetic children and adults serves many important purposes for each country. In addition to promoting patients' interests, there is a role for setting of standards, referral for care, ensuring availability of equipment and drugs, disseminating information through professional and lay journals,
conferences and meetings. These agencies may also translate technological and educational advances to the local economic and cultural situation. Voluntary organizations in some countries may wish to support biomedical and health care research. International nongovernmental agencies such as the International Diabetes Federation assist nations worldwide with professional education and setting of standards.

Sources of information include surveys, interviews and voluntary, consumer, business and industrial groups concerned with diabetes.

Allied agency section summary

- Private, voluntary, professional and lay organizations with interest and activities in the field of diabetes should be identified.
- Involvement of these organizations in programme planning and implementation is advantageous.
- Lay organizations representing the interest of individuals with diabetes serve many important purposes.

4.1.5 Availability of insulin, oral agents, supplies and patient equipment for diabetes management

Special supplies (e.g. insulin, oral hypoglycemic agents, syringes, devices and strips for blood and urine testing) and in some cases patient aids (e.g. vision aids, therapeutic shoes, mobility aids, prostheses) are needed to maintain diabetic individuals. WHO has identified insulin as a “lifesaving drug” and the sulfonylureas as an “essential drug”. Availability of prescribed medication is a problem in many countries due to taxes, distribution difficulties, costs and resale factors. Therefore, national and local diabetes programmes must ensure availability, distribution and reasonable charges since up to 60% of diabetic patients in some countries depend on pharmacological agents to control their disease.\(^{38}\)

Even though insulin may now be produced by recombinant DNA techniques, the majority of the world's insulin is derived from animal sources of varying purity. Although WHO has identified insulin as a lifesaving drug, its availability in many countries is notably limited while the price it commands is high.\(^{39}\) Uniformity in the strength of insulin, types of syringes, and policy on syringe reuse is recommended to minimize the confusion experienced by many patients and professionals. Reuse of needles by more than one subject raises the threat of transmission of hepatitis and AIDS. Governmental responsibility for procurement, storage, inventory, taxation, marketing and distribution of diabetes pharmaceuticals also needs to be stipulated.

Sources of information include patient interviews, surveys, pharmacy records, and medication and supply procurement records from governmental and private sources. With data on the current diabetic
population, medication utilization, and estimated proportion of the patients receiving prescribed medications and special supplies, forecasts can be made.

Pharmaceuticals and supplies section summary

- WHO has identified insulin and sulfonylureas as essential drugs, but their distribution is often limited and their cost unduly high.
- The national, provincial and local responsibility for availability of diabetes medication, its distribution and resale needs to be assessed.
- Provision of other diabetes patient supplies may be considered in the light of the availability of technology and resources.

4.1.6 Current diabetes policies

A critical review of the current national, provincial, and local legislation, government policies, health plans and regulations is needed to identify specific positions, if any, related to diabetes. Comparison between policies for diabetes and those for other chronic diseases needs to be made in order to establish priorities.

Sources of information include major national, provincial, and local legislation, policies and health care plans, special surveys and the national or provincial budget.

Diabetes policy section summary

- Describe existing diabetes policy directives.
- Contrast these policies with those for other chronic diseases in order to determine the priority of diabetes.

4.1.7 Diabetes-related fiscal resources and health care costs

Diabetes results in substantial direct and indirect costs. Estimates of direct costs can usually be made by reviewing current operating budgets for national, provincial, and local diabetes and primary health care programmes. Suggested categories for cost analysis include personnel; travel; inpatient and outpatient care, laboratory, rehabilitation and nursing home facilities; equipment; supplies; pharmaceuticals; training and education; capital and research costs. Options for cost-savings should be indicated. An accounting of diabetes care payment methods may reflect governmental, third party and self-pay sources. Estimates of indirect costs may be considered in the light of the economic burden related to the diabetic population's loss of income, disability and premature death. 
Sources of information include national, provincial and local allocations, accounting sources and expenditures for categories reflecting personnel, travel, facilities, supplies and equipment, capital expense and research. Special fiscal surveys, interviews and budget reports may also be needed.

**Diabetes fiscal resources section summary**
- Consider both the direct and indirect costs of diabetes.
- Consider options for service payment or reimbursement.
- Consider cost-saving options.

4.1.8 Agreement on minimum acceptable guidelines/standards for delivery of diabetes health care

In the past decade, many health care professionals have reached consensus on standards and guidelines for diabetic patient care and education. These standards appear to foster teamwork and may offer substantial reward in prevention and delay of diabetes complications, even in the absence of sophisticated technology. An a priori decision on minimum acceptable patient care standards for the country will help in the formulation of service, personnel and resource needs. Standards for laboratory technology may be specified likewise.

In 1986, the European NIDDM Policy Group developed a consensus statement for management of NIDDM. This lead to the subsequent publication of “A Desktop Guide for the Management of Non-insulin-dependent Diabetes Mellitus,” which describes the diagnosis, management and treatment of NIDDM. In 1989, the St. Vincent Declaration, endorsed by almost all European government health departments and patient organizations, was developed in an attempt to reduce the burden of disease and death from diabetes in children and adults by setting goals and 5-year targets (Annex 5). Also available are progress reports from the working groups for the production of guidelines for diabetes care.

Standards for diabetes care have also been developed by the American Diabetes Association (ADA). These “Standards of Medical Care for Patients With Diabetes Mellitus” are adapted in Annex 6 to assist planners project area-wide professional personnel, service and laboratory needs by outlining the minimum medical care recommended for diabetic individuals in a developed country. Another set of recommendations is found in “The prevention and treatment of complications of diabetes mellitus – a guide for primary care practitioners”. Once the diabetes care standards have been determined, key diagnostic and physical indicators can then be specified to monitor patient control and complications. Although many developing countries currently lack the personnel, facilities and resources to meet comprehensive guidelines and standards, the quantifiable criteria presented may assist in planning health
services and defining quality care. In the absence of specific guidelines for developing countries, those countries may wish to select or adapt recommendations from available guidelines for their unique situation.

**Acceptable standards/guidelines for diabetes care section summary**

- Standards of diabetes care have been formulated, though not for developing countries.
- These standards/guidelines can be adapted in order to develop guidelines for any given set of circumstances.
- Acceptable levels of diabetes care for the country should be specified during the planning period.

4.1.9 Comparison of diabetes state-of-the-art practices and resources with estimates for future needs and resources based on minimum acceptable standards

One of the most creative aspects of planning is the synthesis of basic programme assumptions and the situational analysis findings described in sections 4.1.1 – 4.1.8 to describe problem areas. After combining this information into succinct problem statements, medium and long-term measurable objectives can be formulated addressing each problem area. To meet each objective, numerous logical strategies can be proposed and various scenarios simulated. Potential constraints that could present unexpected difficulties can be identified. Cost data affixed to each strategy will help to determine cost effectiveness of each approach. The planning team can recommend realistic and achievable objectives, strategies, programme impacts and approximate costs to the diabetes advisory committee for further refinement and priority rating.

To the extent the data will allow, morbidity and mortality rates can be projected over five and ten years. Projections for reductions in morbidity/mortality, given implementation of combinations of strategies, can indicate potential benefits and estimated costs associated with each programme objective. The following example presents three potential strategies used to achieve the objective of reducing by 5% the annual rate of lower extremity amputations in diabetic individuals.

**Figure 1** – assumes current services continue (baseline $)

**Figure 2** – assumes ongoing services (baseline $)

- plus adding a foot care programme for N high risk patients at a cost of Y per patient.

\[ \text{Total} = [\text{baseline} + (N \times Y)] \]

**Figure 3** – assumes ongoing services (baseline $) plus adding foot care programme for N high risk patients plus professional education for Z professionals at cost A;

\[ \text{Total} = [\text{baseline} + (N \times Y) + (Z \times A)] \]
Figure 1

--- Actual diabetes amputation rate
-- -- -- Projected diabetes amputation rate assuming same course
-- --- --- Projected diabetes amputation rate adding patient education
******** Projected diabetes amputation rate adding patient and professional education

The difference achievable after instituting patient foot care education is shown in Figure 2 while Figure 3 shows the difference obtainable instituting both patient and professional education at a modest additional cost.

Economies of scale may be considered for strategies common to multiple objectives. For example, comprehensive patient education and professional education programmes could be conducted rather than courses on specific complications.

Comparing current needs to future estimates section summary

- Briefly describe particular problems or inequities identified by working through sections 4.1.1 to 4.1.8.
- Formulate measurable objectives and strategies addressing problem areas.
- Contrast existing needs and resources to those projected for the future (e.g., five and ten years).

4.2 Programme planning – objectives and strategies for medium and long-term programmes

4.2.1 Forming a diabetes advisory committee

A national diabetes advisory committee is recommended to advise on issues of planning, priority setting, resource allocation, programme operation and evaluation. Its role may also extend to advising the ministry of health and the legislative arm of government on policy, training, research, programme and budgetary needs.

Committee membership should be both multidisciplinary and intersectoral, representing the diabetes, health care, academic, research, business, voluntary and consumer communities. Regional and minority representation is desirable to insure a balanced perspective. Regular or ex-officio membership may be extended to representatives from national
or regional agencies and programmes offering related services, e.g., finance or education. A high level of commitment is desired because ultimately the success of the programme is based on the committee's enthusiasm, commitment and willingness to advocate for resources. The optimal time to convene the advisory committee is after the commencement of the situational analysis, but before the planning group completes the data collection, to allow advisory committee members to contribute to the planning process.

This committee has a unique role in advising the health agency regarding development of its diabetes programme. Specifically, it should advise on objectives and priorities in a timely and systematic way. The committee could also recommend to the ministry of health a programme operating budget and a location within the agency. The advisory committee would meet regularly to review programme progress and make recommendations. Staff support for this committee should be available from the planning group or the ministry of health. A specific time period, not to exceed one year, would encompass the planning period.

The diabetes advisory committee will ultimately forward to the ministry of health and/or the legislature its recommendations for programme configuration, organization, objectives, strategies and budget. Coordination with the manager of the primary health care system is important for service and resource cohesion.

**Diabetes advisory committee section summary**

- A diabetes advisory group is recommended to advise the health agency in general.
- It should be convened after the commencement of the situational analysis but before the conclusion of the planning process.
- This advisory group can set priorities and review programme direction and operation.

4.2.2. Developing the programme infrastructure

Unless the diabetes programme location in the national health agency is based on a legislative mandate, a review of programme placement by the diabetes advisory committee is recommended. The programme infrastructure must be described clearly both horizontally and vertically. In most countries, diabetes programme efforts will build upon an existing primary health care system. Thus, agency placement that facilitates this coordination is desirable. Where recipients of diabetes services also receive service from other ministry of health programmes, coordination at the national, provincial and local levels is needed. Examples of programmes with potential for coordination include chronic disease control, risk reduction, health education, maternal/child health, and those for aging and elderly citizens.
Timely identification of the diabetes programme director will allow his/her active participation in the planning process. It is recommended this individual be a strong leader recognizable within the agency, the diabetes community and the country. The programme director will coordinate programme efforts within the ministry and with other ministries and programmes. Ongoing communication between the programme director, legislators, other ministries and the fiscal planning office may help advocate for programme resources and insure political and administrative commitment.

The national programme extends from the ministry of health through the national director to the service delivery sites using a network of centres, units, teams and community workers. Bidirectional communication, information, and referral is essential to smooth national and local programme operation. Vertical links will formally connect the community workers, teams, units and centres with the central office while lateral links will support utilization of effective strategies across health teams, units and centres as outlined in Figure 4 and discussed in Section 4.2.3. The role for community and lay workers in the programme needs careful description, including training and responsibilities.

The diabetes programme director and/or the diabetes advisory committee may receive concurrent recommendations from key international consultants or advisors reflecting state-of-the-art practices in areas such as epidemiology, education and translation of diabetes technology. Multisectoral health specialists familiar with the national/local situation or knowledgeable in community organization, professional education and quality assurance can likewise advise during programme design and implementation. Programme personnel, advisors or consultants should assist in coordinating the practice of physicians, pharmacists, nurses, nutritionists, educators, epidemiologists, biostatisticians, managers and health workers. An information system may be needed to link programme planning, management, implementation, surveillance and evaluation and to link programme personnel throughout the country.

Developing the programme infrastructure section summary

- Recruit a strong diabetes programme director.
- Describe the location of the programme within the health agency including vertical and horizontal links with the primary health care programme.
- Outline a programme information system to facilitate communication, management of data and logistics.

4.2.3 Developing diabetes teams, units and centres

Ideally, the national diabetes programme will augment the country's existing primary health care infrastructure with special health care workers, diabetes teams, units and centres to deliver care which meets
designated guidelines/standards. Centres, units, teams and health workers need to be involved in determining how best to work within the national or regional programme to achieve the stated objectives. The administrative network linking the programme with centres, units, teams and health workers will benefit from some decentralization in organization and operation.

In developing countries, diabetes care may be provided by paramedical staff, health workers, other lay workers, health extension officers or trained volunteers working at aid posts or in rural health centres. These individuals working at the primary level of care need skills to make basic diagnoses and provide essential drugs. Most likely, physicians will manage diabetes and its complications in secondary health care settings. When the formation of teams, units and centres is not possible, local providers should continue to deliver the best primary care and education possible, given competing national priorities. The matrix in Figure 4 illustrates minimal, desirable and optimal levels of diabetes programme development and corresponding options based on primary, secondary and tertiary care configurations. For example, in a country with minimal development and resources, the tertiary care provided could be from a diabetes team whilst in a highly developed country, the team might provide primary diabetes care. The desirable situation for health care would be that a team be available at the secondary level of care.

Figure 4
Options for level of diabetes care given level of development and resources

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Primary</th>
<th>Secondary</th>
<th>Tertiary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Paramedical staff</td>
<td>Physician</td>
<td>Diabetes team</td>
</tr>
<tr>
<td>Minimal</td>
<td>Basic diagnostics</td>
<td>Basic education</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Essential drugs</td>
<td>Basic treatment of complications</td>
<td></td>
</tr>
<tr>
<td>Desirable</td>
<td>Physician</td>
<td>Diabetes team</td>
<td>Diabetes unit</td>
</tr>
<tr>
<td></td>
<td>Basic education</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Basic treatment of complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optimal</td>
<td>Diabetes team</td>
<td>Diabetes unit</td>
<td>Diabetes centre</td>
</tr>
</tbody>
</table>

A diabetes team is comprised of a physician and a professional educator. This is the fundamental configuration for provision of quality diabetes care and education. The physician who will lead the team should have an interest in diabetes as he/she will be responsible for delivering a
continuum of care ranging from stabilizing newly diagnosed patients to maintaining patients with long-term disease and an array of complications. The professional educator with the knowledge and ability to educate diabetes patients may represent one of several disciplines (nursing, dietary, health education, pharmacy). It is recommended that team members work in close physical proximity to coordinate care optimally. Their specific roles may be defined further during the planning process. Access to care in reasonable proximity to patients' residences is desirable. Patients with complicated disease should be referred to a diabetic unit or centre for more specialized care.

Team members will meet with community leaders several times each year to discuss services provided and receive local suggestions and observations. These discussions may serve to improve programme services, patient acceptability and overall coordination of care. Basic medical data and surveillance of complications will be maintained on individuals receiving care from the team. As service delivery moves from team to unit to centre, increasing technology is anticipated.

A diabetes unit is comprised of a diabetologist/endocrinologist, or an internist with special diabetes training, a professional educator and at least three additional multidisciplinary diabetes care professionals who work in close proximity and provide coordinated diabetes health care, e.g. a podiatrist, dietitian and nephrologist. The unit will receive referrals from teams of those diabetic individuals whose care requirements are complex and who could benefit from the broader range of care. Patients requiring still more complex care and hospitalization should be referred to diabetes centres.

A diabetes centre is a tertiary care referral facility which provides a comprehensive range of health care services. To qualify as a diabetes centre, personnel would include at least one diabetologist/endocrinologist, two professional educators of differing disciplines, several physician specialists able to diagnose and treat different diabetes complications and representatives from two additional health professions with complimentary expertise. The personnel at these multidisciplinary diabetes centres would provide coordinated care, with personnel working in close physical proximity.

Ideally, centres may also conduct diabetes research to benefit the diabetic population. Education and professional training should be available at the centre level. Some decentralized patient management, registry, and surveillance data may be maintained by centres on those individuals receiving care from the teams and units within their geographic area. Cooperation of centre staff with other programmes, organizations, government and voluntary agencies is encouraged. Training opportunities may be offered to staff from neighbouring countries lacking these capabilities.

To encourage and recognize excellence among teams, units and centres a competitive system might be introduced awarding outstanding applicants special programme enhancements, such as additional personnel, equipment, supplies, research support or educational opportunities.
The type or amount of the award and the restrictions for its use could be determined by national or local considerations.

**Diabetes teams, units and centres section summary**

- Diabetes teams, units and centres are recommended as care delivery configurations.
- Consider current and projected personnel needs in planning for diabetes programme services.
- Countries unable to consider this approach initially may apply these concepts at some future time.
- Opportunities for training should be shared.

### 4.2.4 Developing programme priorities, objectives and budget

Each country will need to develop a framework suited to its needs. Planners may benefit from the WHO document “Managerial process for national health development – guiding principles”[48] (Annex 7) which describes the stepwise and cyclic process of programme planning as suggested above. Special attention might be given to opportunities for efficiencies within the existing system by using untapped, underutilized or reallocated resources.

The planning group will draft a brief problem statement and quantifiable objective describing what could be done, by whom, when, and where and to what extent the problems identified in the situational analysis could be remedied. Accompanying each objective would be strategies, activities or methods to reduce or remedy the problem and achieve the objective. Cost estimates affixed to each strategy could be summed to estimate the cost per objective. Activities common to several objectives or strategies can be combined as “common support activities”. One such example influenced by the national primary care network and its integration with the diabetes programme is the system for diabetes data collection, analysis and dissemination. Availability and suitability of existing computer systems and software packages should be explored to augment patient care and surveillance. The relatively low cost of such systems makes them a practical reality for all countries today. Annex 8 outlines a national diabetes programme plan.

The planning group is responsible for drafting objectives, identifying strategies and estimating future costs, for example, over five and ten year periods. The advisory committee then recommends the priority order for phased implementation based upon programme needs, cost effectiveness of various objectives and methods and the national or local situation. Considerations will include what is relevant and achievable, given the time frame and anticipated resources.
The following programme development example illustrates this point:

Objective:
The diabetes programme within the ministry of health will implement a diabetes programme, to reach 80% of the area's diabetic population by 1996 and 99% by the year 2001. (estimated cost at 5 years = $ and at ten years = $$)

Examples of strategies:
1. Collaborate with the primary care network in recruiting, training and placing an additional N1 specialist physicians, N2 family practice physicians, N3 diabetes nurse educators and N4 diabetes programme managers to institute diabetes teams, units and centres throughout the area. \[(N1 + N2 + N3 + N4) = \$ \text{cost estimate}\]

2. Provide contemporary diabetes education to 95% of the members of teams, units and centres during 1992. (\$ \text{cost estimate})

A number of common activities will influence the entire programme and should receive particular attention, including:

(a). The organization and interrelationships between primary health care delivery, diabetes care delivery and voluntary organizations
(b). The standards of care for managing patients with diabetes
(c). Education and training of professional and community health personnel
(d). The priority to be given to primary, secondary and tertiary prevention
(e). Patient and community education
(f). The programme information and communication network
(g). Research
(h). Surveillance
(i). Evaluation

The programme budget will rely on data collected during the situational analysis to estimate current and projected five and ten year costs. The programme budget represents multiple assumptions and many alternatives. Therefore, computer spreadsheets could expedite the process of computing cost options. On the opposite side of the ledger, potential funding sources and government revenues, health insurance funds, corporate or voluntary contributions and patient fees over five and ten years can be estimated. This information is needed prior to programme submission to governmental or legislative channels. Contingency plans identifying the highest programme priorities are suggested in the event that full programme funding is not received. The advisory committee may also establish a minimum funding level below which implementation of a quality programme would not be possible.

As the programme planning phase is completed, soliciting input from professional, voluntary and other allied organizations with interest in diabetes may provide planners and the advisory committee with important feedback. This is also an opportunity to inform constituents about the programme and enlist support for meeting gaps between service needs and resources.
Programme priorities section summary

- Planners will draft measurable objectives to address each problem described in Section 4.1.9.
- Methods or strategies that could be used to achieve each objective will be indicated.
- The cost for each objective is estimated by summing the costs for the proposed methods and strategies.
- Objectives and strategies can be placed in the priority order best suited to the country’s short, medium and long term needs.
- Allied and nongovernmental organizations can provide feedback on the proposed plan.
5. Implementing the diabetes programme

5.1 Preparing to implement the diabetes programme

Once the programme objectives, budget and time frame are developed, formal dialogue between the government programme, policymakers and the programme director ensues. Other groups with allied interests may assist by promoting the programme. Based on the programme description of what will be done, by whom, where, when, how and at what cost, the ministry of health should be prepared to make a commitment to the diabetes programme in policy and resources. When the policy or resource process requires additional legislative action, the duration between plan completion and funding may need to be extended. Until the plan is formally approved, only informal, limited implementation activities are advised.

Once the programme authorization and resource allocation is announced, formal preparations for phased implementation need to proceed. It is recommended that the period from notification of programme authorization/funding to actual programme service delivery be less than 18 months. Annual work plans should be developed outlining the time frame for phased implementation of activities over the initial years.

Preparing to implement the programme section summary

- The advisory group and programme director should provide information on the diabetes programme plan to ministry of health, legislative and other officials.
- Ministry of health commitment to the plan in policy, principle and resources is recommended before implementation commences.
- The period from formal programme approval to delivery of patient services should require less than 18 months and proceed according to the plan.

5.2 Coordinating national, provincial and local diabetes programme implementation

Implementation activities continue the planning process and formally commence once programme policy and funding decisions are made. Programme leadership and management skills are particularly crucial at this juncture as the director will need to oversee progress in several areas
concurrently to insure the diabetes programme infrastructure, trained personnel, facilities, equipment and supplies are all in place for the scheduled delivery of patient services.

Informal agreements between authorities responsible for the nation's primary care network and the diabetes programme can be formalized detailing programme expectations for case-finding, standards of care, preventive and curative services. How the objectives and common activities selected in section 4.2.4 will translate into clinical roles and responsibilities should be indicated. Strategies for cooperation at all programme levels can be described. The mechanisms to monitor quality control at all levels of the programme can be agreed upon a priori and alternatives for overcoming potential problems considered.

Programme management will benefit from an explicit network for patient referral, information and communication flow, data collection and surveillance. Early organization of this network will allow the programme director and his/her staff timely information to guide the many aspects of programme development, management and operation.

Personnel issues are paramount and efforts to identify and recruit personnel can now proceed through formal channels. The central programme staff, once identified, need to collaborate with appropriate provincial and local officials in the selection of personnel to carry out the local programme. Diabetes programme managers are recommended to assist care providers within geographic regions. Recognizing that professionals with similar credentials may have widely differing diabetes care abilities, orientation and education may benefit programme personnel of all disciplines. Available education and programme training materials developed by one country can be shared with other countries and adapted to meet local needs.

The programme will need to determine how diabetic individuals will be identified, scheduled for service and included in the diabetes patient roster or registry. Likewise, plans for assuring the quality of diabetes care need to be specified. Computerized programmes have been developed to address this need. Other important patient considerations include transportation to primary care or referral sites, translators, ability to contact or communicate with patients between clinic visits and financial assistance for purchase of supplies and pharmaceuticals.

Support services and programme logistics to be addressed include those mentioned in sections 4.1.4 and 4.1.5, such as procurement of programme space, facilities, supplies, equipment, pharmaceuticals and transportation. Upon completion of these planning activities, formal patient care and education begins. Some newly developed programmes have pilot clinics or trial runs to ensure patient services are ready for operation while others phase in services by locality and region.

After service delivery has begun, programme managers can address issues such as utilization, monitoring delivery of care and education, and adequacy of data. Process evaluation measures will be used to guide early programme implementation, whereas after one to two years of programme
operation, measurement of outcomes will take on more importance.

**Coordinated programme implementation section summary**

- Agreements can be formalized with the national primary care network describing strategies for programme cooperation at all levels.
- A network for information and communication flow, data collection and surveillance can be implemented to enhance programme management, operation and evaluation.
- Central programme staff, once identified, can collaborate with regional and local officials to select personnel to carry out the local programme.
- Training and orientation is indicated for all programme personnel and can be shared by other countries.
- Programme logistics, including facilities, supplies, equipment and transportation need early attention.
- Patient logistics needing attention include identification of diabetic individuals, scheduling and transportation.
- A diabetes programme is outlined in Annex 8.

**5.3 Implementing minimum standards of care by diabetes teams, units and centres**

Desirable diabetes patient care standards/guidelines and the resultant services are described in section 4.1.8. Local standards can be adapted from these published sources. These standards stimulate provision of coordinated multidisciplinary care by professionals and they clarify goals of education and treatment for patients.

**5.3.1 Primary prevention – avoiding the onset of disease**

It is universally acknowledged that prevention of disease is better than subsequent cure. This is even more important when there is doubt whether the pathological abnormality may be reversed, as is the case for diabetes. Therefore, much attention has been paid to the possibility of primary prevention of diabetes.30-32

Two basic strategies have been proposed. The high risk approach seeks to intervene selectively in those subjects with acknowledged risk factors, whilst the population strategy attempts to modify levels of risk factors in the community as a whole. The high risk and population strategies are generally regarded as complimentary, but in planning a diabetes prevention programme for an individual community it is necessary to decide the relative utility of these approaches for the particular setting. This is determined by available resources, the epidemiological profile of diabetes in the population and other considerations discussed in more detail elsewhere.30,32
IDDM

Strong associations with various blood genetic markers indicate an important genetic contribution to risk of IDDM and these may also be used to identify individuals at high risk in affected families. Screening for genetic predisposition in the general community has not yet become feasible, partly because of the rarity of IDDM in most societies and consequently the low yield.

Substantial geographical differences in incidence of IDDM also suggest powerful environmental influences, although these elude clarification. Viruses, toxins and lifestyle factors such as avoiding breastfeeding have received attention but none is proven. At the present time primary prevention of IDDM in the general community is not a feasible option, although it remains a possibility for the future, especially within the families of index cases.

NIDDM

Although familial, NIDDM is not strongly associated with any known genetic marker. However, environmental associations are better understood than those for IDDM. NIDDM is consistently associated with cultural change and urbanization in developing societies. The relationships obesity, physical inactivity and high fat/simple carbohydrate diet are widely regarded as causal.

In the absence of full understanding of the environmental precipitants of NIDDM, the alarming epidemic of NIDDM and cardiovascular disease in many newly industrialized countries has lead to a commitment of integrated programmes for primary prevention, based upon lifestyle modification, as previously described above. However, the notion that risk factors for NIDDM may vary between populations suggests the value of determining risk profiles for individual communities prior to designing locally appropriate preventive action.

Primary prevention section summary

- Approaches to primary prevention include those targeting high risk individuals as well as whole communities.
- Both IDDM and NIDDM have genetic and environmental determinants, which are not entirely understood.
- Integrated programmes for primary prevention of noncommunicable diseases are based upon lifestyle modification.

5.3.2 Secondary prevention – early detection and prompt treatment

Screening for undiagnosed diabetes is not widely recommended in most communities because of uncertainty of yield, diagnostic and treatment availability and doubts over the cost-effectiveness of the strategy. For individuals at elevated diabetes risk, diabetes screening is routinely
performed by analyzing a blood or urine sample for glucose. A wide variety of screening policies and practices exist worldwide, and the WHO diagnostic values are given in Annex 2. The Second International Conference on Gestational Diabetes recommended universal screening of all pregnant women for diabetes during the 24–28 week of pregnancy. Ideally, this screening should be incorporated into all prenatal care programmes. General recommendations for categories of risk factors that are associated with the development of diabetes have also been published.

IDDM

Population screening for IDDM is not indicated given the low incidence, the lead time between onset of pathology and presence of symptoms and the lack of available experimental immunosuppressant drug treatment for individuals found during the pre-clinical period with islet cell antibodies. Continued research is needed before strategies for widespread screening for islet cell antibodies in biological relatives of patients with IDDM are instituted.

NIDDM

In populations with unusual susceptibility, population-based measures to identify asymptomatic NIDDM are warranted. High risk individuals within populations include those with a family history of diabetes, the obese, certain ethnic groups, prior gestational diabetes, impaired glucose tolerance and to a lesser extent, any subject aged 40 years or over who also has one of the above risk factors, significant hyperlipidemia or hypertension. Diabetes screening requires the use of a carefully collected sample and a standardized test analyzed with calibrated equipment that does not yield excess numbers of false positives or negatives. Diabetes screening should only be undertaken if personnel and facilities are available to confirm the diagnosis and institute treatment.

Concurrent community activities may increase public awareness of diabetes signs and symptoms. Facilities where assistance is available should be advertised. Ongoing awareness activities can be integrated into local settings, such as schools, factories, worksites, community gathering places, outpatient clinics, hospitals, and pharmacies.

Secondary prevention section summary

- Guidelines for diabetes screening are available.
- Screening for IDDM is unwarranted.
- Special screening programmes for NIDDM are indicated in populations and individuals at high risk.
- Community and public awareness concerning diabetes activities may be beneficial.
5.3.3 Tertiary prevention – delaying and/or preventing diabetes complications

In the situational analysis, baseline rates were computed for the major complications of diabetes. National and local programmes can address each complication with specific objectives and strategies aimed at reducing morbidity, disability and mortality over the next five and ten years.

Scientific rationale formed the basis for recommending complication specific programme actions in the St. Vincent Declaration\textsuperscript{44} and the U.S. Year 2000 Objectives.\textsuperscript{35} Priority areas for tertiary prevention include:

\textbf{Diabetic ketoacidosis}: may be prevented by improving glycaemic control, patient self care knowledge, appropriate actions and prompt contact with health care providers when problems develop.

\textbf{Amputation}: many lower extremity amputations might be prevented with improved self care, suitable footwear, reduction of risk factors and prompt physician care for problems.

\textbf{Blindness}: many cases of diabetes related blindness could be prevented with early detection and full treatment of diabetic retinopathy, as outlined in a recent WHO position paper\textsuperscript{56} and in the protocol for screening for diabetic retinopathy in Europe.\textsuperscript{57}

\textbf{Cardiovascular Disease}: major alterable cardiovascular risk factors which need priority attention in diabetic populations are: control of hypertension, cigarette smoking and hyperlipidemias.

\textbf{Renal Disease}: control of blood pressure and application of research findings on glucose control, low protein diets and pharmacological agents are thought to be beneficial for the avoidance of end stage renal disease.

\textbf{Complications of pregnancy}: for women with pre-existing diabetes, strict glucose control prior to conception and throughout the pregnancy is recommended. For other pregnant women, universal screening for gestational diabetes may be instituted to identify women needing treatment. These measures may reduce rates of adverse birth outcomes in diabetic women to approximately by those of nondiabetic women.

The health planners and advisory group should consider these complications in their problem description and propose quantified objectives and strategies over five and ten year periods. Achievement of the recommended reductions will require concerted efforts for an extended period of time. Self-monitoring of blood glucose is a highly recommended strategy for the general reduction of the long-term complications of diabetes.\textsuperscript{43,58}
Tertiary prevention section summary

- Rationale and specific patient and professional actions are available to prevent or delay major diabetes complications.
- Economies of scale are available by coordinating prevention/education programmes for professionals and similarly coordinating programmes for patients.
- Reductions in complications may require long-term action.
- Self-monitoring of blood glucose is highly recommended.

5.3.4 Rehabilitation and special assistance services

Despite vigorous prevention programmes, many diabetic individuals will develop disabling complications which impair their ability to conduct activities of normal daily living. The major impairments include severe visual loss or blindness, insensate lower extremities, amputation, renal failure requiring dialysis, male impotence and the residual effects of cardiovascular events. Resultant functional and cognitive impairments substantially reduce the ability of the individual to maintain independence, diminish the quality of life and force affected individuals from their normal environments into supervised care settings. Local plans may be indicated for application of rehabilitation services. Benefits of rehabilitation include added productive, quality years of life and decreased disability costs.

The goal of rehabilitation is to reduce disability. In conjunction with medical management, physical reconditioning, occupational and physical retraining, and continued research and development efforts are needed to identify measures to restore self-care abilities and enhance the quality of life of severely affected individuals. Examples of advances which can now assist these patients are insulin syringes and glucose monitors for the visually impaired, therapeutic footwear for at-risk feet, and mobility aids for individuals with limited ambulatory ability.

Rehabilitation section summary

- Many diabetic individuals will develop disabling complications.
- Associated costs are high.
- In some cases, rehabilitation can restore self-care abilities and enhance the quality of life.

5.4 Diabetes research

Achieving the ultimate diabetes research goal, diabetes prevention, will require concerted basic science efforts to elucidate and alter the
aetiological mechanisms involved. Many biomedical research advances of
the last decade have increased our understanding of cellular level
processes related to diabetes. In countries with diabetes research
capabilities, national commitment and support is indicated. In some
countries, basic epidemiological research is still required.

Important treatment advances such as applying recombinant DNA
techniques to produce human insulin, developing insulin infusion devices
and improving self blood glucose monitoring equipment have all advanced
diabetes patient care. Research is needed to develop and evaluate patient
management, improve cost-effective health care delivery and prevent
complications. Strategies to sustain lifelong behavior changes in areas
such as diet, exercise, weight control and self-monitoring are needed to
assist patients each day in their lifelong struggle to manage their diabetes.

Although biomedical treatment and health care research is desirable it
may not be feasible nor an appropriate priority in many developing
countries. However, even small scale research at the local level using
carefully standardized methodology can make valuable contributions
particularly in the field of epidemiology and provision of health services.
In many countries, translation or application of available research findings
may improve patient welfare.

**Research section summary**

- **Important biomedical and treatment advances are being made
  for diabetes.**
- **Research support and activities are needed – but they should be
  compatible with national resources and overall priorities.**
- **Translation or application of research findings may improve
  patient welfare.**

### 5.5 Implementing a diabetes surveillance system

The major functions of a diabetes surveillance system are 1) to track
morbidity and mortality and guide the development of national and local
priorities and policies, 2) to help formulate control strategies, 3) to serve
as a programme management tool for planning, monitoring and evaluating
programme activities, 4) to assist with translation of research findings by
identifying individuals at risk who could benefit from specific
interventions, 5) to assist with epidemiological research and analysis
and 6) to coordinate treatment to avoid multiple and/or contradictory
treatment in patients receiving care at several sites.

Even though diabetes is not necessarily a lifelong condition, nor a
routinely reportable disease, development of a registry needs thoughtful
consideration (Annex 4). Registries may be very time consuming, labor
intensive and expensive. Typically, registries enrol newly diagnosed cases
which they follow on a regular basis until death or migration. Therefore, a
diabetes registry within a defined population can provide information on
disease incidence, duration, prevalence and other epidemiological measures while also serving tracking, care coordination and research purposes. Service providers will find a registry or roster of diabetic individuals a useful management and surveillance tool. Conversely, periodic patient and population surveys could provide some of the information provided through a registry at a greatly reduced cost.

If computer technology is available, patient information can be linked with vital statistics, hospital discharge and health care cost data to expand the diabetes surveillance capability. When linking computerized data sets, caution should be exercised to protect the rights of the individuals identified therein. Normally, data should be presented only in summary form unless patient consent is obtained.

The data collected during routine diabetes surveillance are similar to those outlined in the situational analysis, i.e., those concerning demography, morbidity, disability and mortality. Data that will not be utilized should not be collected. Data analysis should be presented on a regular basis since surveillance findings motivate health professionals. Regular publication is recommended to inform administrative and political officials and the general public of progress and trends.

**Surveillance system section summary**

- **Surveillance systems are useful for programme direction, management and evaluation.**
- **Surveillance systems can assist in assessing programme process and outcome data.**
- **With computer technology, linkage of patient information with vital statistics and health care cost data can expand surveillance capability.**
- **Specific surveillance activities for registries include assessment of morbidity, mortality, and disability.**
- **Surveillance findings need to be regularly disseminated.**
6. Programme evaluation

Programme evaluation is a continuation of the programme planning and implementation cycle based on monitoring overall programme efficiency and effectiveness. Policy makers will want to know whether the programme results in a change in health status of the population and what reprogramming is indicated. Managers will want to know if the focus on service is adequate and whether the resources are adequate and appropriately deployed.

The evaluation process is simplified with the use of measurable performance objectives. At the completion of the first year of the programme, an assessment can be made on whether strategies to meet the objective have been implemented and at what cost. At the conclusion of the third and fifth years of the programme, a report to the advisory committee should indicate the degree to which objectives have been met, which strategies were most effective and what reprogramming is recommended. This may result in revised or new objectives. At the conclusion of years one, three and five it is important to answer several questions regarding programme focus:

1) Are the goals the same?
2) Are the objectives still appropriate for the stated problems?
3) Has the priority order changed?
4) Have the strategies and activities collectively reduced or eliminated the problem addressed by the objective?
5) Is the agency committed to the programme?
6) Are the resources allocated to the programme sufficient?

Reporting both programme successes and failures to members of the diabetes professional community through regular publication channels or professional meetings will foster movement toward effective approaches and save considerable time and resources.

An annual review of programme surveillance and management data performed at the local, provincial and national level will help to compare the actual and projected programme process and outcomes. Less frequent tracking is indicated for incident cases and rare outcomes, such as blindness, amputation, chronic renal failure and diabetic ketoacidosis.
Programme evaluation section summary

- Evaluation is a natural continuation of programme planning and implementation.
- Quantifiable objectives accelerate streamlined and focused evaluation.
- Modifying the strategies/methods when objectives are not met may ultimately result in cost savings and improved patient outcomes.
- Periodically, the care delivered should be compared to that outlined in section 4.1.8.
7. Adapting the WHO national programme guidelines to the local situation

Needs and problems in formulating strategies for the prevention and control of diabetes vary greatly between WHO regions and at the local and country level within regions. Therefore, it will be necessary to adapt these guidelines to produce the optimal plan for an individual situation.

In formulating these guidelines, the philosophy adopted was to target the document to the mid-point in the range of resource potential, administrative complexity and diabetes severity. Inevitably, there is a wide dispersion around such an average. Therefore, the initial situational analysis will determine the scale of the approach to be adopted in the planning and implementation phases. It is recommended that these guidelines be used as support and guidance for the preparation of specific national or local guidelines which will form the basis for individual programmes. An example of local guidelines for diabetes programme development for Palestinian refugees has recently been published.\(^1\)

In developing its programme for diabetes, WHO has designated a global network of collaborating centres in the field of diabetes.\(^2\) These centres have international standing and may be able to assist with national and local programme development, as may the Diabetes and Other Noncommunicable Diseases Unit at WHO Headquarters in Geneva and the Regional Advisers for noncommunicable diseases at the WHO Regional Offices in Brazzaville (Africa), Washington, D. C. (The Americas), Alexandria (Eastern Mediterranean), Copenhagen (Europe), New Delhi (Southeast Asia) and Manila (Western Pacific).

The WHO resolution on diabetes mellitus (Annex 1) also invites Member States to share among themselves opportunities for training and further education in the clinical and public health aspects of diabetes. WHO-cosponsored global and regional training courses in epidemiology and public health aspects of diabetes are now held regularly and the International Diabetes Federation is also developing a series of training courses in planning and delivery of diabetes care. National and local programme directors are encouraged to avail themselves of the opportunities provided by these and other international courses.
Adapting the WHO guidelines to the local situation summary

- Each country will need to adapt these guidelines to produce the optimal plan for the local situation.
- WHO and its network of diabetes collaborating centres may be able to assist in the development of diabetes programmes.
- WHO and the International Diabetes Federation co-sponsor regular courses on epidemiology, public health and planning and delivery of diabetes care. Programme directors are advised to avail themselves of such opportunities.
8. References

23. SPITZER, W. O. & MANN, K. V. The public’s health is too important to be left to public health workers. Annals of Internal Medicine, 111:939–942 (1989).


9. Glossary

**Insulin-dependent diabetes mellitus** (IDDM or Type 1) – is found most often in childhood with secondary peaks in early and late adulthood. It is characterized by rapid onset of clinical symptoms and requires prompt medical treatment and regular use of insulin for survival.

**Non-insulin-dependent diabetes mellitus** (NIDDM or Type 2) – is found primarily in adults. It accounts for approximately 9% of diagnosed diabetes and is characterized by a gradual onset of symptoms.

**Malnutrition related diabetes mellitus** (MRDM) – may have a high prevalence in some tropical countries in young, underweight individuals. Although insulin may be required for metabolic control, it is not prone to ketosis.

**Gestational diabetes mellitus** (GDM) – glucose intolerance detected during pregnancy which needs reclassification post partum. Occurring in 2–5% of pregnancies in developed countries, it is considered the most common medical complication of pregnancy.

**Impaired glucose tolerance** (IGT) – glycemic response to an oral glucose tolerance test intermediate between normal tolerance and diabetes. A proportion of individuals with IGT progress to diabetes.

**Hyperglycemia** – elevations of blood glucose which over an extended duration are associated with the development of diabetes complications.

**Health** – a state of complete physical, mental and social well being, and not merely the absence of disease or infirmity.

**Primary health care** – essential health care based on practical, scientifically sound and socially acceptable methods and technologies made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain.\(^2\)

**Diabetes control team** – a primary care physician and a professional diabetes educator working together to provide coordinated diabetes health care.

**Diabetes control unit** – a diabetologist, endocrinologist or internist with special diabetes training, a professional diabetes educator and three additional multidisciplinary diabetes care professionals working together in close physical proximity delivering coordinated diabetes health care.

**Diabetes control centre** – a tertiary care referral centre which provides a comprehensive range of diabetes health care services. Professional staff include a diabetologist/endocrinologist, two professional diabetes
educators of differing disciplines, several physician specialists with
text in treatment of different diabetes complications and at least two
additional health professionals with expertise in diabetes care
representing disciplines not otherwise represented. This multidisciplinary
diabetes centre staff will provide coordinated care, work in close physical
proximity and may be involved in diabetes research.

**Primary prevention** – activities that prevent a disease from occurring in
susceptible individuals. These activities may reflect modification of
environmental and behavioral risk factors.

**Secondary prevention** – activities, such as screening, to detect disease
early and institute prompt treatment.

**Tertiary prevention** – delaying or preventing complications of disease by
effective treatment, education and metabolic control.

**Effectiveness** – an expression of the desired effect of a programme,
service, institution or support activity in reducing a health problem or
improving an unsatisfactory health situation. Thus, effectiveness
measures the degree of attainment of the predetermined objectives and
targets of the programme, services, institutions and support activities.\(^48\)

**Efficiency** – the relationship between the results obtained from a health
programme and the efforts expended on it in terms of human, financial
and other resources, health processes and technology and time.\(^49\)

**Intersectoral** – activities which involve multidisciplinary health
professionals, professionals from other disciplines, e.g., economists,
lawyers health insurance specialists, communication specialists,
psychologists, health policy planners and administrators, as well as
nonprofessionals representing wide, health-related interests including
those of the patient.\(^27\)

**High technology** – the application of scientific developments to achieve
health care advances.

**Situational analysis** – that portion of the planning process involving the
collection and analysis of demographic, epidemiological, personnel and
facilities data and related health care resources.
Annex 1

Forty-second World Health Assembly
Agenda item 18.2

19 May 1989

Prevention and Control of Diabetes Mellitus

The Forty-second World Health Assembly,

Recognizing that diabetes mellitus is a chronic, debilitating and costly disease attended by severe complications including blindness and heart and kidney disease;

Noting that diabetes already represents a significant burden on the public health services of Member States, and that the problem is growing, especially in developing countries;

Aware of the support of the International Diabetes Federation and the WHO collaborating centres on diabetes;

1. Invites Member States:

   • to assess the national importance of diabetes;
   • to implement population-based measures, appropriate to the local situation, to prevent and control diabetes;
   • to share with other Member States opportunities for training and further education in the clinical and public health aspects of diabetes;
   • to establish a model for the integrated approach to the prevention and control of diabetes at community level;

2. Requests the Director-General to strengthen WHO activities to prevent and control diabetes, in order:

   • to provide support for the activities of Member States with respect to the prevention and community control of diabetes and its complications;
   • to foster relations with the International Diabetes Federation and other similar bodies with a view to expanding the scope of joint activities in the prevention and control of diabetes;
   • to mobilize the collective resources of the WHO collaborating centres on diabetes.

Thirteenth plenary meeting, 19 May 1989
A42/VR/13
Diagnostic Values for the Oral Glucose Tolerance Test

The oral glucose tolerance test (OGTT) is principally used for diagnosis when blood glucose levels are equivocal, during pregnancy, or in an epidemiological setting to screen for diabetes and impaired glucose tolerance.

The OGTT should be administered in the morning after at least three days of unrestricted diet (greater than 150 g of carbohydrate daily) and usual physical activity. The test should be preceded by an overnight fast of 10–16 hours, during which water may be drunk. Smoking is not permitted during the test. The presence of factors that influence interpretation of the results of the test must be recorded (e.g., medications, inactivity, infection, etc.).

After collection of the fasting blood sample, the subject should drink 75 g of glucose (or partial hydrolysates of starch of the equivalent carbohydrate content) in 250–300 ml of water over the course of 5 minutes. For children, the test load should be 1.75 g of glucose per kg body weight up to a total of 75 g of glucose. Blood samples must be collected 2 hours after the test load; if appropriate, samples may also be taken every half an hour during this period (see section 2.2).

Unless the glucose concentration can be determined immediately, the blood sample should be collected in a tube containing sodium fluoride (6 mg per ml whole blood) and centrifuged to separate the plasma; the plasma should be frozen until the glucose concentration can be estimated. For interpretation of results, refer to Table 1 on page 11.

* Reproduced from WHO Technical Report Series no. 727†
Table 1  Diagnostic values for the oral glucose tolerance test

<table>
<thead>
<tr>
<th></th>
<th>Glucose concentration, mmol/litre (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole blood</td>
</tr>
<tr>
<td></td>
<td>Venous</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>Fasting value</td>
<td>≥ 6.7</td>
</tr>
<tr>
<td></td>
<td>(≥ 120)</td>
</tr>
<tr>
<td>2 hrs after glucose load¹</td>
<td>≥ 10.0</td>
</tr>
<tr>
<td></td>
<td>(≥ 180)</td>
</tr>
<tr>
<td>Impaired glucose tolerance</td>
<td></td>
</tr>
<tr>
<td>Fasting value</td>
<td>&lt; 6.7</td>
</tr>
<tr>
<td></td>
<td>(&lt; 120)</td>
</tr>
<tr>
<td>2 hrs after glucose load¹</td>
<td>6.7–10.0</td>
</tr>
<tr>
<td></td>
<td>(120–180)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ For epidemiological or population screening purposes the 2-hour value after 75 g oral glucose may be used alone of with the fasting value. The fasting value alone is considered less reliable since true fasting cannot be assured and spurious diagnosis of diabetes may more readily occur.
### Sample Patient Registry Format and Coding Instructions

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Coding scheme</th>
<th>Patient Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Today's, date</td>
<td></td>
<td><em><strong>/</strong></em>/<em><strong>/</strong></em></td>
</tr>
<tr>
<td>2.</td>
<td>Service site</td>
<td></td>
<td><em><strong>/</strong></em>/___</td>
</tr>
<tr>
<td>3.</td>
<td>Region</td>
<td></td>
<td>___</td>
</tr>
<tr>
<td>4.</td>
<td>CASID</td>
<td>Case identification number</td>
<td>[<em><strong>/</strong></em>/<em><strong>/</strong></em>]</td>
</tr>
<tr>
<td>5.</td>
<td>DREG</td>
<td>Date of registration</td>
<td><em><strong>/</strong></em>/<em><strong>/</strong></em></td>
</tr>
<tr>
<td>6.</td>
<td>SEX</td>
<td>Sex</td>
<td>[___]</td>
</tr>
<tr>
<td>7.</td>
<td>ETHNIC</td>
<td>Ethnic group</td>
<td>[___]</td>
</tr>
<tr>
<td>8.</td>
<td>DBIRTH</td>
<td>Date of birth (day/month/year)</td>
<td><em><strong>/</strong></em>/<em><strong>/</strong></em></td>
</tr>
<tr>
<td>9.</td>
<td>DMDX</td>
<td>Date diabetes diagnosed (day/month/year)</td>
<td><em><strong>/</strong></em>/<em><strong>/</strong></em></td>
</tr>
<tr>
<td>10.</td>
<td>DMTYPE</td>
<td>Type of diabetes</td>
<td>[___]</td>
</tr>
<tr>
<td>11.</td>
<td>TYPERX</td>
<td>Type of treatment</td>
<td>[___]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = IDDM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = NIDDM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = MRDM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 = GDM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9 = DK</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 = insulin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = oral agent</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = diet only</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 = no treatment</td>
<td></td>
</tr>
<tr>
<td>Key Questions 12-16:</td>
<td>0 = None</td>
<td>1-8 Record Number</td>
<td>9 = No Information</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------</td>
<td>-------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>12. NOSIBS</td>
<td>Number of siblings</td>
<td>[—]</td>
<td></td>
</tr>
<tr>
<td>13. SIBSDM</td>
<td>Number of siblings affected with diabetes</td>
<td>[—]</td>
<td></td>
</tr>
<tr>
<td>14. PARENTDM</td>
<td>Number of affected parents</td>
<td>[—]</td>
<td></td>
</tr>
<tr>
<td>15. NOCHILD</td>
<td>Number of children</td>
<td>[—]</td>
<td></td>
</tr>
<tr>
<td>16. CHILDDM</td>
<td>Number of children affected with diabetes</td>
<td>[—]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key Questions 17-24:</th>
<th>1 = Yes</th>
<th>2 = No</th>
<th>9 = Don’t Know</th>
</tr>
</thead>
</table>

Complication definitions follow on next page

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>DK</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. DKA</td>
<td>History of diabetic ketoacidosis</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>18. NEURO</td>
<td>History of neuropathy</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>19. RETIN</td>
<td>History of retinopathy</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>20. HBP</td>
<td>History of hypertension</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>21. MI</td>
<td>History of MI or open heart surgery for coronary occlusion</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>22. STROKE</td>
<td>History of stroke</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>23. LEA</td>
<td>History of lower extremity amputation</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>24. ESRD</td>
<td>History of end stage renal disease</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Name: _______________________________________
Address: _______________________________________
City: __________________________ State: __________________________
Phone (if available): __________________________
Date patient consent signed: __ __/ __ __/ __ __

Name of another person who will always know your whereabout: __________________________
Name: _______________________________________
Address: _______________________________________
City: __________________________ State: __________________________
Phone (if available): __________________________
Relationship: __________________________
Complication definitions (Examples only)

17. Diabetic ketoacidosis: an acute metabolic condition with an absolute or relative deficiency of insulin, an excess of counter-regulatory hormones and marked hyperglycemia
   Yes if present; no otherwise

18. Presence of neuropathy
   Yes if any one of the following are positive; no otherwise
   - absent ankle reflex
   - decreased discrimination of pin prick, position or vibratory sense in lower extremities
   - complaint of symmetrical numbness, hypersensitivity or burning in feet
   - unexplained sharp, shooting pains along a single limb gastroparesis
   - signs and symptoms (e.g. diarrhoea, atonic bladder, or orthostatic hypotension) thought by MD to be acute neuropathy

19. Presence of retinopathy
   Yes if any one of the following are positive; no otherwise
   - nonproliferative retinopathy – presence of microaneurysms, haemorrhages, hard exudates or cotton wool spots
   - proliferative retinopathy

20. Presence of high blood pressure: past physician diagnosis of high blood pressure and/or blood pressure levels ≥ 140/90 on three occasions
   Yes if present; no otherwise

21. History of myocardial infarction or coronary artery bypass surgery for coronary occlusion
   Yes if present; no otherwise

22. History of stroke; physician diagnosis of a stroke, cerebral infarction or haemorrhage
   Yes if present; no otherwise

23. History of lower extremity amputation; removal of a nonviable portion of a lower extremity
   Yes if present; no otherwise

24. History of end stage renal disease; renal failure requiring dialysis or transplantation for survival
   Yes if present; no otherwise
Annex 4

Tenth Revision of International Classification of Diseases:
Diabetes Mellitus

Chapter IV: Endocrine, Nutritional and Metabolic Diseases (E)

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Note: All neoplasms, whether functionally active or not, are classified in Chapter II. Appropriate codes in this chapter (i.e. E05.8, E07.0, E16–E31, E34,) may be used, if desired, as additional codes to indicate either functional activity by neoplasms and ectopic endocrine tissue or hyperfunction and hypofunction of endocrine glands associated with neoplasms and other conditions classified elsewhere.

$ Excludes: complications of pregnancy, childbirth and the puerperium (000–099) symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00–R99)
Transitory endocrine and metabolic disorders specific to fetus and newborn (P70–P74)

This chapter contains the following blocks:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E00–E07</td>
<td>Disorders of thyroid gland</td>
</tr>
<tr>
<td>E10–E14</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>$E15–E16</td>
<td>Other disorders of glucose regulation and pancreatic internal secretion</td>
</tr>
<tr>
<td>E20–E35</td>
<td>Disorders of other endocrine glands</td>
</tr>
<tr>
<td>E40–E46</td>
<td>Malnutrition</td>
</tr>
<tr>
<td>E50–E64</td>
<td>Other nutritional deficiencies</td>
</tr>
<tr>
<td>E65–E68</td>
<td>Obesity and other hyperalimentation</td>
</tr>
<tr>
<td>E70–E90</td>
<td>Metabolic disorders</td>
</tr>
</tbody>
</table>

Asterisk categories for this chapter are provided as follows:

- E35* | Endocrine disorder in diseases classified elsewhere
- E90* | Nutritional and metabolic disorders in diseases classified elsewhere
Diabetes mellitus (E10–E14)

The following fourth-character subdivisions are for use with categories E10–E14:

.0 With coma

$ Diabetic
  ● coma with or without ketoacidosis
  ● hyperosmolar coma
  ● hypoglycaemic coma

$ Hyperglycaemic coma NOS

Use additional external cause code (Chapter XX), if desired, to identify drug, if drug-induced

.1 With ketoacidosis

$ Diabetic:
  ● acidosis
  ● ketoacidosis (without mention of coma)

.2+ With renal complications
Diabetic nephropathy (N08.3*)
Intracapillary glomerulonephrosis (N08.3*)
Kimmelstiel-Wilson syndrome (N08.3*)

.3+ With ophthalmic complications
Diabetic:
  ● cataract (H28.0*)
  ● retinopathy (H36.0*)

.4+ With neurological complications
Diabetic:
  ● amyotrophy (G73.0*)
  ● autonomic neuropathy (G99.0*)
  ● mononeuropathy (59.0*)
  ● polyneuropathy (G63.2*)
  ● autonomic (G99.0*)

$ With peripheral circulatory complications
Diabetic:
  ● gangrene
  ● peripheral angiopathy + (179.2*)

$ ulcer

.6 With other specified complications
Diabetic arthropathy + (M14.2*)
  ● neuropathic + (M14.6*)

.7 With multiple complications

.8 With unspecified complications

.9 Without complications
E10  **Insulin-dependent diabetes mellitus**  
(see page 000 for subdivisions)

Includes:  
- diabetes (mellitus):
  - brittle  
  - juvenile-onset  
  - ketosis-prone  
  - type I

$  Excludes:  
- diabetes mellitus (in):
  - malnutrition-related (E12.-)
  - neonatal (P70.2)
  - pregnancy, childbirth and the puerperium (024.-)
  - glycosuria:
    - NOS (R81)
    - renal (E74.8)
  - impaired glucose tolerance (R73.0)
  - postsurgical hypoinsulinaemia (E89.1)

Use additional external cause code (Chapter XX), if desired, to identify drug, if drug-induced

E11  **Noninsulin-dependent diabetes mellitus**  
(see page 000 for subdivisions)

Includes:  
- diabetes (mellitus) (nonobese) (obese):
  - adult-onset  
  - maturity-onset  
  - nonketotic  
  - stable  
  - type II  

$  noninsulin-dependent diabetes of the young

$  Excludes:  
- diabetes mellitus (in):
  - malnutrition-related (E12.-)
  - neonatal (P70.2)
  - pregnancy, childbirth and the puerperium (024.-)
  - glycosuria:
    - NOS (R81)
    - renal (E74.8)
  - impaired glucose tolerance (R73.0)
  - postsurgical hypoinsulinaemia (E89.1)

Use additional external cause code (Chapter XX). If desired, to identify drug, if drug-induced.

E12  **Malnutrition-related diabetes mellitus**  
(see page 000 for subdivisions)

$  Includes:  
- malnutrition-related diabetes mellitus:
  - insulin-dependent  
  - noninsulin-dependent
Excludes: diabetes mellitus in pregnancy, childbirth and the puerperium (024.–)
glycosuria:
• NOS (R81)
• renal (E74.8)
impaired glucose tolerance (R73.0)
neonatal diabetes mellitus (P70.2)
postoperative hypoinsulinemia (E89.1)

E13 **Other specified diabetes mellitus**
(see page 000 for subdivisions)

$$ Excludes: \text{diabetes mellitus (in)}:
• insulin-dependent (E10.–)
• malnutrition-related (E12.–)
• neonatal (P70.2)
• noninsulin-dependent (E11.–)
• pregnancy, childbirth and the puerperium (024.–)
glycosuria:
• NOS (R81)
• renal (E74.8)
impaired glucose tolerance (R73.0)
postoperative hypoinsulinemia (E89.1)

E14 **Unspecified diabetes mellitus**
(see page 000 for subdivisions)

Includes: diabetes NOS

$$ Excludes: \text{diabetes mellitus (in)}:
• insulin-dependent (E10.–)
• malnutrition-related (E12.–)
• neonatal (P70.2)
• noninsulin-dependent (E11.–)
• pregnancy, childbirth and the puerperium (024.–)
glycosuria:
• NOS (R81)
• renal (E74.8)
impaired glucose tolerance (R73.0)
postoperative hypoinsulinemia (E89.1)
Annex 5

DIABETES MELLITUS IN EUROPE:
A PROBLEM AT ALL AGES IN ALL COUNTRIES.
A Model for Prevention and Self Care
SAINT VINCENT (ITALY), 10–12 OCTOBER 1989

A Meeting Organized by WHO and IDF in Europe

Diabetes Care and Research in Europe
The Saint Vincent Declaration

Representatives of Government Health Departments and patients organisations from all European countries met with diabetes experts under the aegis of the Regional Offices of the World Health Organisation and the International Diabetes Federation in St. Vincent, Italy, on October 10–12, 1989. They unanimously agreed upon the following recommendations and urged that they should be presented in all countries throughout Europe for implementation.

Diabetes mellitus is a major and growing European health problem, a problem at all ages and in all countries. It causes prolonged ill-health and early death. It threatens at least ten million European citizens.

It is within the power of national Governments and Health Departments to create conditions in which a major reduction in this heavy burden of disease and death can be achieved. Countries should give formal recognition to the diabetes problem and deploy resources for its solution. Plans for the prevention, identification and treatment of diabetes and particularly its complications – blindness, renal failure, gangrene and amputation, aggravated coronary heart disease and stroke – should be formulated at local, national and European regional levels. Investment now will earn great dividends in reduction of human misery and in massive savings of human and material resources.

General goals and five-year targets listed below can be achieved by the organised activities of the medical services in active partnership with diabetic citizens, their families, friends and workmates and their organisations; in the management of their own diabetes and the education for it; in the planning, provision and quality audit of health care; in national, regional and international organisations for disseminating information about health maintenance; in promoting and applying research.

General goals for people – children and adults – with diabetes

• Sustained improvement in health experience and a life approaching normal expectation in quality and quantity.
• Prevention and cure of diabetes and of its complications by intensifying research effort.
Five-year targets

Elaborate, initiate and evaluate comprehensive programmes for detection and control of diabetes and of its complications with self-care and community support as major components.

Raise awareness in the population and among health care professionals of the present opportunities and the future needs for prevention of the complications of diabetes and of diabetes itself.

Organise training and teaching in diabetes management and care for people of all ages with diabetes, for their families, friends and working associates and for the health care team.

Ensure that care for children with diabetes is provided by individuals and teams specialised both in the management of diabetes and of children, and that families with a diabetic child get the necessary social, economic and emotional support.

Reinforce existing centres of excellence in diabetes care, education and research. Create new centres where the need and potential exist.

Promote independence, equity and self-sufficiency for all people with diabetes – children, adolescents, those in the working years of life and the elderly.

Remove hindrances to the fullest possible integration of the diabetic citizen into society.

Implement effective measures for the prevention of costly complications

- Reduce new blindness due to diabetes by one third or more.
- Reduce numbers of people entering end-stage diabetic renal failure by at least one third.
- Reduce by one half the rate of limb amputations for diabetic gangrene.
- Cut morbidity and mortality from coronary heart disease in the diabetic by vigorous programmes of risk factor reduction.
- Achieve pregnancy outcome in the diabetic woman that approximates that of the non-diabetic woman.

Establish monitoring and control systems using state of the art information technology for quality assurance of diabetes health care provision and for laboratory and technical procedures in diabetes diagnosis, treatment and self-management.

Promote European and international collaboration in programmes of diabetes research and development through national, regional and WHO agencies and in active partnership with diabetes patients organisations.

Take urgent action in the spirit of the WHO programme, “Health for All” to establish joint machinery between WHO and IDF, European Region, to initiate, accelerate and facilitate the implementation of these recommendations.

At the conclusion of the St. Vincent meeting, all those attending formally pledged themselves to strong and decisive action in seeking implementation of the recommendations on their return home.
Annex 6

Projecting Annual Outpatient Clinical Services by Area for Individuals with Diabetes

Service Area

Estimated incident cases
A. IDDM
B. NIDDM
C. GDM

Estimated prevalent cases
D. IDDM
E. NIDDM
These recommendations must be tailored depending on the individual, risk factors, presence of complications and coexisting conditions.

<table>
<thead>
<tr>
<th>Recommended Service</th>
<th>Annual Frequency Visits</th>
<th>Estimated Service Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New Patients</td>
<td>Continuing Patients</td>
</tr>
<tr>
<td>IDDM</td>
<td>IDDM</td>
<td>NIDDM</td>
</tr>
<tr>
<td>Extensive history &amp; physical</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Comprehensive history &amp; physical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary provider brief encounter</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Est. special symptomatic care units</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other Health Providers service</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>BP, Wi (if Juvenile Ht &amp; Growth)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye exam</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Foot exam</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dietary education</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Patient self care education</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Laboratory services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RBO or FPG</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Glb</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Lipid profile</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Serum creatinine</td>
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<td>1</td>
</tr>
<tr>
<td>UA/urine protein</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>T4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>EKG (in adults)</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Based on ADA's standards of Medical care for Patients with Diabetes Mellitus.
Outline of a National Diabetes Programme Plan*

1. Executive summary

The executive summary is a 2–3 page succinct description of the major programme priorities and resources needed for their achievement. This may include the following:

- the national health policy positions on diabetes or chronic diseases and an estimate of the annual national health budget allocated to diabetes and other chronic diseases
- the national health service delivery configuration
- an overview of the diabetes problem in the country
- a list of goals and objectives for dealing with the diabetes problem ranging from the national to the local level
- the programme's proposed organizational structure including location within the agency, the national diabetes advisory committee, plans for international consultants and an assessment of whether the current national health infrastructure can support the proposed programme
- barriers to achieving the objectives such as fiscal, manpower, equipment and proposed remedies
- an estimate of the financial resources required for the programme for years one to five. This includes a summary of expenditures specifying initial start-up costs, recurrent costs and summarizing projected revenue sources, e.g. national government, fee-for-service or other external support

2. Cover page with programme title

3. Table of Contents

4. Country profile at a glance

A two page summary of the country’s demography, geography, economy and cultural characteristics, including a map
5. List of abbreviations and definitions

A list of abbreviations and definitions of specialist terms used in the text should be included.

6. Overall programme goals and objectives

Based on a brief description of the problem, formulate a measurable objective quantifying to the extent possible both the current situation and the proposed situation

- long-term objectives
- intermediate/medium-term objectives

7. Specific strategies to achieve each objective

Each objective may utilize multiple strategies and at differing times. Therefore each strategy should be indicated with time and cost estimates. Activities common to all or to several strategies, such as employment and training of personnel for para-professionals, teams, units or centers could be combined in a section titled “common support activities.”

8. The information system to link together the programme planning, management, implementation, surveillance and evaluation

9. Time frame

Plot the time anticipated for each objective and strategy using a Gantt chart as illustrated below.

Example of Gantt Chart

```
1/92  1/93  1/94  1/95  1/96  1/97

Objective 1
Strategy A...
Strategy B...
Strategy C...

Objective 2
Strategy A...
Strategy B...

Objective 3
Strategy A...
Strategy B...
Strategy C...
Strategy D...
Strategy E...
```
10. Evaluation

Plans for ongoing evaluation for management purposes and periodic detailed evaluation for reprogramming purposes

11. Detailed Budget

11.1 Expenditures

<table>
<thead>
<tr>
<th>Expenditure</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>Initial start-up costs</td>
<td></td>
</tr>
<tr>
<td>Personnel</td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td></td>
</tr>
<tr>
<td>Current expenses (examples)</td>
<td></td>
</tr>
<tr>
<td>medical equipment</td>
<td></td>
</tr>
<tr>
<td>educational supplies</td>
<td></td>
</tr>
<tr>
<td>computer equipment</td>
<td></td>
</tr>
<tr>
<td>Recurrent costs</td>
<td></td>
</tr>
<tr>
<td>Personnel</td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td></td>
</tr>
<tr>
<td>Current expenses (examples)</td>
<td></td>
</tr>
<tr>
<td>medical equipment</td>
<td></td>
</tr>
<tr>
<td>supplies</td>
<td></td>
</tr>
<tr>
<td>pharmaceuticals</td>
<td></td>
</tr>
<tr>
<td>educational supplies</td>
<td></td>
</tr>
<tr>
<td>specific strategies</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

11.2 Revenue

<table>
<thead>
<tr>
<th>Source</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>National government</td>
<td></td>
</tr>
<tr>
<td>Fee-for-service</td>
<td></td>
</tr>
<tr>
<td>External support</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

The budget for year one should include costs for each objective and strategy and an overall estimate of the cost for professional workers, teams, units and centers.

*Adapted from WHO AIDS Series 1 Guidelines for the development of a national AIDS prevention and control programme (1988).
Figure 5

Gantt chart indicating hypothetical timelines for planning and implementing a national programme for diabetes mellitus

1. Decision to plan a national programme
2. Assemble planning group(s)
3. Determine timeframe and approach
4. Situational analysis
   (4.1.1 to 4.1.8)
   Situational analysis
   (4.1.9)
   Develop diabetes advisory committee (4.2.1)
   Develop programme infrastructure (4.2.2)
   Develop teams, units and centres (4.2.3)
   Develop programme priorities (4.2.4)
   Submit programme for approval and resources
   Governmental approval
5. Preparing to implement the programme e.g. finalize agreements personnel, facilities...
   Phase-in implementation and delivery of patient care
   Programme operation
   Programme surveillance
   Programme evaluation

Months
1  6  12  18  24