American University of Armenia
Department of Public Health

Education Program for Non-Insulin-Dependent (Type-2) Diabetes Mellitus Patients, aged 40-45, in Yerevan and Evaluation of the Program

MPH Thesis Project
Community Service Grant Proposal Framework

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Executive Summary

Diabetes education programs are widely implemented in many countries and have scientific evidence of their success.

The objective of this paper is to propose implementation and evaluation plan of an education program for patients with Diabetes Mellitus (DM) Type-2, aged 40-45, in Yerevan.

DM is a great public health problem in Armenia. It is considered as a serious public health problem, posing a significant burden in mortality, morbidity and cost. Deaths from Diabetes Mellitus (DM) are mostly due to its complications. The prevalence of DM among adults and teenagers was 1237.2 per 100,000 population and the death rate was 31.78 per 100,000 population in Armenia in 1998. The absolute registered number of diabetic patients was 34,761. An increase is registered in death rates during the last 10 years, which grew from 11.72 in 1988 to 31.78 per 100,000 population in 1998; incidence rates grew from 65.2 in 1994 to 86.5 per 100,000 population in 1998.

The increasing burden of DM and its complications is alarming. But much of this burden can be prevented with behavioral changes, education for self-management, self-control of diabetes. All of the above mentioned prove the existence of an urgent need for diabetes prevention programs in Armenia. Self-control and monitoring of blood glucose are the key elements in this education program, stressing low caloric intake, control of body weight, and control of blood glucose by physical activity. The program emphasizes prevention by behavioral and knowledge changes. This education program aims: 1) to prevent such complications of diabetes, as diabetic retinopathy, neuropathy, nephropathy and ischemic heart disease; 2) to reduce mortality and disability from diabetic complications; 3) to gain additional years of life; 4) to improve the quality of life among diabetic patients; 5) reduce expenditures for medical care. Four endocrinologists will conduct this program for 272 patients. Ten lessons will be conducted with 10-11 patients in each group.

Quasi-Experimental design was chosen for program evaluation. It involves an intervention (IG) and control (CG) groups, both given a pre-test and a post-test, but in which the CP and IP do not have pre-experimental sampling equivalence. Simple random sampling will be used to select each sample group. The sample frame for each group will be the list of diabetic patients type-2, aged 40-45, living in Yerevan, having a history of registered DM equal or less than 12 months, registered in that polyclinic. Each sample will be drawn randomly, using random start. Randomly will be drawn numbers between last and first ones on the list, sampling without replacement, using random digit tables.

The total budget for this proposal will be $ 38,752.21.
Specific Aims / Objectives

The following proposal is aimed to implement and evaluate the Education Program for non-insulin dependent (type 2) diabetic patients, aged 40-45, in Yerevan. The program's goals are:

- prevention of complications in diabetic type-2 patients
- reduction of mortality and disability from diabetic complications
- gaining additional years of life
- improvement in quality of life among diabetic patients
- reduction of expenditures for medical care.

Deaths from Diabetes Mellitus (DM) are mostly due to its complications. Such risk factors were emphasized for diabetic complications as sedentary lifestyle, physical inactivity, high caloric intake, obesity, high blood pressure, smoking, alcohol intake and high blood glucose levels. The program emphasizes prevention of diabetic complications by behavioral and knowledge changes. Among behavioral factors, priority was given to such high-risk behaviors as sedentary lifestyle, physical inactivity and high caloric diets. Persons with diabetes should learn how to

- Monitor their blood glucose.
- Negotiate a meal plan with a dietitian.
- Achieve and maintain recommended exercise/activity levels.
- Adjust their insulin as needed (if applicable).
- Prevent hypoglycemia, neuropathy, retinopathy, nephropathy and cardiovascular complications.

The program’s objectives are as follows:

**Impact Objectives:**

1. 1 year from the end of the program, the difference of the mean knowledge score in the group of diabetic type-2 patients, aged 40-45, living in Yerevan, who attended education classes will be at least 10% higher compared to the mean knowledge score in the group of patients who did not attend education classes.

2. 1 year from the end of the program, the proportion of diabetic type-2 patients, aged 40-45, self-controlling blood glucose levels by changing diet and physical activity and passed education classes will be on 15% higher compared to those patients who self-controlled blood glucose by diet and physical activity but did not passed education classes.

The indicators for impact objectives will be correspondingly 1) the mean knowledge score changes, regarding diet and physical activity, and 2) the proportions of diabetic type-2 patients, aged 40-45, self-controlling blood glucose levels by changing diet and physical activity, aged 40-45, living in Yerevan.
Outcome objectives:

1. 3 years from the end of the program, the prevalence of diabetic retinopathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who attended education classes will be at least 30% lower compared to the prevalence of retinopathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who did not attend education classes.

2. 3 years from the end of the program, the prevalence of diabetic neuropathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who attended education classes, will be at least 20% lower compared to the prevalence of neuropathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who did not attend education classes.

3. 3 years from the end of the program, the prevalence of diabetic nephropathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who attended education classes will be at least 20% lower compared to the prevalence of nephropathy among type-2 diabetic patients, aged 40-45, living in Yerevan, who did not attend education classes.

4. 3 years from the end of the program, the prevalence of Ischaemic Heart Disease (IHD) among type-2 diabetic patients, aged 40-45, living in Yerevan, who attended education classes, will be at least 20% lower compared to the IHD among type-2 diabetic patients in control group who did not attend education classes. The indicators for outcome objectives will be correspondingly the prevalence of retinopathy, neuropathy, nephropathy, IHD among diabetic type-2 patients, aged 40-45, living in Yerevan.

Background

According to the WHO definition of Diabetes Mellitus in the untreated state “it is recognized by chronic elevation of the concentration of glucose in the blood (hyperglycemia)”\(^1\). DM comprises an etiologically and clinically heterogeneous group of hyperglycemic disorders. The term diabetes describes either a deficiency of insulin or a decreased ability of the body to use insulin, a hormone secreted by the pancreas. Insulin allows glucose (sugar) to enter cells and be converted to energy. Insulin is also needed to synthesize protein and store fats. In uncontrolled diabetes, glucose and lipids (fats) remain in the bloodstream and, with time, damage vital organs and contribute to heart disease.

There are two major types of DM: insulin - dependent DM (Type 1) and non-insulin- dependent DM (NIDDM - Type 2). NIDDM is the most common form, affecting 90% - 95% of diabetes patients, and appears after the age of 40\(^2\). DM is considered as a serious public health problem, posing a significant burden in mortality, morbidity and cost \(^3\). It is the seventh leading cause of death in the US, contributing to more than 193,000 deaths each year\(^3\). More than 18% of adults in the US over age 65 have diabetes\(^3\).

Disability and death in NIDDM result from the degenerative complications of the disease. Diabetes leads to such complications as diabetic retinopathy, neuropathy, nephropathy, ischaemic heart disease, stroke, gangrene, blindness, kidney failure, amputations\(^3\). In the US, DM is the leading...
cause of blindness in adults 20-74 years old, of end-stage kidney failure, gangrene, myocardial infarction and stroke\textsuperscript{4}. In the US, each year about 12,000 to 24,000 diabetic people become blind, 28,000 develop kidney failure, 67,000 undergo lower-extremity amputations\textsuperscript{3}. People with diabetes are 2 to 4 times more likely to develop heart disease or stroke than people without diabetes. According to the American Diabetes Association, the nation spent more than $ 98 billion on diabetes in 1997, on direct and indirect costs\textsuperscript{3}, the costs related to undiagnosed diabetes are unknown.

DM is a great public health problem in Armenia as well. Data taken from the Ministry of Health show, that ,in 1998, the absolute registered number of diabetic patients among adults and teenagers was 34,761 cases. There are recorded high prevalence (1237.2 per 100,000 population), death rates (31.78 per 100,000 population) of DM, ( see table 1, Appendix1); an increase in incidence rates during recent years ( from 65.2 in 1994 to 86.5 per 100,000 population in 1998 ), and an increase in death rates (from 11.72 in 1988 up to 31.78 per 100,000 population in 1998).

The actual number of diabetics is believed to be higher. During the last years, the attendance of patients in hospitals and polyclinics was reduced due to the fee issue, so it can be assumed that there are high numbers of undiagnosed cases.

Many of these diabetics are not in a position to buy medicine, dietary food, and means of diagnostics. Many seek professional aid only in case of severe decompensation. The population of Armenia in 1998 was estimated as 3,794,700 which in fact is less due to migration. Taking into consideration the underestimation of the numerator and the overestimation of the denominator, it can be assumed that the prevalence of DM is much higher in Armenia.

The increasing burden of DM and its complications is alarming. The number of cases of DM worldwide is expected to rise more than twofold during the next twenty-five years\textsuperscript{5}, By 2025, there will be 300 million people with diabetes worldwide But much of this burden can be prevented with behavioral changes, education for self-management, self-control of diabetes. The Saint Vincent Declaration outlined goals to reduce diabetes-related amputations by 50% and blindness by 30 % by the year 2000.

The following interentions shown in the literature\textsuperscript{2} can prevent the burden of this disease:

- Community based screening for DM
- Early detection and treatment of diabetic complications among diabetic patients
- Education programs for diabetic patients.

Taking into consideration the available resources, cost-effectiveness of each strategy, easiness of its implementation, the bad socio-economic conditions of patients in Armenia ( fee issue), the education intervention is the more preferable one. It is essential to organize such education.

Many patients are unaware of the methods of self-controlling and treating diabetes. All of the above mentioned prove the existence of an urgent need for a diabetes prevention program in Armenia. Much of this burden can be prevented by the provision of education programs for self-
management, self-control of diabetes, promoting lifelong physical activity and healthy eating among young people. Much of the burden of this major public health problem can be prevented with better education for diabetes self-management and early detection of complications.

Early detection and treatment can prevent 90% of blindness. At least half of the new cases of diabetes-related kidney failure could be prevented each year. Over half of the amputations could be prevented. The Maine Diabetes Control Program arranged a diabetes outpatient education program in more than 30 hospitals and health centers, resulting in a 32% reduction in hospital admissions in a 3 year period. Participants of the Michigan Diabetes Control Program experienced a 45% lower rate of hospitalizations, a 31% lower rate of lower-extremity amputations, and a 237% lower death rate compared with nonparticipants.

The correction of the metabolic and hormonal abnormalities of type-2 diabetes may prevent or retard the development of complications. Both heredity and environment are believed to be important in the etiology of NIDDM. Differences between ethnic groups may be attributable to a genetic risk for NIDDM, while differences within an ethnic group may be attributable to environmental factors. The high prevalence of NIDDM among Micronesians of NAURU (34%) and Pima Indians of Arizona (40%), appears to be a relatively recent development that followed a change in the pattern of food intake. This change from the chronic caloric deprivation to caloric abundance led to an increase of obesity and diabetes among this population. A similar phenomenon of urbanization has been described in the Pacific Islander and Australian aboriginal. Presumably the changes in lifestyle result in obesity which facilitates predisposition for NIDDM. Obesity induces insulin resistance which can convert normoglycemic persons into hyperglycemic patients. Among Japanese Americans in Seattle, Washington, those persons with NIDDM were found to be consuming a diet that was significantly higher in animal fat and animal protein and lower in carbohydrate than were persons with normal glucose tolerance. Since weight gain is important in the pathogenesis of insulin resistance, prevention of it through dietary measures and exercise should be at the cornerstone of NIDDM prevention. Regular physical activity reduces the risk of dying from coronary heart disease and high blood pressure, helps to control blood glucose and weight, and increases insulin sensitivity. Control of stress, smoking, weight and high caloric intake, hypercholesterolemia, blood pressure slow the development of cardiovascular complications of DM, prevent gangrene, mortality from myocardial infarction. A 2 year randomized prospective study suggested that intensive glucoregulation prevented deterioration of renal and sensory nerve function.
Nodular glomerulosclerosis was present in 53% of hyperglycemic Pima Indians, but has never been demonstrated in a normoglycemic Pima\textsuperscript{14}. Diabetic microangiopathy (glomerulosclerosis\textsuperscript{15} and retinopathy\textsuperscript{16}) rarely occurs in the absence of the diabetes metabolic abnormalities. Avoidance of alcohol consumption, physical injury to nerves can prevent peripheral polyneuropathy. Prevention of trauma will prevent foot ulcer and amputations\textsuperscript{4}.

Thus self-control and monitoring of blood glucose are the key elements in education of diabetes, stressing the low caloric intake, controlling of body weight, and physical activity.

**Methodology.**

*Program metodology*

The learning process is based on patient-centered strategy. Small groups will be formed with 10-11 patients in each. The education materials should be provided in a form of handouts, lectures and video tapes. The interaction with patients during the lecture should be very active, instructor will ask questions and interact with each patient during the lecture. The home tasks, written assignments, distribution of written answers (see Table 2. Appendix 3) will help in understanding the education materials for each patient. Demonstration of video educational films about each topic will emphasize the content of the lecture. Quizzes, written assignments will identify the results of the education process.

*Education Course Objectives:* After completing the whole course, the successful patient will be able:

- To design diabetic diet and caloric needs of the body for different levels of physical activity;
- To change diabetic diet and level of physical activity according to the levels of blood glucose;
- To know the basic issues of Carbohydrate Counting, the method of “Exchange Lists”;
- To know the rules of insulin therapy, risks of it, types and acting duration of each type of insulin;
- To explain the risk factors of diabetic neuropathy, nephropathy, retinopathy, cardiovascular complications;
- To explain the prevention guidelines for foot ulcers, blindness, foot amputations;
- To explain the detection, prevention, management of such diabetic acute complications, as Diabetic Ketoacidotic Coma (DKC), Hyperosmolar Coma, Hypoglycemia;
- To explain the short-term and long-term effects of Hyperglycemia.

*Course content:* (see Appendix 2, “Education Program”)

For each group there will be 10 lessons, 1 lesson each day conducted by class instructor (endocrinologist). Each lesson will last 1 hour for each group. The syllabus will be: (Table 2. Appendix 3).

*Lesson 1: The Diabetic Diet, body caloric needs.*

*Lesson 2: The Carbohydrate Counting and Exchange Lists.*

*Lesson 3. The changes in diet and levels of physical activity according to the blood glucose levels.*

*Lesson 4: The Insulin therapy, the rules, and risks of it, types of insulin, storage, Hypoglycemia.*
Lesson 5. The early detection, prevention and management of acute diabetic complications.
Lesson 7. The risk factors for diabetic nephropathy.
Lesson 8. The risk factors for diabetic retinopathy.
Lesson 10. The prevention of foot ulcers and amputation.

Course Content organization: (see the table 2. On Appendix 3).

Evaluation methodology

The most powerful type of design to assess the impact of the intervention is an experimental design. Specifying program goals and objectives, the goal oriented evaluation approach will be used. The evaluation question will be: “Does the program:

- affect the knowledge regarding diabetic diet intake, physical activity and other risk factors for complications?
- affect the prevalence of retinopathy, neuropathy, nephropathy, and ischaemic heart disease?

Such an approach has a disadvantage; it can miss unintended consequences. To assess the amount of difference in means and proportions quantitative research will be conducted, answering objectively to "How many".

Random assignment of subjects to intervention/education group will establish comparability between 2 groups, prevent biases and control confounders. In order to assess the real impact of this intervention it is essential to avoid the dissemination of the education information among the control group patients. That is why the polyclinic for intervention will be assigned but not randomly selected. It will be one located in a district of the city. In case of lacking the full experimental control over the ability to randomize assignment to intervention Quasi-Experimental design in preferable. Nevertheless there are only 4 endocrinology departments in Yerevan and it is expected that patients during a one year - program period could become patients of these hospitals and disseminate the education information among controls, but this probably will be small, and insignificant. The intervention should be assigned to a polyclinic, located in one district of Yerevan, and the control polyclinic should be in another district, far from the first, avoiding dissemination of information.

Quasi-Experimental Non-equivalent Control Group Design model is represented:

<table>
<thead>
<tr>
<th>Intervention</th>
<th>0₁</th>
<th>x</th>
<th>0₁'</th>
<th>0₁''</th>
<th>0=observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyclinic (IP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x= education program</td>
</tr>
<tr>
<td>Control Polyclinic (CP)</td>
<td>0₂</td>
<td>0₂'</td>
<td>0₂''</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Baseline data  after 1 year  after 3 years
It involves an intervention and control group. Both will be given a pre-test and a post-test, but the CP and IP will not have pre-experimental sampling equivalence.

The first consideration in sampling a universe for study is that it should be representative of the population about which information is required: the distribution of risk factors, different levels of socio-economic situation. Probability sampling design would be chosen to maximize heterogeneity and representativeness of the sample, to increase external validity of the study, to minimize systematic errors and costs. But such design does not guard against the possibility of getting a "bad", unrepresentative sample. Random sampling will give to every eligible individual an equal chance of being selected, however this method is labor intensive. Simple random sampling will be used to select each sample group. The sample frame for each group will be the list of diabetic patients type 2, aged 40-45, living in Yerevan, having a history of registered DM equal or less than 12 months, registered in that polyclinic. Each sample will be drawn randomly, using random start. Randomly will be drawn numbers between last and first ones on the list, sampling without replacement, using Random Digit Tables.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention group</strong></td>
<td>Patients, who have NIDDM, aged 40-45, having duration of DM less or equal to 12 months, living during the last 3 years in Yerevan, being registered in polyclinic assigned to intervention group.</td>
</tr>
<tr>
<td><strong>Control group</strong></td>
<td>Patients who have NIDDM, aged 40-45, having duration of DM less or equal to 12 months, living during the last 3 years in Yerevan, being registered in polyclinic which was assigned to control group.</td>
</tr>
</tbody>
</table>

The dependent variables for each objective will be:

**Impact**

**Objectives:**

No. 1. Behavioral risk factors related knowledge level (mean knowledge score)

Indicator will be mean knowledge score in each group of patients.

No. 2 Proportion of patients self-controlling blood glucose by changes in diet and physical activity. Indicator will be proportion of diabetic patients type-2, aged 40-45, living in Yerevan and self-controlling blood glucose by diet and physical activity. Numerator is number of self-controlling patients in each group, denominator will be the total number of patients in each group.

**Outcome**

**Objectives:**

No. 1. Prevalence of neuropathy

No. 2. Prevalence of nephropathy
No.3. Prevalence of retinopathy
No.4. Prevalence of Ischaemic Heart Disease

Numerators will be correspondingly numbers of patients with retinopathy neuropathy, nephropathy, IDH, in each group, while denominators will be the total number of patients in each group.

The Independent variable is the education program itself.

The Confounders that could affect the true outcome of the intervention are as follows;

- **SES**
  availability of information sources, diabetic diet, laboratory tests, drugs;
- **Age**
  age is a risk factor for developing diabetes complications;
- **Initial body mass index**
  obesity is a risk factor for cardiovascular disease, cerebral stroke, gangrene of lower extremities.
- **Smoking**
  is a risk factor for cardiovascular disease, cerebral stroke, gangrene of lower extremities.
- **Physical activity**
  passive life-style is a risk factor, increases predisposition to cardiovascular complications, hypercholesterolaemia, or other diseases, precipitates onset of complications.
- **Gender**
  is a risk factor for several complications(M-gangrene, F-CHD)
- **Education**
  the scientific literature is more available for educated patients.

Patients in control group may have similar information due to qualified endocrinologist in the polyclinic, but this is not expected to be systematic and broad. The first post-test will be done after one year from the beginning of the program, during the same month as the pre-test, using the same questionnaire; the second post-test after 3 years from the beginning. Before the intervention the baseline data will be collected by questionnaire to assess:

- The knowledge regarding the behavioral risk factors in each group
- The proportion of patients is each group self-controlling blood glucose by diet and physical activity.

Data to be collected by questionnaire include basic demographic information, (age, gender, education) medical history, lifestyle risk factors (smoking, alcohol intake). Every correct answer would have 3 scores, and the mean knowledge score would be calculated. Laboratory tests, physical examination will be performed in each group to assess:

- **Physical activity levels**- moderate activity would be defined as 30 minute of brisk walking five or more times a week. (would be assessed by asking: ”On average, in a week, how many times do you walk 30 minutes?”).
- **Initial body mass index**-
BMI = \frac{\text{weight(kg)}}{\text{height(m}^2\text{)}}

Weight will be measured by a mechanical traditional beam balance, applying correction for clothing. Height should be measured without shoes with the subject standing fully erect on a flat surface, heel buttock shoulders flat to the wall and looking straight ahead. 

- **Blood pressure levels** - measured after 5-minute rest period in the right arm using a standard mercury sphygmomanometer. Systolic pressure is recorded at the first appearance of sounds, diastolic one at the disappearance of sounds. Normal range is less than 140 mm Hg systolic and 90 diastolic pressure for Armenia. After 30 seconds the measurements will be repeated.

- **Glycosylated hemoglobin HbA\textsubscript{1c} levels** - the levels correlate with the fasting serum glucose levels\textsuperscript{18,19}. Will be measured by high performance liquid chromatography\textsuperscript{5} (normal range is 4.5 - 6.2%).

- **Urinary albumin levels.**

- **12-lead electrocardiogram.**

The following diabetic complications will be recorded in baseline data. The diagnostic criteria are defined in order to avoid misclassification.

- **Diabetic nephropathy** - can be diagnosed in a case of persistent albuminuria (any level), presence of diabetic retinopathy\textsuperscript{30}.

- **Diabetic retinopathy** - will be diagnosed in a case of one or more microaneurysm in one eye, or its progression as a two-step change in grade. Direct ophthalmoscopy with pupil dilation will be carried out.

- **Diabetic neuropathy** - in a case of either both ankle or both knee reflexes loss.

- **Ischaemic Heart Disease** - based on WHO clinical criteria for IHD and confirmed by electrocardiographic abnormalities (Q waves, left bundle branch block, ST-T changes), recorded angina pectoris, myocardial infarction, heart failure\textsuperscript{5}.

The first post-test should be performed after 1 year from the end of the intervention, using the same questionnaire in 2 groups, assessing only impact outcomes. The second post-test data collection will be done after 3 years from the end of intervention, by physical examination and laboratory tests. It will include only data on prevalence of diabetic neuropathy, retinopathy, nephropathy, IHD and death rates (diabetes-related and from other causes). The measurement tools should be the same laboratory tests and physical exams as for the baseline data collection.

The mechanical beam balance should be checked each day with a standard weight (not lighter than the average weight of subjects to be examined), sphygmomanometers should be checked for accuracy every day, may be rotated between observers to prevent reader bias. To prevent misclassification bias the definitions of diagnostic criteria are given. To prevent non-response bias non-responders will be given a chance to be examined on weekends. The use of a standardized questionnaire, training of
interviewers, will reduce interview bias. Non – responders will be visited in their homes in the evenings to determine the nature of differences in distribution of age, gender in 2 groups, causes for not being interviewed. To control coverage error is essential to eliminate the appearance of subjects several times in the frame sample.

The same objective measures should be employed in the 2 groups in the diagnostic process to avoid subjective judgments of the respondents, to prevent surveillance bias. Some in the control group may have a similar type of information but it is not expected to be broad, systematic (contamination).

The sample size will be computed so that the probability of obtaining a significance level will be \( P=0.9 \). To determine the sample size for 2 samples whose mean knowledge level are to be compared, setting \( \alpha=0.05(Z_\alpha=1.64); \beta=0.1 \) (power 90%, \( Z_\beta=1.28 \)) the following formula will be used:

\[
n = \frac{(Z_\alpha + Z_\beta)^2 \sigma^2}{\Delta^2} = \frac{(1.64 + 1.28)^2 \times 15^2}{10^2} = 38.7 \approx 39
\]

assuming that sample standard deviations are equal \( \sigma_1=\sigma_2=\sigma \); sample sizes are equal \( n_1=n_2=n \). Assume that \( \sigma=15 \) (have no data from pilot sample or literature for Armenia), the total knowledge score will be 100, therefore 10% difference will result in 10 units difference: \( \Delta=d_i - d_c=10 \). The sample size for each group will be 39 for 1 – tailed test (change towards one direction, mean scores increase). In a case of \( \beta=0.2 \) (\( Z_\beta=0.84 \)) \( n=28 \).

To determine the sample size for 2 samples whose proportions are to be compared, setting \( \alpha=0.05(Z_\alpha=1.64); \beta=0.1 \) (power 90%, \( Z_\beta=1.28 \)), the formula is to be used,

\[
n = \frac{(Z_\alpha + Z_\beta)^2 2P(1-P)}{\Delta^2} = \frac{(1.64 + 1.28)^2 \times 0.5 \times 0.5}{0.15^2} = 189.7 \approx 190
\]

\( P \) is assumed to be 0.5 to produce maximal sample size, since proportion is unknown.

For impact objective #2, to detect 15% difference (\( \Delta=0.15 \)) in proportion of people self–controlling blood glucose, the size needed for each group will be \( n=190 \), (1-tailed test). In a case of \( \beta=0.2 \) (\( Z_\beta=0.84 \)) \( n=137 \). To detect 30% decrease in retinopathy in each group sample size will be \( n=48 \), to detect 20% lower neuropathy, nephropathy and CHD \( n=107 \).

The biggest number is \( n=190 \). After adjustment for expected response rate of 70% sample size is:

\[
n = \frac{190 \times 100}{70} = 271.4 \approx 272
\]

**Threats to design**

The internal and external validity determine the strengths and limitations of design. The more external validity, the more the generalizability of program effects. The more the comparability of groups, the more the internal validity of the design. There are 12 factors jeopardizing validity. 

13
Table 3. Threats to Internal and External Validity

<table>
<thead>
<tr>
<th>Threat</th>
<th>Yes +</th>
<th>No -</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>+</td>
<td></td>
<td>Other possible education programs between measurements can affect outcome during the program period.</td>
</tr>
<tr>
<td>Maturation</td>
<td>-</td>
<td></td>
<td>Systematic psychological or biological changes among the study population due to the passage of time (growing older, will occur equally in both groups.)</td>
</tr>
<tr>
<td>Testing</td>
<td>-</td>
<td></td>
<td>The pre-intervention testing can enforce patients to get answers to questions, but it will occur equally in 2 groups.</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>-</td>
<td></td>
<td>The instrument, diagnostic criteria, the location (CP) for pre- and post-testing are the same.</td>
</tr>
<tr>
<td>Statistical regression</td>
<td>-</td>
<td></td>
<td>The testing population is not selected due to extreme characteristic, which will “regress” back towards the population mean.</td>
</tr>
<tr>
<td>Selection bias</td>
<td>+</td>
<td></td>
<td>Intervention and comparison groups may differ in characteristics (education, availability of information sources, quality of providing health care in polyclinic)</td>
</tr>
<tr>
<td>Attrition or experimental mortality</td>
<td>+</td>
<td></td>
<td>The likelihood of dropping out of program can be different in the 2 groups due to emigration and other causes.</td>
</tr>
<tr>
<td>Interaction of Selection</td>
<td>+</td>
<td></td>
<td>The participant patients of IG can be motivated</td>
</tr>
<tr>
<td>Testing- Program</td>
<td>+</td>
<td></td>
<td>The pre – test can increase the target population’s sensitivity to the program.</td>
</tr>
<tr>
<td>Selection- Education Interaction</td>
<td>+</td>
<td></td>
<td>The outcome data can not be generalized for Armenia. The characteristics of target population of Yerevan differ from those in districts (education level, access to information).</td>
</tr>
<tr>
<td>Reactive – situational effects of experimental procedures</td>
<td>+</td>
<td></td>
<td>The “aura” surrounding the program evaluation could affect the observed impact objectives</td>
</tr>
<tr>
<td>Multiple Program Interference</td>
<td>-</td>
<td></td>
<td>No other program is expected to be done.</td>
</tr>
</tbody>
</table>

It is very essential to anticipate sources lowering reliability and prevent them. The more the reliability of measuring instrument, the more consistent the results on repeated measurements. To increase the inter–rater reliability, each patient will be examined by 2 ophthalmologists, 2 neuropathologists.
Table 4. Sources lowering reliability and prevention of them

<table>
<thead>
<tr>
<th>Sources</th>
<th>Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>Questions will be in a form to get objective, truthful answers.</td>
</tr>
<tr>
<td>Observer/Rater/Interviewer</td>
<td>Choosing appropriate data collectors, training them. Confirmation of each diagnosis by 2 different persons (same specialists) for each patient.</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>Questionnaire: pre-tested, good worded, understandable.</td>
</tr>
<tr>
<td></td>
<td>Diagnostic procedures: criteria are defined for each diagnosis to prevent random error.</td>
</tr>
<tr>
<td></td>
<td>Laboratory test: The same tests will be performed during the base line and II post-test data collection, using the same criteria.</td>
</tr>
<tr>
<td></td>
<td>Sphygmomanometers mechanical beam balance will be rotated every day.</td>
</tr>
<tr>
<td></td>
<td>mechanical beam balance should be checked.</td>
</tr>
</tbody>
</table>

Implementation Synopsis

The program is planned for 3 years, to be held in Yerevan. It is addressed to the Ministry of Health and Non–Governmental Organizations (Red Cross, UMCOR, and UNICEF) for funding and staff support. The Project Coordinator will coordinate the steps of the Program.

The education program is represented in Appendix 2. It is based on the WHO guidelines for prevention of diabetes complications such as neuropathy, retinopathy, nephropathy, CHD, comas (ketoacidotic and hypoglycemic). This program emphasizes changes in such behavioral risk factors as smoking, alcohol intake, high caloric diet, obesity, physical inactivity, bad control of hypertension, hyperglycemia. Patients will be informed about the significance of normal levels of glycosylated haemoglobin (Hb A₁c). This program provides guidelines for both health care providers and patients, how to change diet, levels of physical activity, control body weight. Every patient will receive lectures and education materials every day, be lectured by class instructor/endocrinologist. Such classes will take place in intervention polyclinic (room can be rented in a neighborhood house). There will be quizzes after the 3, 6, 8, lessons, and a final one after the last lesson. (see table 2. Appendix 3). After each quiz the answers will be distributed to patients, and if there are any questions they will get answers after the lessons. The instructor will control the self-monitoring of patients for each month during 3 years, by the results of blood glucose levels. Each patient will keep a diary for each day, / what were medications (type, dosage), diet and level of physical activity/. Then special instructions will be given to each patient by the instructor, after being checked, during each visit.
(once, twice a week) The patients will be followed up during 3 years, by the instructors, (telephone contact, visiting, diaries).

Each instructor will have 4 courses. The first 3 will have 7 groups (70 patients for each instructor), and the fourth will have 6 groups (62 patients in 6 groups). After completing the first one in 11 days for 2 groups they will begin it for another 2 groups. The education courses duration for each instructor will be 44 days. /7×10×3+4×10+2×11=272 /.

Table 5. The timetable for 4 instructors will be:

<table>
<thead>
<tr>
<th>Instructor</th>
<th>1st “44 days”</th>
<th>2nd “44 days”</th>
<th>3rd “44 days”</th>
<th>4th “44 days”</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Instructor</td>
<td>7 gr.(2+2+2+1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second Instructor</td>
<td></td>
<td>7 gr.(2+2+2+1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Third Instructor</td>
<td></td>
<td></td>
<td>7 groups</td>
<td></td>
</tr>
<tr>
<td>Fourth Instructor</td>
<td></td>
<td></td>
<td></td>
<td>6 groups</td>
</tr>
</tbody>
</table>

The duration of the whole education program will be 176 days (with Sundays). (see table 7).

The project coordinator will manage the whole process.

Table 6. The timetable for one instructor for one course will be the following:

<table>
<thead>
<tr>
<th>Group #1</th>
<th>Day 1st</th>
<th>Day 2nd</th>
<th>Day 3rd</th>
<th>Day 4 th</th>
<th>Day 5 th</th>
<th>Day 6 th</th>
<th>Day 7 th</th>
<th>Day 8 th</th>
<th>Day 9 th</th>
<th>Day 10 th</th>
<th>1 Day is Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00-11:00</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Group #2</td>
<td>Day 1st</td>
<td>Day 2nd</td>
<td>Day 3rd</td>
<td>Day 4 th</td>
<td>Day 5 th</td>
<td>Day 6 th</td>
<td>Day 7 th</td>
<td>Day 8 th</td>
<td>Day 9 th</td>
<td>Day 10 th</td>
<td>1 Day is Sunday</td>
</tr>
<tr>
<td>11:15-12:15</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>

The patients will be located in front of Instructor, round the table:

```
  ● ● ● ● ● ● ●
  ● ● ● ● ● ●
  ● ● ● ● ● ●●
```

Eight interviewers during 17 days (without Sundays) using self-administered questionnaire will conduct baseline data collection. One interviewer will interview 4 patients per day (2 hours to find the house and interview 1 patient). 544 patients will be interviewed (2x272). The questionnaire was developed after analyzing the WHO guidelines on prevention and risk – factors for DM complications. The first version was pretested on 10 patients, DM-2, in the Republic Center of Endocrinology. The first 10 patients were chosen during 20 days.

To assess how the education process is going on the following objectives are suggested:

- 95% of the curriculum will be followed by 100% of the trainers
- 90% of patients will attend 80% or more of lectures.
Attendance can be influenced by inconvenience of location or hours. To assess the coverage rate of intended the classes, patients attendance will be measured, using “absent-present” class records for each lesson.

Four class instructors will train eight data collectors during 1-2 days. Each instructor will train2 interviewers. Written informed consents will be distributed to the patients, where they will be invited to Control Polyclinic in 4 days to pass free testing and examination. Patients have to read and sign the consent form in case of willingness to participate. After confirmation of the diagnosis, the conclusions will be sent to the endocrinologist of the polyclinic.

Table 7. Timetable of Activities.

<table>
<thead>
<tr>
<th>Activities</th>
<th>January</th>
<th>Febr.01- April 14</th>
<th>April 15- Sept.30</th>
<th>October</th>
<th>Novemb</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline Data Collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training of interviewers during 1-2 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient’s Interviewing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During 17 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during 100 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Examination by Specialists</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during 100 days</td>
<td>100 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation/ Program Monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 groups for 4 Instruct. 11 days per group, 1 hour for each group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>176 days (with Sundays)</td>
<td>25 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. First post-test Data Collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(After 1 Year from the end of education)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during 17 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D. Analysis and Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. Second post-test Data Collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(After 3 years from the end of education)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during 100 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F. Analysis and Final Report</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>in 10 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Two neuropathologists and two ophthalmologists will conduct baseline data collection, laboratory tests will be performed to detect HbA1C and urinary albumin. Five hundred forty four patients would be examined and tested during 100 days.
Two neuropathologists, two ophtalmologists and endocrinologist will test each patient. Endocrinologist/class instructor will collect the final records. Each patient will have identification (ID) number. The same ID will have 2 neurologic and 2 ophthalmologic diagnoses. The first post-test data will be collected after the end of education, by the same 8 data collectors, using the same questionnaire, during the same month as baseline data. The second post-test data will be collected by testing and examining by the same specialists, collecting data on HbA1C and urinary albumin levels and complications (neuropathy, retinopathy, nephropathy, IHD). The analyzing and reporting will be done during 10 days after the end of each phase of data collection. The final results will be reported and disseminated to ministry of Health and National Institute of Health of Armenia.

**Figure 4. Flow chart to examine one patient**

Data Analysis and Statistics

Data Analysis aims to determine whether the detected effects are due to the intervention only and not to something else. The Power of the study will be estimated (using “Stata”). Frequency distributions, histograms and descriptive analyses will be used to characterize the population. The differences in the prevalence of retinopathy, nephropathy and death rates between 2 groups (CG and IG) will be tested by analyses of variance /ANOVA/ and Chi-square tests. Chi-square tests of the
independence of the intervention and prevalence of neuropathy, retinopathy and nephropathy, death rates will be conducted. \((r \times c \text{ tables, } df=(r-1)(c-1))\).

Comparison of mean knowledge levels between 2 independent groups (CG and IG) will be made using Student’s t-test \((df=n-1)\), assuming random samples from a normally distributed population.

Comparison of proportions of patient’s self-controlling blood glucose by diet and exercises between 2 independent samples will be made using 1-tailed t-test statistics, assuming having random sample from normally distributed population. The P-values, the Confidence Intervals will be tested. Odds ratios and their 95% confidence intervals will be determined for dependent variables (prevalence of neuropathy, retinopathy, nephropathy). Changes in the parameters within each group before and after intervention will be tested by paired t-test or Wilcoxon rank test for non-parametric data. The association between variables will be tested by Spearman’s rank correlation ratio.

Multiple logistic regression will be used to test the effect of education (Hb A_{1c} as a continuous variable) and each dependent variable, estimable OR-s and their 95% CI-s for each variable by maximum likelihood estimation.

It is essential to observe the relationship between the different variables, to define possible effect modifiers. Age, gender adjustment and stratification by levels of education, SES, blood pressure, HbA_{1c} and initial BMI will be done. The response rates in groups will be determined. The differences in distribution, composition of non-respondents, dropouts will be considered. For inter-observer variation estimation of the Kappa-statistics and its 95% CI will be performed.

Practical significance of the results will be estimated as well as the statistical significance. Statistically significant results may be so small that they may be meaningless in a “real-word” sense. While statistically non significant ones may have far-reaching public health implications. Even a small reduction in prevalence of diabetic complications, even not statistically significant, can be practically significant, can make difference in Public Health, and change the overall life expectancy because of the high prevalence of DM.

**Ethics**

The proposed education intervention is beneficial; it is free of any potential harmful effects and leads to improved health for patients with DM (meeting the Helsinki 1975 Declaration of needs of ethical principles.) Although intervention is restricted only to the intervention group patients, the equitable selection of subjects for this group is insured. Before being included into the survey process, the informed consent must be obtained from all participants. In this consent form the nature of the study; the reasons for doing it will be mentioned, to enable the patient to make a decision on whether or not to participate. Participants will be informed of expected benefits of participation, way of maintaining confidentiality, and the possibility to withdraw the consent any time. Each individual will have a personal ID and the list of names will be kept separately.
After the end of the program education brochures will be distributed to control group patients. Patients will be under the endocrinologist’s / instructor’s / supervision during the class; bus fee will be repaid.

Budget

The anticipated time for the program is 3 years. The Permanent Staff will consist of the Project Coordinator. She will work during the 9 months of the first year and 5 months during the post-test data collection (collection of first and second post-test data and analyzing). Additional temporary staff will be hired, consisting of 8 Data collectors, and a data Analyst, only during the intervention implementation and evaluation periods. 4 Class Instructors /endocrinologists/ will follow-up patients for 3 years. The Data Analyst will prepare and present a report within 2 weeks after the end of each data collection. The final report will be presented within 3 weeks after the second data collection. The cost distribution with activities is shown on table 8. Salaries include taxes. The budget is $38,752.21.

Table 8. Budget

<p>| Permanent Staff Project Coordinator (1 prs.) | $300 per month -14 months | $300 ×14=$ 4200 |
| Hired Staff | Data collectors (8 prs.) | $10 per person per day for data collection 17 day each phase -2 phases | $10× 8 ×17=$ 1360 |
| Class Instructors (Endocrinologists) (4 prs.) | Each pers. will educate each group for 10 days, and follow up patients for 3 years (36 months) Each will train 2 data collectors in 1 day | $100× 4×36=$ 14400 |
| Data Analyst (1 prs.) | Will analyze during 10 days in each phase-$15 per day (2 phases) | $15× 2×10=$ 300 |
| Physicians | Ophthalmologist (2 prs.) | $200 per person-2 phases- 100 days each | $200× 4×2=$ 1600 |
| | Neuropathologist (2 prs.) | | |
| Laboratory Examination | Hb A₁c | $2 per test per person | $4× 544×2=$ 4352 |
| | Urinary Albumine | $2 per test per person | |
| | 2 phases | | |
| Xerox-Copy of education materials and questionnaires, pencils #8 | 10 drams per page -28 pages of educ. material and 4 pages of questionnaire (2 phases) | $10/540× 28×272= $ 141 |
| | | $10/540× 4×544×2= $ 80.6 |
| | | #8 pencils- $ 0.1 |
| Video Cassette Recorder | $150 | $150 |
| Video Tapes #5 | $10 per tape | $10× 5 =$50 |</p>
<table>
<thead>
<tr>
<th>Incentives</th>
<th>Transport Cost</th>
<th>100 drams ( = $100/540) per patient per day</th>
<th>272 × $100/540 × 10 = $503.7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Subtotal</td>
<td></td>
<td>$27,137.40</td>
</tr>
<tr>
<td>Unexpected needs</td>
<td>5% of the subtotal</td>
<td>5% of the $27,137.40 = $1,356.87</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subtotal</td>
<td></td>
<td>$28,494.27</td>
</tr>
<tr>
<td>Administrative fee</td>
<td>36% of the subtotal</td>
<td>36% of $28,494.27 = $10,257.94</td>
<td></td>
</tr>
<tr>
<td>Total Budget</td>
<td></td>
<td></td>
<td>$38,752.21</td>
</tr>
</tbody>
</table>

References.


17. Franz MJ; Monk A; Barry B. *Effectiveness of medical nutrition therapy provided by dietitians in the management of Non-insulin dependent Diabetes Mellitus: a randomized, controlled clinical trial.* Journal of American Diet. Association; 95(9): 1009-1017.


Appendix 1.

Table 1. The Annualized Incidence Rates, Prevalence Rates, and Death Rates of Diabetes Mellitus in Adults and Teenagers

(absolute numbers and numbers per 100,000 population)

(results of the Center of Statistics)

<table>
<thead>
<tr>
<th>Years</th>
<th>Number of new cases of DM among adults and teenagers</th>
<th>Number of cases of DM among adults and teenagers</th>
<th>Death Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per 100,000 population</td>
<td>Absolute numbers</td>
<td>Per 100,000 population</td>
</tr>
<tr>
<td>1988</td>
<td>136.9</td>
<td>3321</td>
<td>1219</td>
</tr>
<tr>
<td>1989</td>
<td>151.7</td>
<td>3704</td>
<td>1275.5</td>
</tr>
<tr>
<td>1990</td>
<td>183.6</td>
<td>4546</td>
<td>1434.1</td>
</tr>
<tr>
<td>1991</td>
<td>150.9</td>
<td>3792</td>
<td>1495.6</td>
</tr>
<tr>
<td>1992</td>
<td>81.6</td>
<td>2089</td>
<td>1434.2</td>
</tr>
<tr>
<td>1993</td>
<td>80</td>
<td>2086</td>
<td>1499.7</td>
</tr>
<tr>
<td>1994</td>
<td>65.2</td>
<td>1684</td>
<td>1568.8</td>
</tr>
<tr>
<td>1995</td>
<td>68</td>
<td>1825</td>
<td>1349.5</td>
</tr>
<tr>
<td>1996</td>
<td>73.7</td>
<td>2007</td>
<td>1306.8</td>
</tr>
<tr>
<td>1997</td>
<td>79.9</td>
<td>2210</td>
<td>1252.3</td>
</tr>
<tr>
<td>1998</td>
<td>86.5</td>
<td>2431</td>
<td>1237.2</td>
</tr>
</tbody>
</table>

Figure 1. The Annualized Prevalence Rates of Diabetes Among Adults and Teenagers per 100,000 population
Figure 2. The Annualized Incidence Rates of Diabetes Among Adults and teenagers per 100,000 population

![Incidence Rates Chart]

Figure 3. The Annualized Death Rates of Diabetes Mellitus Among Adults and teenagers per 100,000 population

![Death Rates Chart]
Appendix 2.

Education Program for Patients having Diabetes Mellitus
Type-2, aged 40-45, living in Yerevan

1. Action Plan for patients
2. Guidelines for health care providers

Course Objectives

After completing the whole course, the successful patient will be able:

- To design diabetic diet and caloric needs of the body for different levels of physical activity;
- To change diabetic diet and level of physical activity according to the levels of blood glucose;
- To know the basic issues of Carbohydrate Counting, the method of “Exchange Lists”;
- To know the rules of insulin therapy, risks of it, types and acting duration of each type of insulin;
- To explain the risk factors of diabetic neuropathy, nephropathy, retinopathy, cardiovascular complications;
- To explain the prevention guidelines for foot ulcers, blindness, foot amputations;
- To explain the detection, prevention, management of such diabetic acute complications, as Diabetic Ketoacidotic Coma (DKC), Hyperosmolar Coma, Hypoglycemia;
- To explain the short-term and long-term effects of Hyperglycemia.

Course content:

There will be 10 lessons, 1 lesson each day for each group, conducted by class instructor (endocrinologist). Each lesson will last 1 hour. The syllabus is:

Lesson 1: The Diabetic Diet and body caloric needs.
Lesson 2: The Carbohydrate Counting and Exchange Lists.
Lesson 3: The changes in prescribing diet and levels of physical activity.
Lesson 4: Insulin therapy, the rules, and risks of it, types of insulin, storage of it; Hyperglycemia.
Lesson 5: The early detection, prevention and management of acute complications: DKC, Hyperosmolar coma.
Lesson 6: The effects of uncontrolled Hyperglycemia. The risk factors for diabetic neuropathy.
Lesson 7: The risk factors for diabetic nephropathy.
Lesson 8: The risk factors for diabetic retinopathy.
Lesson 9: The risk factors for diabetic cardiovascular complications.
Lesson 10: The prevention of foot ulcers and amputation.

(The following sequence of lessons I used, based on my own experience as an endocrinologist)

The timetable for one course of program (4 different groups of the same instructor)

<table>
<thead>
<tr>
<th>Groups Hours</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Day 8</th>
<th>Day 9</th>
<th>Day 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gr. # 1 10am-11am</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Gr. #2 11am-12pm</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

The instructor will manage all this process. After the 3, 6, 8, lessons there will be a quiz in 10min. And a final one after the last lesson. After each quiz answers will be distributed to patients. The instructor will control the patients for the other each month by the results of blood glucose levels. Each patient will keep a diary for each day, (what pills, name and dosage, diet and level of physical activity). The instructor will give special instructions to each patient after each visit (once a month), checking diaries. The instructor will follow the patients during 3 years, (telephone calls, visits, diary checks).

**********

Lesson 1. The Diabetic Diet
When prescribing a diabetic diet, there are three objectives, or priorities, to consider:

**Caloric Prescription**

**Macronutrient Distribution (carbohydrate, protein, and fat)**

**Synchronization with Insulin**

Macronutrients are the components of food that are measured in grams. The three major classes of macronutrients are CARBOHYDRATE, PROTEIN, and FAT. To review, the general recommendations for macronutrients are: 

- **FAT:** up to 30% of daily calories
- **PROTEIN:** 10-20% of daily calories
- **CARBOHYDRATE:** 50-60% of daily calories.

To determine a caloric requirement, you must first know the person’s Desirable Body Weight. You then need to decide if the person needs to gain or lose weight to reach their Desirable Body Weight. The daily caloric requirements can be thought of consisting of two components. First of all, we need calories (or energy) to meet our vegetative functions. This is called the BASAL caloric requirement. These are the functions of brain, heart, respiratory muscles, and other functions that go on even when we are not physically active. Estimating the daily basal caloric requirement is pretty straightforward. To calculate the basal caloric requirement, multiply the desirable body weight, in pounds, by 10. For example, if the desirable body weight is 140 pounds, then the basal caloric requirement is 1400 calories. For typical sedentary activity levels, multiply the desirable body weight by 13. For those with very active jobs/lifestyles, multiply the desirable body weight by 15. These formulas are useful for determining weight-maintaining caloric requirements. To gain weight, additional calories are needed. To lose weight, fewer calories should be consumed. A pound of body weight is equivalent to 3500 calories.

Describe diet to Aram. He is a 27-year-old; he is 5 feet 10 inches tall, weighs 234 pounds. He just fractured both of his legs while bung jumping. He will be at bed rest for the next two weeks. What is his caloric requirement? -166 pounds. Why? - Remember, 106 pounds for the first 5 feet, and 6 pounds per inch for every inch above 5 feet. What is his basal caloric requirement? First we need his desirable body weight. For the first 5 feet for a male, we allow 106 pounds. For each inch above 5 feet, allow 6 pounds per inch. For Aram, that means 106 pounds (for the first 5 feet) plus 60 pounds (for the 10 inches above 5 feet), or a total of 166 pounds.

His basal caloric requirement is estimated by multiplying the desirable body weight by 10. So, 10 times 166 are 1660. So far, we haven't been concerned with activity, since he is laid up in bed. But he will need additional calories when he starts to move around and exercise. People who have sedentary lifestyles tend to require fewer calories for activity than people who are active in work and leisure do. Many people have difficulty characterizing their activity level. The typical person who works in an office, does occasional walking and lifting, and participates in sport or exercise activities for 2-5 hours per week would still be considered to have a sedentary lifestyle. To provide activity-related calories, you can multiply the desirable body weight by a factor of 3 for sedentary people and a factor of 5 for more active people. So, to review, caloric requirements can be calculated as follows: For sedentary people, multiply their desirable body weight by a factor of 13 (the basal factor of 10 plus the activity factor of 3). For more active people, multiply their desirable body weight by a factor of 15 (the basal factor of 10 plus the activity factor of 5).

Women tend to require fewer calories than men do, even when activity levels are comparable. So do older people, and overweight people. In these situations, you may need to just use the basal factor of 10 without an activity factor.

Let’s figure out Aram's caloric requirement. He is a second-year medical resident. His activity level is sedentary. He is 5 feet 10 inches tall, and he has a desirable body weight of 166 pounds. What is his total caloric requirement? He is 5 feet 10 inches tall, so he has a desirable body weight of 166 pounds, but actually weighs 234 pounds. A pound is equivalent to 3500 calories. So, to lose a pound a week, he needs to consume 500 calories per day less than his maintenance. How much is that? -- His desirable body weight is 106 pounds (for the first 5 feet) plus 60 pounds (for the next 10 inches), for a total of 166 pounds. We can add 10%, or 16.6 pounds for his large frame, for a total weight of 182.6 pounds. We give him a caloric intake of 13 times 183, as a sedentary male, or 2379 calories. Finally, we subtract 500 calories to allow for a one pound per week weight reduction, giving us --- How many total calories per day? --- 1879 calories.

**Consider the percentage of fat in the diet.** What do you think is the usual fat consumption? People with diabetes, due to the greater risk of atherosclerosis, generally need to keep dietary fat below 30% of their total calories. Saturated fats are metabolized in such a way as to raise the serum cholesterol. Unsaturated fats do not. Current recommendations for fat intake are as follows:

- **Saturated Fat:** less than 10% of daily calories
- **Polyunsaturated Fat:** up to 10% of daily calories
- **Monounsaturated Fat:** remainder of daily fat calories

So, an easy way to remember this is that fat should comprise 30% of the daily calories, divided evenly among saturated, polyunsaturated and monounsaturated. The reason for so much emphasis on saturated fat is that it is more important in determining the blood cholesterol level than the amount of cholesterol in the diet.

**Protein intake** should be restricted in people with diabetes? The correct answer is maybe. Traditionally, it was recommended that 20% of total calories be derived from protein Many protein-containing foods are also...
high in fat - such as dairy products and meat products. So, high protein diets tend to be high fat. 2. In many cases, a high protein diet can accelerate the loss of kidney function in many types of kidney disease, including diabetic nephropathy. So, current recommendations are for 10% to 20% protein.

* Current dietary recommendations aim for 50-60% of calories to be derived from carbohydrate. Prior to the availability of insulin or oral hypoglycemic agents, the symptoms of high blood glucose (thirst, excessive urination, weight loss) could only be managed by restriction of dietary carbohydrate. Historically, low carbohydrate diets were thus used as the only method for treating diabetes. Obviously, such severe carbohydrate restriction is no longer necessary, and is not advisable for most people, since low carbohydrate means higher fat and protein intakes.

**Is cholesterol a macronutrient?** Cholesterol is not considered a macronutrient. Remember macronutrients are foods whose daily intake are measured in grams; foods measured in milligrams are considered micronutrients.

* Which of the following food groups have carbohydrates?
  - Milk/dairy products?
  - Meats/cheeses?
  - Green vegetables?
  - Fats, such as butter, oils or mayonnaise?

Milk/dairy products, fruits, breads/starchy vegetables and green vegetables all have carbohydrate. Meats, cheeses and fats do not.

**Just a Little Exercise is Terrific for Your Health**

The doctor wants you to lose weight and exercise more. But you can't, you've tried, and you just can't. But you can. Adopting a healthy diet and lifestyle is all about making permanent personal changes.

**Benefits of low-intensity exercise:**

- **Increased Insulin Sensitivity.** Exercise does not promote more production of insulin, but it increases insulin sensitivity by enhancing receptor site binding. This effect can persist for several hours, up to 24 hours in some individuals. Due to it, non-insulin dependent diabetics may be able to reduce doses of medication (oral hypoglycemic medications or insulin). *Even a few modest walks a week can reduce your insulin needs.*

- **A Better Control of Blood Glucose.** This more effective control is the key to reducing complications of diabetic. Modest physical activity just one day a week significantly reduces risk of diabetes, better control of blood glucose with less insulin.

- **Reduction of Others Cardiovascular Risk Factors.** The exercise contributes for improvement of serum lipids; it reduces LDL and triglycerides and increases HDL cholesterol. The reduction of blood pressure is an other benefit from exercising. Helps replace the nicotine high of smoking.

- **Loss of weight and decreased stress are consequences of exercising.**
  - Boosts "basal metabolic rate": the rate the body burns calories while at rest. Boosts the immune system (Low-to-moderate-intensity exercises). Helps the body win down to sleep. Less stress and anxiety.

  The crucial factor is the total amount of exercise.¹ How much is enough? About 30 minutes a day¹. It doesn't even have to be a half-hour all at once. Any short-duration exercise that adds up to 30 minutes works just as well. Our ancestors didn't set aside time to exercise. They simply led physically active lives. They walked a great deal. They chopped wood, pumped water, churned butter, raised their food and washed their clothes largely by hand and developed substantially less type 2 diabetes than we see today.

**Calories Used by Daily Activities**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Calories/hr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting</td>
<td>100</td>
</tr>
<tr>
<td>Standing</td>
<td>140</td>
</tr>
<tr>
<td>Making beds</td>
<td>135</td>
</tr>
<tr>
<td>Housework</td>
<td>150-250</td>
</tr>
<tr>
<td>Strolling</td>
<td>210</td>
</tr>
<tr>
<td>Raking leaves</td>
<td>225</td>
</tr>
<tr>
<td>Gardening</td>
<td>300-450</td>
</tr>
</tbody>
</table>
Risks of Exercise

The great risk of exercising for diabetics occurs when blood glucose level is not very well controlled or when complications of diabetes are already present. Only with a strict control the diabetic can avoid hypoglycemia or hyperglycemia, which can be fatal.

Diabetics with peripheral neuropathy or microangiopathy must avoid exercise that may traumatize the feet. The shoes and socks must be very comfortable and, if possible, jogging and jumping exercises should be avoid (preference to swimming). Strenuous exercises have to be avoided by patients with proliferative retinopathy in order to do not increase dramatically blood pressure. Swimming is recommended, but never alone or without a strict control of blood glucose to avoid a fatal hypoglycemia.

Assessment of Exercising Diabetics

The monitoring of blood glucose level before, during, and after an exercise is very important for a safe participation in sports. A metabolic control of ketones must be done too before the beginning of exercise; if ketosis has begun before exercising, ketone production will continue to rise dangerously.

A familial history of coronaropathy or hypertension must be investigated, such as a valuation of serum lipoproteins.

1- Recent levels of glycosylated hemoglobin must be satisfactory
2- Frequent control of blood glucose (3 times /day)
3- Recognize the early signs of hypoglycemia
4- A candy or sugar tablet must always be carried with diabetics during exercise
5- A strategy for insulin dose, before and after exercise
6- Any kind of identification, warning for a diabetic person, must be present during exercise.

Strategy for Exercising Diabetics Control

Before Exercising:

1- If blood glucose was lower than 130 mg/dl, diabetics should take two carbohydrate exchange (60 kcal is one carbohydrate exchange) for 35 /45 min of mild exercise (<60% of VO2 max).
2- If blood glucose was between 130 and 180 mg/dl, diabetics should take only one carbohydrate exchange for a mild exercise.
3- If blood glucose was between 180 and 240 mg/dl, diabetics should not take any carbohydrate exchange for a mild exercise, but if exercise will be intense or long (more than 30 min.) diabetics should make another glucose test during exercise and follow the criteria shown above.
4- If blood glucose was 250mg/dL or higher, the exercise must be cancelled. A urinary ketone test should be done and a new insulin dose can be necessary.

Reference

1. The American College of Sports Medicine (ACSM) and the federal Centers for Disease Control and Prevention (CDC)

How Fit Are You Now?

1. How many flights of stairs do you typically climb each day?
   none ... 0 points;  1 to 5 ... 1 point; 6 to 9... 2 points; 10+ ... 3 points.
2. How many hours a week do you do household chores (cooking, cleaning, laundry, etc.)?
   1 point for each hour up to 5

3. When you take your children to parks and playgrounds, how often do you run, climb, slide, and swing with them?
   Never... 0 points;   Sometimes...1 point;  Usually.... 2 points;    Always ... 3 points

4. How many miles do you walk each day (1 mile = 20 city blocks)?
   Less than 1 mile ...  0  points;   1 mile  ...  2  points;     2 miles ...4  points;  3 miles...  6  points; above 4 miles ... 10  points.

5. Do you have trouble opening jars?
   Often  ... 0  points;    Sometimes ... 1  point;      Rarely …  2  points

Scoring:  0-3  Uh-oh, you're out of shape and need to become more active starting right now.
   4-7  You're moderately active, but you'd reap major health rewards by picking up your pace.
   8 [  Congratulations! Even if you don't have a formal exercise program, you're getting enough to add to your health and well being.

Reference
Bryant Stamford, Ph.D., director of the Health Promotion Center at the University of Louisville School of Medicine in Kentucky developed this test.

Lesson 2. Exchange Lists and Carbohydrate counting

Class Instructor will distribute “Exchange Lists” to each patient.

Different foods may have varying impact on blood glucose levels even if they contain equivalent amounts of carbohydrate, due to different rates of digestion and absorption from the intestinal tract. The Exchange Lists for meal planning group foods with similar amounts of carbohydrate, but does not account for the different rates of digestion or absorption of the carbohydrate. (Instructor will distribute Exchange Lists to patients and explain).

The glycemic index is a measure of how a given food raises blood glucose levels, compared to pure glucose. It is based on a portion of the food containing 50 grams of carbohydrate. It is an average based on many different people, since individuals vary in their response to carbohydrates. Carbohydrates are usually thought of in two categories - simple carbohydrates and complex carbohydrates. Simple carbohydrates are monosaccharides or disaccharides – very simple chemical structures. Simple carbohydrates do not need to be digested in the intestinal tract before they are absorbed into the blood stream. Therefore, they raise the blood sugar level relatively quickly. Complex carbohydrates are polysaccharides - long chains of monosaccharides that are linked together. They must be digested before they can be absorbed. As a result, their effect on the blood sugar level tends to be slower, and less pronounced. Different foods may have varying impact on blood glucose levels even if they contain equivalent amounts of carbohydrate due to different rates of digestion and absorption from the intestinal tract. The Exchange Lists for meal planning group foods with similar amounts of carbohydrate, but does not account for the different rates of digestion or absorption of the carbohydrate (e.g. complex versus simple carbohydrates). It is based on a portion of the food containing 50 grams of carbohydrate. It is an average based on many different people, since individuals vary in their response to carbohydrates. Many patients will increase their premeal insulin dose if they are eating foods that have a high glycemic index, in order to prevent the rise in blood glucose that would otherwise occur. The diabetic diet does not need to completely eliminate simple carbohydrates. The quantity consumed at any given meal, though, may need to be limited to prevent an excessive rise in postprandial glucose levels. Simple carbohydrates are monosaccharides or disaccharides - they do not need extensive digestion prior to absorption in the intestine. Simple carbohydrates are also referred to as simple sugars or concentrated carbohydrates. Complex carbohydrates, or starches, need to be digested (or 'broken down') into simple carbohydrates prior to absorption. They theoretically should cause a
more gradual rise in blood glucose levels than a simple carbohydrate. The Glycemic index of a carbohydrate containing food compares the area of the two-hour blood glucose response curve to an equivalent amount of glucose. The Glycemic index is expressed as the percentage of the blood glucose response curve for a food containing 50 grams of carbohydrate compared to oral glucose.

\[
\text{Glycemic Index} = \frac{2 \text{ hr glucose response for food (50 grams of carb.)}}{2 \text{ hr glucose response for 50 grams of glucose}}
\]

Using the glycemic index, carrots turn out to have a greater impact on blood glucose than ice cream or table sugar. Here are some examples of glycemic index values for selected foods:

<table>
<thead>
<tr>
<th>STARCH GROUP:</th>
<th>Bread 70%</th>
<th>Pasta 50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>VEGETABLE GROUP:</td>
<td>Potato 70%</td>
<td>Lentils 30%</td>
</tr>
<tr>
<td></td>
<td>Carrots 92%</td>
<td>Raisins 64%</td>
</tr>
<tr>
<td>FRUIT GROUP:</td>
<td>Apples 39%</td>
<td>Orange Juice 46%</td>
</tr>
<tr>
<td></td>
<td>Milk 33%</td>
<td>Ice Cream 36%</td>
</tr>
</tbody>
</table>

Using the Glycemic index, we see that different types of sugar vary in their impact on blood glucose levels. The Glycemic index for different sugars are as follows:

- Table Sugar (Sucrose): 60%
- Milk Sugar (Lactose): 33%
- Fructose: 20%
- Glucose: 100%

Guess how many carrots contain 50 grams of carbohydrates?? - Five whole carrots!!! When was the last time you ate 5 whole carrots!!! So you see, Glycemic index has limitations when we consider real-life portion sizes. In general, each food should be considered for its glycemic impact in the context of typical portion sizes. Simple carbohydrates, which tend to have a greater glycemic impact, may need to be limited in, but not eliminated from, the diabetic diet.

**CARBOHYDRATE COUNTING**: is a method of meal planning which is simpler, in some ways, than the Exchange Lists method. The Exchange Lists groups foods into 6 categories, based on their macronutrient content. Patients are given a menu plan, which allows them a certain number of portions of each food group at each meal. Carbohydrate counting, as the name implies, simply looks at the carbohydrate content of the food. Carbohydrates are the principal macronutrient, which causes the blood glucose to rise. Protein has only about 40% the impact on the blood glucose as carbohydrate does. Fat has almost no impact on blood glucose levels.

There are two methods of using carbohydrate counting that we're going to review. In one method, a range of carbohydrate is specified for each meal or snack, and the patient chooses foods with the appropriate carbohydrate content. Use a Carbohydrate Counting Guide to determine whether the following meal fits into the prescribed carbohydrate quota.

**CARBOHYDRATE QUOTA FOR LUNCH: 30-50 grams**

Two all beef patties, Special sauce, Lettuce, Cheese, Pickles, Onions, Sesame seed bun.

Let's go over this. The all beef patties have no carbohydrate. The special sauce - we're not sure about. Probably made up of mostly fat. Lettuce has 13 grams per HEAD! Forget about it. Cheese has nothing. Pickles and onions are 'vegetables' - 5 grams per cup - also negligible. The bun has 25 grams, and that accounts for most of the carbohydrate. If you figure the lettuce, onions and pickles may all add up to 5 grams, then we're probably in range. The special sauce, if it has sugar, will put us over. Think about your last meal. How many grams of carbohydrate did you eat? This method of using carbohydrate counting (we'll call it the 'quota method') gives some flexibility in food choices.

A second method of using carbohydrate counting is the 'algorithm method'. In this method, an algorithm (or formula) for calculating an insulin dose is developed which varies, based on the carbohydrate intake. For example, 1 unit of Regular insulin may be required for every 5 grams of carbohydrate. You said that you ate 4 grams of carbohydrate for your last meal. How much insulin should you have taken? As you can see, this method of using carbohydrate counting (we'll call it the 'quota method') gives some flexibility in food choices.

A second method of using carbohydrate counting is the 'algorithm method'. In this method, an algorithm (or formula) for calculating an insulin dose is developed which varies, based on the carbohydrate intake. For example, 1 unit of Regular insulin may be required for every 5 grams of carbohydrate. You said that you ate 4 grams of carbohydrate for your last meal. How much insulin should you have taken? Answer is 0 or 1. This method gives even more flexibility in meal planning, but it does require taking Regular insulin before each meal. It also does not take into account the impact of protein or fat on blood glucose levels, calorie intake or lipid status. A nutrition counselor best uses carbohydrate counting in conjunction with periodic dietary history assessments. This dietary review will address calorie, lipid and other nutritional priorities.
Lesson 3.

Twenty Questions on prescribing diabetic diet

Now there are 20 answers with questions, which would help to understand the material.

1. What is the desirable body weight for a woman who is 66 inches tall and has a medium body frame?
   a) 110 pounds  b) 120 pounds  c) 130 pounds  d) 140 pounds  e) 145 pounds

Discussion: To calculate the desirable body weight for a woman, allow 100 pounds for the first 5 feet, and add 5 pounds per inch for every inch above 5 feet. This formula is based on a medium body frame. For small body frames, subtract 10%. For large body frames, add 10%.

This woman is 66 inches, or 5 feet 6 inches, tall. We allow 100 pounds for the first 5 feet, and then add 5 pounds per inch for the 6 inches above 5 feet, or 30 pounds, giving her a desirable body weight of 100 + 30, or 130 pounds.

2. A young male diabetic patient is 5 feet 10 inches tall and weighs 140 pounds. He works as a lab technician. How many total calories will he need to eat each day to gain approximately one pound per week?
   a) 1800  b) 2100  c) 2600  d) 3100  e) 3600

Discussion: To gain a pound a week, a person needs to consume 3500 calories per week (or 500 calories per day) above their maintenance level. This patient is 5 feet 10 inches tall and weighs 140 pounds.

We need to determine his desirable body weight to determine his weight-maintaining calories. Then we need to add supplemental calories to allow for a weight gain of one pound per week. To calculate desirable body weight for a man, allow 106 pounds for the first 5 feet, and add 6 pounds per inch for each inch above 5 feet (plus/minus 10% correction for body frame). This patient is 5 feet 10 inches tall; allow 106 pounds for the first 5 feet and an additional 60 pounds (6 pounds per inch) for the additional 10 inches above 5 feet, for a total of 166 pounds. To calculate weight-maintaining calories for this man, assuming typical sedentary lifestyle, multiply his desirable body weight of 166 pounds by 13, resulting in a weight-maintaining calorie level of 2158 calories. To allow for a one pound per week weight gain, add 3500 calories per week, or 500 calories per day (3500 calories divided by 7 days). This results in a calorie prescription of 2158 + 500, or 2658 calories.

3. A 23 year old woman has been found to have insulin-dependent diabetes. A reasonable dietary prescription would include:
   a) 35% of total calories from carbohydrate.
      b) 50% of total calories from carbohydrate.
   c) 35% of total calories from protein.
   d) 50% of total calories from protein.
   e) 20% of total calories from fat.

Discussion: The 1994 recommendations for macronutrient distribution in diabetes suggest 10% to 20% of daily calories be derived from protein. The balance is distributed between carbohydrate and fat. Most diabetes experts recommend the following distribution:

   CARBOHYDRATES - 50-60% of total calories
   PROTEIN - 10-20% of total calories
   FAT - less than 30% of total calories

4. Which of the following is FALSE?
   a) Foods containing equivalent amounts of carbohydrate vary in their effect on blood glucose.
   b) Desserts such as ice cream should be avoided because of their great impact on blood glucose.
   c) The glycemic index is intended to be a better predictor of postprandial hyperglycemia than the Exchange Lists.
   d) Individuals vary in their response to specific carbohydrate-containing foods.
   e) Potatoes have a higher glycemic index than table sugar.

Discussion: Potatoes have a higher glycemic index than table sugar (sucrose). Ice cream has a relatively low glycemic index; it does have a large amount of fat, and is best avoided for that reason.

5. How many Meat exchanges are in the following meal:

32
Cheeseburger with 4 ounces of cooked hamburger, 1 ounce of Cheddar Cheese, 2 ounces of bacon, on a Hamburger bun; 4 ounces of broccoli; French fries; a 6 ounce glass of tomato juice.

a) 1  b) 4  c) 5  d) 6  e) 7

Discussion: Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or ’Exchanges' depending on similarities in macronutrient composition. The Meat list includes foods containing protein and fat, but no carbohydrate. The Meat list includes meat, eggs and cheese. In this meal, there are 4 Meat exchanges in the 4 ounces of hamburger and 1 Meat exchange in the 1 ounce slice of cheese, for a total of 5 Meat exchanges. The remaining components belong to different lists, or exchanges, as follows: Bacon – Fat, Hamburger bun - Bread/Starch, Broccoli – Vegetable, French Fries - Bread/Starch, Tomato Juice – Vegetable.

6. Which of the following all belong to the same Exchange list?
   a) milk, cheddar cheese, plain yogurt
   b) hamburger, cheddar cheese, bacon
   c) hamburger, cottage cheese, tuna fish
   d) whole wheat bread, spaghetti, asparagus
   e) grapefruit, cottage cheese, lettuce

Discussion: Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or ’Exchanges' depending on similarities in macronutrient composition. Meat, fish and cheese all belong to the Meat List, having protein and fat, but no carbohydrate. Milk belongs to the Milk list (12 gr of carbohydrate, 8 grams of protein and 1-8 grams of fat per exchange). Bacon belongs to the Fat list (5 grams of fat, but no protein or carbohydrate per exchange). Bread and pasta belong to the Starch list (15 grams of carbohydrate, 3 grams of protein, and no fat per exchange). Asparagus belongs to the Vegetable list (5 grams of carbohydrate, 2 grams of protein, and no fat per exchange). Grapefruit belongs to the Fruit list (15 grams of carbohydrate, no protein, and no fat per exchange). Lettuce is a free food.

7. Aram’s diet plan includes a midafternoon snack consisting of 1 fruit exchange and one meat exchange. Which of the following choices would fit his meal plan?
   a) 1 banana and 1 ounce of salami
   b) 1 peach and 1 ounce of salami
   c) 1 apple turnover and a scrambled egg
   d) 4 ounces of sugar free cherry jello and 1 ounce of cheddar cheese
   e) 1/2 peach and 1 ounce of cheddar cheese

Discussion: Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or ’Exchanges' depending on similarities in macronutrient composition. A portion on the list, or exchange, may not be a typical meal portion. For example, a meat exchange is equivalent to one ounce of meat - not a typical portion size for most people. As another example, a fruit exchange is equivalent to 15 grams of carbohydrate - one whole peach has 15 grams of carbohydrate, but one whole banana has 30 grams. So, a fruit exchange for bananas would be only 1/2 of a banana. A whole banana actually is equivalent to two fruit exchanges.

8. Using the Exchange lists, estimate the number of calories in the following meal: broccoli omelet prepared in a no-stick pan (3 eggs, 1/2 cup broccoli), two slices of dry toast, 8 ounces of freshly squeezed orange juice, black coffee.
   a)350  b)500  c)600  d)700  e)800

Discussion: To calculate the number of calories in this meal, use the Exchange Lists, as follows. 3 eggs are equal to 3 meat exchanges; assume 75 calories per exchange (meat exchanges vary from 55-100), for a total of 225. 1/2 cup of broccoli is equal to 1 vegetable exchange, or 25 calories. 2 slices of toast is equal to 2 bread exchanges, or 160 calories. 8 oz. of juice is equal to 2 fruit exchanges, or 120 calories. Black coffee has no calories. Total = 225 + 25 + 160 + 120 = 530.

9. A 28 year old woman has been diagnosed with gestational diabetes. To control this, she has been put on a controlled carbohydrate diet. Her meal plan consists of the following distribution of carbohydrate:
   Breakfast: 35-50 grams of carbohydrate
   Morning snack: 10-25 grams of carbohydrate
   Lunch: 35-55 grams of carbohydrate
   Midafternoon snack: 10-25 grams of carbohydrate
   Dinner: 35-60 grams of carbohydrate
   Bedtime snack: 10-25 grams of carbohydrate

Which of the following would be an appropriate meal choice for breakfast?
   a) two scrambled eggs with bacon
   b) two scrambled eggs with bacon and cheese, 6 ounces of orange juice
c) two scrambled eggs with bacon and cheese, 2 slices of dry toast

d) two scrambled eggs with bacon, 4 ounces of orange juice

✓ e) two scrambled eggs with bacon and cheese, 2 slices of buttered toast, 4 ounces of orange juice

**Discussion:** In using a controlled carbohydrate diet meal planning, the carbohydrate content of the meal should fit into the targeted carbohydrate goal. In this example, breakfast is targeted at 35-50 grams of carbohydrate. Eggs, bacon, cheese and butter have no carbohydrate. Choice 'a' has no carbohydrate. In choice 'b', orange juice has 15 grams per 4 ounces, or 22.5 grams per 6 ounces. In choice 'c', toast has 15 grams per slice, or 30 grams per 2 slices. In choice 'd', 4 ounces of juice has 15 grams of carbohydrate. The correct choice is 'e', with 30 grams of carbohydrate for the two slices of bread, and 15 grams of carbohydrate for the 4 ounces of juice.

10. Which of the following foods have no carbohydrate?

a) eggplant parmigiana  
b) cheese ravioli  
c) lean pastrami  
d) skim milk  
e) 2% milk

**Discussion:** Eggplant is a vegetable, and has carbohydrate. Ravioli is a starch, and has carbohydrate. Pastrami is meat - it has meat and protein, but no carbohydrate. All types of milk have carbohydrate.

11. What is the desirable body weight for a man who is 72 inches tall and has a medium body frame?

a) 160 lbs.  
b) 170 lbs.  
✓ c) 180 lbs.  
d) 200 lbs.  
e) 210 lbs.

To calculate desirable body weight for a man, allow 106 pounds for the first 5 feet, and add 6 pounds per inch for each inch above 5 feet (plus/minus 10% correction for body frame). This patient is 6 feet tall; allow 106 pounds for the first 5 feet, and an additional 72 pounds (or 6 pounds per inch) for the additional 12 inches above 5 feet, for a total of 178 pounds.

12. A female diabetic patient is 5 feet 8 inches tall and weighs 160 pounds. How many total calories will she need to eat each day to lose approximately 1 pound per week?

a) 800  
b) 1000  
✓ c) 1300  
d) 1800  
e) 2100

Calorie requirements can be estimated from a person's desirable body weight. To determine a weight-maintaining calorie level, the following method can be used: For typical sedentary activity levels, multiply the desirable body weight by 13. For those with very active jobs/lifestyles, multiply the desirable body weight by 15. These formulas are useful for determining weight-maintaining calorie requirements. To gain weight, additional calories are needed. To lose weight, fewer calories should be consumed. A pound of body weight is equivalent to 3500 calories. So, to lose a pound a week, a person needs to consume 3500 calories per week (or 500 calories per day) below their maintenance level.

This patient is 5 feet 8 inches tall and weighs 160 pounds. First, we need to determine her desirable body weight to determine her weight-maintaining calories. Then we need to subtract calories to allow a weight loss of one pound per week. To calculate desirable body weight for a woman, allow 100 pounds for the first 5 feet, and add 5 pounds per inch for each inch above 5 feet (plus/minus 10% correction for body frame). This patient is 5 feet 8 inches tall; allow 100 pounds for the first 5 feet, and an additional 40 pounds (or 5 pounds per inch) for the 8 inches above 5 feet, for a total of 140 pounds. To calculate weight-maintaining calories for this woman, assuming typical sedentary lifestyle, multiply her desirable body weight of 140 pounds by 13, resulting in a weight-maintaining calorie level of 1820 calories. To allow for a one pound per week weight gain, subtract 3500 calories per week, or 500 calories per day (3500 calories divided by 7 days). This results in a calorie prescription of 1820 minus 500, or 1320 calories.

13) A 23 year old woman has been found to have insulin-dependent diabetes. A reasonable dietary prescription would include:

✓ a) 20% of total calories from protein  
b) 30% of total calories from protein  
c) 20% of total calories from carbohydrate  
d) 40% of total calories from carbohydrate  
e) 15% of total calories from fat

The 1994 recommendations for macronutrient distribution in diabetes suggest 10% to 20% of daily calories be derived from protein. The balance is distributed between carbohydrate and fat. Most diabetes experts recommend the following distribution:  

- CARBOHYDRATES - 50-60% of total calories  
- PROTEIN - 10-20% of total calories  
- FAT - less than 30% of total calories

The 1994 dietary recommendations allow for customization and individualization of these guidelines.

14. Which of the following is FALSE?

a) Foods in the Bread/Starch group may have different effects on postprandial blood glucose levels.
b) Carrots are not desirable in the diabetic diet because of their high glycemic index.
c) In deciding on a premeal insulin dose, a patient should consider the glycemic index of the meal.
d) Simple carbohydrates can have a lower glycemic index than complex carbohydrates.
e) Rice has a higher glycemic index than milk.

Rice has a higher glycemic index than milk. Carrots have a high glycemic index. However, this is based on a portion containing 50 grams of carbohydrate; for carrots, this is 10 cups. This is obviously not a typical portion size. The typical portion size should be considered when using glycemic index for meal planning.

15. How many Starch Exchanges are in the following meal: Tuna fish sandwich with 4 leaves of lettuce on whole wheat bread, 1/4 pound (1/2 cup) side order of potato salad, 1/2 cup of carrot sticks, 1 inch thick slice of watermelon, 8 ounces of 2% milk.

\[
\begin{align*}
\text{a) 1} & \quad \text{b) 2} & \quad \text{c) 3} & \quad \text{d) 4} & \quad \text{e) 6}
\end{align*}
\]

Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or 'Exchanges' depending on similarities in macronutrient composition. The Starch/Bread list contains foods with 15 grams of carbohydrate, 3 grams of protein and no fat. This meal has the following Starch exchanges:

- two slices of bread = 2 Starch exchanges
- 1/2 cup of potato (salad) = 1 Starch exchange

16. Which of the following all belong to the same Exchange list?

- a) tuna fish, cheddar cheese, egg
- b) milk, cheddar cheese, egg
- c) bagel, lox, cream cheese
- d) broccoli, asparagus, rice
- e) beef, chicken, bacon

Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or 'Exchanges' depending on similarities in macronutrient composition. Meat, fish and cheese all belong to the Meat List, having protein and fat, but no carbohydrate. Milk belongs to the Milk list. Bagel and rice belong to the Starch list. Broccoli and of 1 milk asparagus belong to the Vegetable list. Bacon belongs to the Fat list.

17. Karine is an 8-year-old with newly diagnosed insulin dependent diabetes. Her diet plan includes a bedtime snack consisting 1 bread exchange and 1 fruit exchange. Which of the following choices would fit her meal plan?

- a) 4 ounces of milk, a hard roll and a peach
- b) 4 ounces of milk, a slice of toast and a peach
- c) 8 ounces of milk, a slice of toast and a peach
- d) 8 ounces of milk, a hard roll and a teaspoon of fruit jam
- e) 8 ounces of yogurt and a peach

Using the Exchange Lists for Meal Planning, foods are grouped into 6 different lists, or 'Exchanges' depending on similarities in macronutrient composition. A portion on the list or exchange, may not be a typical meal portion. For example, a milk exchange is equivalent to eight ounces of milk - this may not a typical portion size for some people. As another example, a fruit exchange is equivalent to 15 grams of carbohydrate - one whole peach has 15 grams of carbohydrate, but one whole banana has 30 grams. So, a fruit exchange for bananas would be only 1/2 of a banana. A whole banana actually is equivalent to two fruit exchanges. As a third example, a hard roll is equal to two bread exchanges.

18. Using the Exchange lists, estimate the number of calories in the following meal: tuna salad (3 ounces of tuna packed in water, 2 teaspoons of mayonnaise) on rye toast (2 slices) with lettuce, 8 ounces of skim milk, and a banana

\[
\begin{align*}
\text{a) 350} & \quad \text{b) 450} & \quad \text{c) 600} & \quad \text{d) 750} & \quad \text{e) 900}
\end{align*}
\]

To calculate the number of calories in this meal, use the Exchange Lists, as follows. 3 ounces of tuna is equal to 3 meat exchanges, or 165 calories (assuming a mid-range fat content). 2 teaspoons of mayonnaise is equal to 2 fat exchanges, or 90 calories. 2 slices of toast is equal to 2 bread exchanges, or 160 calories. 8 ounces of skim milk is equal to 1 milk exchange, or 90 calories. 1 banana is equal to 2 fruit exchanges, or 120 calories. Lettuce is free. Total = 165 + 90 + 160 + 90 + 120 = 625 calories.

19. A 42-year-old man has been diagnosed with reactive hypoglycemia. He has been prescribed a controlled carbohydrate diet, consisting of 3 meals and 3 snacks. His has the flexibility to choose the foods he eats, as long as he maintains a consistent carbohydrate intake, as follows:

- **Breakfast:** 35-50 grams of carbohydrate
- **Morning snack:** 10-25 grams of carbohydrate
- **Lunch:** 35-55 grams of carbohydrate
- **Midafternoon snack:** 10-25 grams of carbohydrate
- **Dinner:** 35-60 grams of carbohydrate
- **Bedtime snack:** 10-25 grams of carbohydrate

35
Which of the following would be an appropriate meal choice for lunch?

a) Bacon, lettuce and tomato sandwich
b) Bacon, lettuce and tomato platter (no bread), 4 ounces of cheddar cheese
c) Bacon, lettuce and tomato sandwich, 12 ounces of regular cola
d) Bacon, lettuce and tomato sandwich, 8 ounces of 2% milk
e) Broccoli and cheese omelette (1/2 cup broccoli), 1 slice of buttered whole wheat toast

In using a controlled carbohydrate diet meal planning, the carbohydrate content of the meal should fit into the targeted carbohydrate goal. In this example, lunch is targeted at 35-55 grams of carbohydrate. Eggs, bacon, cheese and butter have no carbohydrate. Lettuce is considered a free food. In choice ‘a’, the sandwich bread has 15 grams per slice, or 30 grams, and the tomato has a minimal amount. In choice ‘b’, there is a minimal amount in the tomato slices In choice ‘c’, there are 30 grams from the bread, and 40 grams in the regular cola. In choice ‘d’, there are 30 grams from the bread and 12 grams in the milk; this is the correct choice. In choice ‘e’, there are 15 grams of carbohydrate for the one slice of toast, and 5 grams for the broccoli.

20. Which of the following foods contain no protein?

a) Salmon      b) whole wheat bread     c) skim milk
d) banana     e) 2% milk

Salmon is on the meat list, and has protein. Bread is on the starch list, and has protein. All types of milk have protein. Banana is on the fruit list, and consists of only carbohydrate.

Lesson 4.  All about Insulin

People with non-insulin-dependent (type 2) diabetes make insulin, but their bodies don’t respond well to it. Some people with type 2 diabetes need diabetes pills or extra insulin in shots to help their bodies use their own insulin better.

Insulin must be injected into the fat under your skin for insulin to get into your blood.

Insulins differ in how they are made, how they work in the body, and price. Today’s insulins are very pure. Allergic reactions to insulin are rare. Insulin comes from either animals or is made in labs by bacteria that have gene instructions to make human insulin.

There are three broad types of insulin, based on: 1. How soon the insulin starts working (onset). 2. When it works the hardest (peak time). 3. How long it lasts in your body (duration).

Short-acting (Regular) insulin usually reaches the blood within 30 minutes after injection. It peaks 2 to 4 hours late and stays in the blood for about 4 to 8 hours. Intermediate-acting (NPH and Lente) insulin reaches the blood 2 to 6 hours after injection. They peak 4 to 14 hours later and stay in the blood for about 14 to 24 hours. Long-acting (Ultralente) insulin takes 6 to 14 hours to start working. It has no peak or a very small peak 14 to 24 hours after injection. It stays in the blood between 20 and 36 hours. Some types of insulin come mixed together. For example, you can buy Regular and NPH insulins already mixed in one bottle.

Insulins come dissolved in liquids at different strengths. U-100 insulin means it has 100 units of insulin per milliliter of fluid. Be sure that the syringe you use matches the insulin strength. U-100 insulin needs a U-100 syringe. U-40 insulin means it has 40 units of insulin per milliliter of fluid.

Storage and Safety. Never store insulin at very cold (less than 36 degrees Fahrenheit) or very hot (over 86 degrees Fahrenheit) temperatures. Extreme temperatures destroy insulin. Do not put your insulin in the freezer or in direct sunlight. Before using any insulin, check the expiration date. Insulin may lose potency slightly if the bottle has been used for more than 30 days. Look at the bottle closely to make sure the insulin looks normal. If you use Regular, it should be perfectly clear, no floating pieces or colors. If you use NPH or Lente, it should be cloudy, with no floating pieces or crystals on the bottle. If you find any problems, return the bottle of insulin for an exchange or refund.

Insulin Therapy

Conventional insulin therapy means taking the same shots at the same times each day, usually a shot in the morning and a shot in the evening. Insulin therapy aims to keep your blood glucose as close to normal as possible. Intensive therapy means either taking three or four shots daily. However, because you are keeping your blood glucose levels lower, there is a chance of more low blood glucose reactions. You may also gain some weight. Factors affect your blood glucose levels include: 1. What you eat. 2. How much and when you
exercise. 3. Where you inject your insulin. 4. When you take your injections. 5. Illness. 6. Stress. When you want to improve your insulin routine, consider: self-monitoring, (predict and avoid low or high blood glucose levels) site rotation (insulin enters the blood at different, speeds when injected at different sites. insulin shots work fastest when given in the abdomen, insulin arrives in the blood a little more slowly from the upper arms and even more slowly from the thighs and buttocks.) Injecting insulin in the same general area (for example, your abdomen) will give you the best results from your insulin. Don’t inject in exactly the same place each time but move around the same area. Timing to time your shots so that insulin goes to work when glucose from your food starts to enter your blood. High morning blood glucose levels before breakfast can be a puzzle. If you haven’t eaten, why did your blood glucose level go up? There are two common reasons: if you have very low blood glucose while sleeping, your body releases glucose from the liver causing a high blood glucose level in the morning; if you have low blood glucose while sleeping, morning nausea and headache may be signs of it. You may need to eat a bedtime snack to avoid low blood glucose in early morning hours. To see whether this is the problem, set your alarm to self-monitor around 2 or 3 am for several nights. The other reason for high fasting blood glucose levels on waking is the dawn phenomenon. Near dawn, the levels of certain hormones in your blood naturally increase. These hormones cause blood glucose to rise, usually around 5 or 6 am. This usually means you need to take a bedtime injection of intermediate- or long-acting insulin that will go to work around dawn.

Syringe Reuse: if you are ill, have open wounds on your hands, or have poor resistance to infection for any reason, you should not risk syringe reuse. Keep the needle clean by keeping it capped when you’re not using it. Don’t try to clean it with alcohol. Alcohol wiping removes the coating that helps the needle slide into the skin easily. Never let anyone use a syringe you’ve already used, and don’t use anyone else’s syringe, ever. Make sure your syringe container doesn’t get recycled.

And effective diabetes self-care is impossible without adopting a healthy diet and lifestyle.

The Symptoms of Hypoglycemia (Low blood sugar)

In a person without diabetes, the body regulates the blood sugar tightly, keeping it within the same general range. But if the blood glucose goes too low, the person experiencing this condition will not feel well. Any person with diabetes who takes an oral hypoglycemic agent or insulin may experience low blood glucose. Severe hypoglycemia occurs more often in patients who are following an intensified insulin therapy protocol (with the target glucose level near the normal range), whose diet and activity vary widely, who have a long duration of diabetes, and/or who have autonomic neuropathy. Patients with a history of severe hypoglycemia are at increased risk for future episodes. Often the cause is multifactorial. A delay or decrease in food intake, vigorous physical activity, and alcohol consumption all may contribute. Hypoglycemia, or low blood sugar, is the most common complication of insulin treatment, occurring in both types of diabetes.

• Early Symptoms The early symptoms are chiefly physical, including trembling, sweating, moderate dizziness and irritability, and a pounding heartbeat. People with low blood sugar can feel very hungry or very tired. The symptoms of hypoglycemia tend to come on much more suddenly.

• More Serious Symptoms These include headache, difficulty concentrating, blurred vision, crying and other mood changes, and lack of coordination. Untreated hypoglycemia can be serious. Don’t drive a motor vehicle in such condition. Mild hypoglycemia can be uncomfortable. Moderate hypoglycemia often leads to confusion, but usually the patient can still treat the condition without seeing a doctor. But with severe hypoglycemia a diabetic is too disoriented to do anything about it, and may fall into a coma or suffer a seizure if medical help is not forthcoming.

Prevention

Patient education and self-monitoring of blood glucose are the best approaches to preventing hypoglycemia. By emphasizing the relation between hypoglycemia and delayed or decreased food intake or increased physical activity, you may help patients anticipate and avoid the condition. If patients regularly and correctly monitor their blood glucose level, impending hypoglycemia may be avoided. To minimize the risk of hypoglycemia, cooperation is required between the patient, family members, other persons close to the patient (including friends, teachers, and colleagues), and health care providers. Stress the importance of such persons knowing the signs and symptoms of hypoglycemia and how to treat it.

Detection

Clinical hypoglycemia (blood glucose level below approximately 60 mg/dl) is associated with adrenergic symptoms (apprehension, tremors, sweating, or palpitations) and neuroglycopenic symptoms (fatigue, headache, confusion, coma, or seizure). Usually, the symptoms of low blood glucose are mild, related to catecholamine release, and easily treated by the patient. Severe hypoglycemia occurs when the patient ignores, inappropriately
treats, lacks, or does not recognize the early warning signs or when glucose counterregulation fails to return the blood glucose level to normal.

**Treatment**

**Guidelines for treating hypoglycemia are as follows:**

<table>
<thead>
<tr>
<th>Person</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td>Eat 10 to 15 grams of rapidly absorbable carbohydrate (3 to 5 pieces of hard candy, 2 to 3 packets of sugar, or 4 ounces of fruit juice) to abort the episode. Repeat in 15 minutes, as necessary.</td>
</tr>
<tr>
<td><strong>Friend or family member</strong></td>
<td>If the patient is unable to treat himself or herself, administer oral carbohydrate. If the patient is unable to swallow, administer glucagon subcutaneously or intramuscularly. For adults give 1.0 mg.</td>
</tr>
<tr>
<td><strong>Practitioner</strong></td>
<td>If the patient shows signs and symptoms of severe hypoglycemia, administer glucagon or inject 25 grams of sterile 50% glucose intravenously. Analyze the cause of the episode. Often, a modest reduction in the insulin dosage should be advised. Reeducate the patient about preventing hypoglycemia by discussing the timing of meals and physical activity, the use of alcohol, and the frequency of self-monitoring of blood glucose. Those patients who develop hypoglycemia while taking oral hypoglycemic agents should be closely monitored for at least 48 to 72 hours to prevent a possible recurrence.</td>
</tr>
</tbody>
</table>

1. Ensure that patients who use oral hypoglycemic agents or insulin understand the signs and symptoms, causes, and treatment of hypoglycemia.
2. Instruct patients who use oral hypoglycemic agents or insulin to wear a bracelet or necklace that identifies them as having diabetes and to carry sugar or some other source of simple carbohydrate that can be used to promptly treat hypoglycemia.
3. Advise persons with diabetes to tell close friends, teachers, or colleagues about their diabetes, how to recognize hypoglycemia and what to do if an emergency occurs.
4. Ensure that patients particularly prone to hypoglycemia who are treated with insulin have glucagon available and that family members and friends know how to administer it.
5. Instruct patients with diminished awareness of the signs and symptoms of hypoglycemia to monitor their blood glucose levels at frequent intervals so that unexpected episodes can be recognized early and more severe hypoglycemia forestalled.
6. Consider changing the level of diabetes control in the following patients:
   - Those who do not or cannot recognize the early warning signs of hypoglycemia.
   - Those who do not understand the educational details of avoiding or treating hypoglycemia.
   - Those whose lifestyle makes them vulnerable to life-threatening episodes of hypoglycemia.

**References**


**Lesson 5. Acute Glycemic Complications**

**Diabetic Ketoacidosis.**

- **Definition:** (DKA) develops when absolute insulin deficiency and excess contra-insulin hormones increase hepatic glucose production, decrease peripheral glucose utilization, and stimulate release of fatty acids from fat cells and production of ketones by the liver. These changes cause hyperglycemia, osmotic diuresis, volume depletion, and acidosis. The annual incidence of DKA ranges from three to eight episodes per 1,000 persons with diabetes. Patients with NIDDM who experience severe stress may secrete more contra-insulin hormones; these further compromise limited insulin secretion, which may in turn lead to DKA. The
mortality rate associated with DKA is less than 5%. Serious medical sequel includes cerebral edema (in young people), aspiration pneumonia, and adult respiratory distress syndrome. The process has two stages.

1. In the early phase is ketonuria and usually develops within an hour or two. The kidneys are unable to cleanse the bloodstream and spill ketones into the urine.
2. If ketonuria is not detected, with a day or so the ketones begin to back up in the blood and it gets very acidic. This is ketoacidosis. If DKA is not detected, it can lead to coma or even death.

**The Symptoms of DKA:** frequent urination, heavy thirst, and general fatigue. The presence of excessive ketones also causes nausea and vomiting, and sometimes gives the breath a sweet odor.

If these symptoms become severe, it is time to contact your doctor or go to the emergency room.

**Prevention**

DKA should be considered preventable. Three general circumstances may allow DKA to develop:

- Low index of suspicion: many people may not know the signs and symptoms of diabetes.
- Inappropriate cessation of insulin therapy: Adolescents with diabetes may not adhere to a prescribed program. Patients with major emotional or psychosocial problems may fail to adhere to their usual medical program.
- Mismanagement of intercurrent illness, often due to inadequate education: intercurrent illness.

Therefore, to prevent DKA or to minimize its extent:

- The health care provider must have a high index of suspicion for DKA. Routine use of a glucose/ketone dipstick may allow for early identification of decompensating diabetes.
- When ill or stressed, the patient should promptly test the glucose level in blood and/or urine for ketones. The patient should follow a sick-day protocol and consult with the physician.

**Be sure your patients with diabetes know the following:**

- If they are at risk for DKA.
- When they are most susceptible to DKA.
- What they can do to prevent DKA.
- When they should contact you.

1. If you feel too sick to eat normally call your health care provider right away. Describe in detail how you feel.
2. Keep taking insulin when you feel sick. Don’t stop taking insulin even if you can’t eat. Your health care provider may change your insulin dose or may tell you to drink liquids that have sugar in them.
3. Weigh yourself every day and write down your weight.
4. Take your temperature every morning and evening. Write down the readings. (For small children or for someone who is breathing through the mouth, use a rectal thermometer.) If your temperature is above normal (99 F), drink extra liquids.
5. If you weigh 80 pounds or more, try to drink at least 12 eight-ounce glasses of liquid per day. Write down how much you drink. If you throw up, call your health care provider right away. You may need to go to the hospital or have special medical treatment.
6. Every 4 hours or before every meal, measure the glucose level in your blood. Write down the results. If the level is less than 60 mg/dl or consistently higher than 240 mg/dl, calls your health care provider. Every 4 hours or each time you pass urine, test your urine for ketones and write down the results.
7. If you start to have trouble breathing, call your health care provider (or have someone do it for you) or go to a nearby emergency room.
8. Every 4 to 6 hours write down whether you feel awake or sleepy. If you feel very sleepy or can’t concentrate, have someone call your health care provider right away.
9. If your health care provider asks you to, call every day to describe your daily record. Your health care provider may adjust your daily insulin dosage.

**Record for Sick Days**

<table>
<thead>
<tr>
<th>How often</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Every day</td>
<td>How much do you weight today?</td>
<td>_____ kg</td>
</tr>
<tr>
<td>Time Interval</td>
<td>Measurement</td>
<td>Time</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>-----------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Every evening</td>
<td>How much did you drink today?</td>
<td></td>
</tr>
<tr>
<td>Every morning and every evening</td>
<td>What is your temperature?</td>
<td>AM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PM</td>
</tr>
<tr>
<td>Every 4 hours or before every meal</td>
<td>How much medication did you take?</td>
<td></td>
</tr>
<tr>
<td>Every 4 hours or before every meal</td>
<td>What is the level of glucose in your blood?</td>
<td></td>
</tr>
<tr>
<td>Every 4 hours or each time you pass urine</td>
<td>What is the level of ketones in your urine?</td>
<td></td>
</tr>
<tr>
<td>Every 4 to 6 hours</td>
<td>How are you breathing?</td>
<td></td>
</tr>
</tbody>
</table>

If you feel unusually sleepy or can't concentrate, have someone call your health care provider or take you to an emergency room.

**Symptoms**: Suspect DKA in any person at any age that has symptoms compatible with hyperglycemia and ketosis, including:
- Altered mental status.
- Fatigue.
- Weight loss.
- Blurred vision.
- Thirst.
- Excessive urination.
- Abdominal pain.
- Enuresis.
- Nausea or vomiting.

Results of a simple glucose/ketone urine dipstick may give guiding information about the presence of diabetes or DKA. If glucose or ketones are present in the urine, the blood glucose level must be measured. All patients with IDDM should be taught to prevent DKA. Encourage patients to monitor their blood glucose level and advise them to monitor the urine for ketones when the blood glucose level is 240 mg/dl or more and/or acute illness develops.

**Treatment**
Insist that patients contact you promptly when the blood glucose level remains at 240 mg/dl or more, ketonuria develops, or acute illness persists. In adult patients, an electrocardiogram should be performed to rule out a silent acute myocardial infarction. Treatment should be done in the hospital. Hospitalize the patient at once. An intensive care unit is the preferred site for the treatment of severe DKA.

**Reference**

**Hyperglycemic Hyperosmolar Nonketotic Coma**
Definition: Hyperglycemic hyperosmolar nonketotic coma (HHNKC) is characterized by severe hyperglycemia (glucose level typically greater than 600 to 800 mg/dl), dehydration, and altered mental status - in the absence of ketosis. In HHNKC, hyperglycemia causes glycosuria. Osmotic diuresis results in volume contraction and a reduction in both the glomerular filtration rate and glucose excretion. Worsening hyperglycemia causes further extracellular hypertention and intracellular dehydration. Central nervous system dysfunction in persons with HHNKC is probably due to hyperosmolarity. HHNKC occurs most often among persons over 60 years of age. Most persons with HHNKC have a history of NIDDM, but in a sizable minority, NIDDM is undiagnosed or untreated. When persons who are chronically ill, debilitated, or institutionalized have mild renal insufficiency and lack normal thirst mechanisms or access to water, they are at risk of developing HHNKC. Acute illnesses (stroke, myocardial infarction, or pneumonia), drugs (diuretics or glucocorticoids), surgery, and, occasionally, large glucose loads (through enteral or parenteral nutrition or peritoneal dialysis) may precipitate HHNKC. The mortality rate for HHNKC has been reported to be as high as 50%, primarily because of the age of the population most at risk and the acute precipitating causes.

**Prevention**
Be alert to the elderly patient who:
• Has a history of NIDDM.
• Has an altered level of consciousness.
• Takes diuretics or glucocorticoids.
• Lacks free access to drinking water.
• Has a poor support system at home or lives in a nursing home.
• Is receiving enteral or parenteral nutrition.

Remind persons responsible for the elderly, the infirm, or the chronically ill to look for the signs and symptoms of diabetes when their patients do not thrive. Recommend that a blood glucose-screening test be performed at the bedside.

For persons with several of these characteristics, periodically monitor the glucose level in the urine or blood. (Monitoring blood glucose is preferred.) If the fasting blood glucose level is above 200 mg/dl, monitor the glucose level more frequently and initiate or adjust hypoglycemic medications as necessary.

**Detection**

The patient with HHNKC has severe hyperglycemia and azotemia without ketoacidosis. The intravascular volume is contracted, and the patient shows signs and symptoms of hypovolemia and severe dehydration. Both diffuse and focal central nervous system deficits may occur. These may include hallucinations, aphasia, nystagm, hemianopsia, hemiplegia, hemisensory deficits, and focal or grand mal seizures. Coma may ensue.

**Treatment**

Therapy is primarily directed at replacement of fluid and electrolytes while supportive care is given. Insulin therapy is designed to slowly over 24 to 48 hours return the blood glucose level to a near normal range. When therapy is successful, the patient may be significantly sensitive to further insulin. Ultimately, the patient may achieve metabolic control through diet and/or oral agents.

**Reference**


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Lesson 6.  

**The Symptoms of Hyperglycemia (high blood sugar)**

• Thirst and Frequent Urination  Everybody's blood is cleansed by the kidneys, which filter out waste products and expel them in the urine. The kidneys also recycle important nutrients like sugar, sending them back into the bloodstream. But if the blood sugar is too high, the blood actually thickens like syrup. When this happens, the kidneys can't handle all of the sugar and some of it will be excreted in the urine, along with an extra amount of fluid. This leads to increased frequency of urination, and also makes you thirsty, since the body becomes dehydrated and needs to replace the water that has been lost.

• Weight Loss: if the body loses sugar through the urine, it also loses calories. If the body is not getting enough energy from blood sugar, it turns to the reserve supply it has stored up in body fat. The body loses weight because of both the loss of water and the use of fat to provide energy.

• Blurred Vision: when the blood sugar is high, sugar can build up in the fluid of the eye, causing the lens to swell. When this happens, the eye can't focus properly and vision blurs. Usually this is a temporary condition that goes away once the blood sugar is stabilized.

• Lack of Energy: many things can cause fatigue. In people with diabetes it often results from lack of insulin, when the body is unable to move sugar into the cells and convert it to energy. The fatigue that results from high blood sugar usually comes on after a meal (or during illness), and it commonly comes on gradually.

• Constant Hunger: no matter how high the blood sugar is, if the body can't convert sugar into energy, it signals for more food.

• Infections: when blood sugar is high, the immune system doesn't work as well as it should. Common infections (such as colds, flu, urinary tract infections and vaginal infections in women) can sometimes take much longer than normal to heal. The germs and viruses that cause these infections flourish in a high sugar environment.
• **Other Symptoms:** nerve pain, especially in the feet. Nausea, vomiting and weakness can sometimes occur when the body is relying on stored fat for energy.

**Diabetic Neuropathy**

**Patient Education Principles:**
- Inform patients about the possible relationship between poor glycemic control and the subsequent development of diabetic neuropathy.
- Explain possible risiordontal disease describes a group of local exposure to chemical toxins and concomitant neural insults that may hasten the development or progression of diabetic neuropathy.
- Stress that because sensory or motor neuropathy may be asymptotic, routine evaluation is necessary even for patients who have no symptoms of neuropathy.
- Explain that diabetic neuropathy can contribute to the development of other complications, including loss of limb.
- Inform patients who have lost sensation in their feet about the importance of caring for their feet, wearing proper shoes, and getting appropriate exercise.
- Discuss the signs and symptoms of autonomic neuropathy.

Explaining the importance of treatment to patients with autonomic neuropathy.

Persons with diabetes who develop neuropathy may have no symptoms or may experience pain, sensory loss, weakness, and autonomic dysfunction. Neuropathy may result in significant morbidity and may contribute to other major complications, such as lower extremity amputation.

**There are three major types of diabetic neuropathy:**
- Distal symmetrical polyneuropathy.
- Focal neuropathy.
- Autonomic neuropathy.

**A. Distal symmetrical polyneuropathy.** This most common of the diabetic neuropathies is characterized by insidious onset, symmetrical distribution, and progressive course. Distal symmetrical polyneuropathy is the result of abnormal neural metabolism, generalized neural ischemia, or both. The onset and course of illness cannot be predicted for an individual patient, but increasing age, male sex, increasing height, longer duration of diabetes, poorer glucose control, hypertension, alcohol consumption, and smoking may be independent risk factors. Approximately 12% of patients have this condition when diabetes is diagnosed, and nearly 60% have it after 25 years.

**Three overlapping clinical syndromes:**
1. **Acute painful neuropathy** often occurs without evidence of other significant neurologic impairment. It may occur early or late and may be associated with the institution of insulin treatment or with abrupt weight loss. Patients develop dysesthesia and paresthesia in the lower extremities. The severe, burning pain is often associated with cutaneous hyperesthesia and is worse at night. Objective evidence of neuropathy may be minimal. Symptoms generally resolve slowly, within months of achieving good glycemic control. Relapses are rare.
2. **Small fiber neuropathy** may occur after only a few years of diabetes. Patients have varying degrees of pain and sensory loss; they usually feel a burning pain and may develop dysesthesia. Prominent features of small fiber neuropathy are distal loss of temperature sensation, pinprick or pressure sensation. Vibratory sensation, position sense, muscle strength, and ankle reflexes are generally unimpaired. Neuropathic ulcers occasionally occur at sites of trauma.
3. **Large fiber neuropathy** generally occurs in the setting of small fiber neuropathy. Patients have impaired distal vibration sensation and impaired distal position sense. Ankle reflexes are reduced or lost. In more severe instances, patients develop sensory ataxia and have a positive Romberg's test. Large fiber neuropathy is most strongly associated with the development of neuropathic foot ulcers and neuropathic arthropathy affecting the interphalangeal, metatarsophalangeal, and ankle joints.

**B. Focal neuropathy:** is an uncommon condition, which occurs after the acute occlusion of a blood vessel produces ischemia in a nerve or group of nerves. The characteristics of focal diabetic neuropathy are sudden onset, an asymmetrical nature, and a self-limited course. Near total recovery gene-rally occurs within two weeks to 18 months. Examples of focal diabetic neuropathies are cranial neuropathies, truncal neuropathies, mononeuropathies, radiculopathies, and plexopathies. Both sensory and motor components may be present.

**C. Autonomic neuropathy.** This troubling complication of diabetes encompasses multiple disturbances affecting the following systems: sudomotor (heat exhaustion), pupillary (poor night vision), adrenomedullary (hypoglycemia unawareness), cardiovascular (orthostatic hypotension, painless myocardial ischemia),
gastrointestinal (gastroparesis, constipation, diarrhea, fecal incontinence), and urogenital (bladder dysfunction, sexual dysfunction).

**The following complications can occur with autonomic neuropathy:**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthostatic hypotension</td>
<td>Suspect this condition when a patient reports having postural fainess, weakness, visual impairment, or syncope. In patients whose intravascular volume is not depleted, autonomic neuropathy may be diagnosed if the systolic blood pressure falls more than 30 Hg or if the diastolic blood pressure falls more than 10 mm Hg when the patient changes from a lying to a standing position.</td>
</tr>
<tr>
<td>Gastroparesis</td>
<td>May be associated with symptoms of anorexia, early satiety, bloating, abdominal pain, nausea, and vomiting. Signs may include weight loss and erratic glycemic control.</td>
</tr>
<tr>
<td>Constipation</td>
<td>A common manifestation that may be difficult to treat.</td>
</tr>
<tr>
<td>Diabetic diarrhea</td>
<td>May last from a few hours to several weeks. May be severe and watery, is generally worse at night, and is often preceded by abdominal cramps. During remissions, the patient may report constipation.</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>Associated with a reduced threshold of conscious rectal sensation, low basal internal sphincter pressure, and reduced voluntary control of the external anal sphincter.</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>Men may experience impotence. Women may experience decreased vaginal lubrication and dyspareunia.</td>
</tr>
<tr>
<td>Diabetic bladder dysfunction</td>
<td>Associated with defective perception of bladder filling and decreased reflex bladder emptying. Patients may strain to initiate a stream, may be unable to completely void, may dribble when urinating, and may have recurrent urinary tract infections.</td>
</tr>
</tbody>
</table>

**Prevention**

Practitioners should urge patients to avoid risk factors associated with the development of peripheral polyneuropathy. Consumption of alcohol, poor nutrition, exposure to chemical toxins, use of certain drugs, and physical injury to the nerves (entrapment, compression).

**Detection**

The practitioner should conduct an interview at each visit—**at least 4 times a year**—to determine the existence of:

- Peripheral pain, paresthesia, or numbness.
- Weakness.
- Hypoglycemia awareness.
- Orthostatic lightheadedness.
- Gastrointestinal symptoms, such as bloating, nausea, vomiting, constipation, diarrhea, and loss of bowel control.
- Urogenital symptoms, such as loss of bladder control and sexual dysfunction.

The practitioner should inspect the feet at each visit—**at least 4 times a year**.

**At least once a year,** the practitioner should perform a physical examination to assess neuralgic function. The practitioner should measure blood pressure and pulse rate (both when the patient is lying down and standing) and should assess the patient's muscle strength, deep tendon reflexes, and sense of touch. Four modalities of touch should be assessed.

**Distal temperature sensation.** Touch a cool piece of metal (such as a tuning fork) to the patient's foot; ask the patient to describe the object's temperature. Another method is to alternately touch the patient's foot with a test tube containing cool water and another containing warm water; ask the patient to distinguish between these objects.

**Distal pinprick or pressure sensation.** Have the patient close his or her eyes. Hold a pin lightly between your thumb and forefinger and touch it to the patient's foot. Ask the patient to say when a sensation is felt and whether the sensation is sharp or dull. Clarify a doubtful response by alternately touching the patient with the point and the head of the pin. As an alternative, pressure sensation can be assessed with a **monofilament.**

**Distal vibratory sensation.** Tap a 128 hz tuning fork and place the end of the handle on a bony surface of the patient, such as the distal first metatarsal head or the malleoli of the ankles. Ask the patient to say when the vibration ceases.

**Position sense.** Have the patient close his or her eyes. Grasp between your thumb and index finger the lateral and medial sides of the patient's toe. Ask the patient to describe the toe's position as you alternately flex and extend it.
The practitioner should exclude other potential causes of neuropathy before attributing a patient's neuropathy to diabetes.

<table>
<thead>
<tr>
<th>Type of neuropathy.</th>
<th>Differential Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal symmetrical polyneuropathy.</td>
<td>Medications: Exposure to toxins, including ethanol, organic; solvents, and heavy metals; Uremia; Hypothyroidism; Pernicious anemia, Intoxication from vitamin B6; Syphilis; Gammopathy or myeloma; Malignancy; Collagen vascular disease; Porphyria; Hereditary neuropathy.</td>
</tr>
</tbody>
</table>

**Treatment**

**Distal symmetrical polyneuropathy.** Often the pain resolves. For patients with painful neuropathy, the practitioner should institute rigorous glucose control. If pain continues, consider using pharmacological agents such as amitriptyline, imipramine, nortriptyline plus fluphenazine, carbamazepine, mexiletine, or capsaicin. Inform patients with distal sensory or motor abnormalities about foot care. Tell patients who have lost sensation in their feet to wear special protective footwear and to avoid activities (such as jogging) that can traumatize the feet.

**Focal neuropathy.** After other causes are excluded, management is palliative. Spontaneous resolution generally occurs within a period of months but may persist over years.

**Autonomic neuropathy.** Various treatments are available for autonomic neuropathy.

**Hypoglycemia unawareness.** If necessary, alter patients' targeted goals for glycemic control. Encourage patients to monitor their blood glucose regularly. Instruct patients to carry with them a source of simple sugar. Patients should also have glucagon available; their family and friends need to know how and when to use it.

**Orthostatic hypotension.** Patients may benefit from improved glycemic control (to reduce glycosuria), from volume and salt repletion, and from mechanical support with waist-high elastic stockings. Vasoconstrictors may be indicated.

**Gastroparesis.** Patients may benefit from correction of metabolic abnormalities (including hyperglycemia, ketosis, and hypokalemia), from dietary modification (eating small, liquid, low-fiber, low-fat meals), and from a prokinetic agent such as metoclopramide.

**Constipation.** Patients may benefit from correction of glycosuria, adequate hydration, a high-fiber diet, and psyllium.

**Diarrhea.** Patients may benefit from a bowel program that includes ingesting dietary fiber and making regular efforts to move the bowels. Another possible treatment is a short-term trial of an antidiarrheal agent (such as loperamide or diphenoxylate hydrochloride and atropine sulfate) or a broad-spectrum antibiotic with anaerobic coverage (such as tetracycline or metronidazole hydrochloride). Metoclopramide may occasionally be beneficial.

**Diabetic bladder dysfunction.** Patients may benefit from treatment to improve bladder emptying and to reduce the risk of urinary tract infection.

**Impotence.** Patients may benefit from noninvasive devices to assist erection, or from papaverine injections.

**References**

2. Cyrus J, Broadstone VL, Pfeifer MA, Greene DA. Diabetic peripheral neuropathy, part II: autonomic neuropathies. The
Lesson 7. Kidney Disease (Diabetic Nephropathy)

Diabetic nephropathy represents a distinct clinical syndrome characterized by albuminuria, hypertension, and progressive renal insufficiency. Diabetic nephropathy can lead to end-stage renal disease (ESRD), a serious condition in which a patient's survival depends on either dialysis or kidney transplantation. The natural history of renal involvement in persons with NIDDM is not well established. Although microalbuminuria has been shown to be associated with the development of clinical diabetic nephropathy, the precise level of microalbuminuria that reliably predicts this condition has yet to be determined. Some individuals with low levels of albuminuria do not develop renal failure. In these persons, albuminuria may be due to the presence of other complicating renal diseases, such as obstructive uropathy, hypertension, or arteriolosclerosis, or may reflect an age-related increase in urinary albumin excretion.

Patient Education Principles:

• Inform patients about the potential renal complications of diabetes.
• Inform patients about the association between hypertension and accelerated renal disease. Discuss the need for regular blood pressure measurements and encourage patients to measure their own blood pressure at home. Stress the importance of treating hypertension.
• Explain the potential role that excessive protein in the diet may play in the pathogenesis and progression of diabetic nephropathy.
• Explain the possible relationship between poor glycemic control and the development of diabetic renal disease.
• Emphasize the importance of achieving and maintaining ideal body weight and of undertaking a regular physical exercise program as strategies for preventing hypertension.
• Review with patients the symptoms of urinary tract infection. Instruct patients to contact their health care provider if such symptoms occur.
• Review with patients which drugs are potentially nephrotoxic. Explain the danger of radiographic dye studies.

Review the natural history of clinical diabetic nephropathy with patients who have this condition. Discuss the therapeutic options dialysis versus transplantation for ESRD.

Prevention

At present, strategies for preventing diabetic nephropathy must be viewed as limited in their effectiveness, since the exact pathogenic factors responsible for this condition are unknown. In patients with albuminuria, blood pressure regulation is of critical importance in slowing the progression to renal failure. Other strategies that may slow the progression of renal disease include limiting the patient’s protein intake, maintaining good glycemic control, promptly treating urinary tract infections, and avoiding potentially nephrotoxic drugs and radiographic dyes.

Detection

At the time of initial diagnosis, all diabetic patients should have a urinalysis performed. If bacteria or white blood cells are seen, a culture should be obtained. Each year, obtain a sensitive quantitative measure of urinary albumin or protein excretion. In general, the protein excretion rate is about one third greater than that for albumin. Thus, a protein excretion rate of approximately 400-mg per 24 hours would correspond to an albumin excretion rate of 300 mg per 24 hours. Measure renal function (serum creatinine and/or creatinine clearance) each year.

Before establishing a diagnosis of diabetic nephropathy, exclude other possible causes of renal disease—particularly, obstructive uropathy and infection. If diabetic retinopathy is not present, suspect a nondiabetic cause of renal disease.

Hypertension is a common development with the onset of diabetic nephropathy or shortly thereafter. If the patient's initial blood pressure is higher than 140/90 mm Hg, at least three additional readings should be obtained over the next month.

Treatment

At present, no known interventions have been shown to reverse clinical diabetic nephropathy. However, practitioners can take several actions to monitor and perhaps slow the progress of this complication:
• Aggressively monitor and treat high blood pressure (>140/90 mm Hg) or significant increments in blood pressure (20/10 mm Hg or greater on careful follow-up) in patients with renal disease.
• Encourage all nonpregnant adults with diabetes, especially those with renal involvement, to limit their daily protein intake to 0.8 g/kg of body weight, as recommended by the American Diabetes Association.
• Strive to achieve good glycemic control, without undue side effects from hypoglycemia, in all diabetic patients, especially those with microalbuminuria.
• Recommend consultation with a diabetologist and/or a nephrologist if patients have microalbuminuria (30 to 300 mg per 24 hours), clinically overt albuminuria (>300 mg per 24 hours), nephrotic syndrome, elevated serum creatinine (>2 mg/dl), or diminished GFR (<50 ml per minute).
• Instruct patients with microalbuminuria or diabetic nephropathy to receive yearly eye examinations.
• Assess cardiovascular risk factors—particularly hypercholesterolemia and cigarette smoking—and provide appropriate treatment, especially for patients with NIDDM.
• Seek and treat other causes of renal disease, particularly obstructive uropathy and infection. Promptly treat any urinary tract infections. Repeat a urine culture after treatment to ensure resolution.

Patients who have developed ESRD will require kidney transplantation, hemodialysis, or peritoneal dialysis to prolong their lives. Because diabetic complications—especially retinopathy and neuropathy, progress more rapidly with the onset of renal failure, dialysis is usually instituted earlier (when the concentration of serum creatinine reaches about 6 mg/dl) for people with diabetes than for those without diabetes. Kidney transplantation is preferable to dialysis when a living relative of the patient is available as a donor; the patient's chances of survival are otherwise about equal among these three courses of treatment. The ultimate choice will require the nephrologist.

References

Lesson 8. Eye Disease

Diabetic retinopathy is often asymptomatic in its most treatable stages. Unfortunately, only about half of persons with diabetes receive adequate eye care. Symptoms: Diabetic retinopathy usually has no symptoms when it first starts to develop. It's even possible to have severe, sight-threatening retinopathy without having any change in vision. When symptoms do occur, they may include black or red "floaters," or spots, in your field of vision. Macular edema can blur or distort your vision, and straight lines may appear warped. Macular edema can also affect how you see colors.

Patient Education Principles:
• Inform patients that sight-threatening eye disease is a common complication of diabetes and may be present even with good vision. Remind them to report all ocular symptoms, since essentially any symptoms may be diabetic in origin.
• Blurred vision while reading may indicate macular edema. The presence of floaters may indicate hemorrhage, and flashing lights may indicate retinal detachment. Inform patients that early detection and appropriate treatment of diabetic eye disease greatly reduces the risk of visual loss.
• Inform patients about the possible relationship between glycemic control and the subsequent development of ocular complications.
• Tell patients about the association between hypertension and diabetic retinopathy. Stress the importance of the diagnosis and continuing treatment of hypertension. Urge patients to work closely with their health care team.
• Help patients understand the natural course and treatment of diabetic retinopathy and the importance of yearly eye examinations.
• Tell patients with diabetic retinopathy about the availability and benefits of early and timely laser photocoagulation therapy in reducing the risk of visual loss.
• Inform patients about their higher risks of cataract formation, open-angle glaucoma, and neovascular glaucoma.
• Tell all patients with any visual impairment (including blindness) about the availability of visual, vocational and psychosocial rehabilitation programs.

| Visual Acuity Test | Measures level of best vision  
|                   | Establishes baseline measurement for future exams  
|                   | Measures need for eyeglasses  

| Tonometry (Glaucoma test) | Measures pressure in the eye to help detect glaucoma  
|                          | Establishes baseline measurements for future examinations  

| External eye exam | Measures eye movements  
|                   | Measures size of the pupils and their ability to respond to light stimulus  

| Retinal examination | Requires pupil dilation for complete evaluation  
|                    | Checks for diabetic retinopathy, diabetic macular edema, and other retinal disease.  

Early detection of diabetic retinopathy is critical. 1. Timely laser surgery can reduce the risk of visual loss from high-risk proliferative diabetic retinopathy by approximately 60%. 2. Timely-laser surgery can reduce the risk of moderate visual loss from clinically significant diabetic macular edema by 50%. 3. Vitrectomy can restore useful vision in some diabetic patients whose retinopathy is too advanced for laser surgery.

Five clinical pathological processes can be recognized in diabetic retinopathy:
• Formation of microaneurysms (outpouchings of the capillary walls).
• Increased vascular permeability of retinal capillaries.
• Closure of retinal capillaries and arterioles.
• Proliferation of new vessels and fibrous tissues.
• Contraction of fibrous tissue and hemorrhage and/or retinal detachment due to traction.

Diabetic macular edema can be associated with any stage of diabetic retinopathy.
Cataracts. Diabetes puts you at risk for cataracts, which cloud the lens and can make you feel as though—ugh you are looking through waxed paper Cataracts are 1.6 times more common in people with diabetes than in those without diabetes. Furthermore, cataracts occur at a younger age and progress more rapidly in people with diabetes. Fortunately, cataract extraction with or without lens implantation is 90% to 95% successful in restoring useful vision, but the surgery is not without potential complications that are more frequent in patients with diabetes. And some changes in vision may simply be a product of aging. If you are older than 50, changes in the fluid that fills the eyeball (the vitreous) can cause translucent or web-like floaters that move as your eye moves. Open-angle glaucoma. Open-angle glaucoma is 1.4 times more common in the diabetic population. The prevalence of glaucoma increases with the patient's age and with the length of time the patient has had diabetes. Medical therapy for open-angle glaucoma is generally effective. Neovascular glaucoma is a more severe type of glaucoma that most commonly occurs among patients with severe proliferative diabetic retinopathy and retinal detachments. It occasionally follows vitrectomy or cataract surgery. Early recognition and emergency panretinal laser surgery may prevent full development of this devastating type of glaucoma. Diagnosis and evaluation require slit-lamp examination of the iris and gonioscopic evaluation of the filtration angle.

**Prevention of Diabetic Retinopathy**
Epidemiological studies have suggested that diabetic retinopathy and diabetic macular edema are associated with poorer glycemic control and higher blood pressure levels. Health care providers should work with their patients to achieve good blood glucose and blood pressure control. Because coexisting medical problems—including hypertension and renal disease—may affect the development and progression of diabetic retinopathy, blood pressure should be routinely measured. If hypertension exists even at borderline levels, it should be monitored and treated as needed. Aspirin treatment (650 mg per day) neither alters the progression of diabetic retinopathy nor increases the risk of vitreous hemorrhage. Therefore, diabetic retinopathy is not a contraindication for the medical use of aspirin.

Because diabetic retinopathy and diabetic macular edema cannot be prevented, routine early evaluation, timely laser surgery, and careful follow-up are critical.

**The following examination schedule is designed to ensure the early detection and monitoring of diabetic eye disease:**
• All patients with non-insulin-dependent diabetes mellitus should have yearly eye examinations including a history of visual symptoms, measurement of visual acuity, measurement of intraocular pressure, and dilation of the pupils with thorough vitreous and retinal examination including stereoscopic examination of the macula.
• Any woman with known diabetes who becomes pregnant should be examined for retinopathy early in the first trimester. Retinopathy may progress very rapidly during pregnancy; close cooperation among the health care team is critical. After the initial eye examination, persons with diabetes should receive complete examinations once a year, unless more frequent examinations are indicated by the presence of abnormalities. The patient should be under the care of a retinal specialist or ophthalmologist experienced in the treatment of diabetic retinopathy when any of the following conditions are identified:

**Proliferative retinopathy.**

**Macular edema.**

**Preproliferative retinopathy (severe or very severe nonproliferative retinopathy).**

**Nonproliferative retinopathy in women during pregnancy.**

Vitrectomy surgery may restore usable vision for some individuals who have lost sight from vitreous hemorrhage or fibrous tissue proliferation with traction detachment. Postsurgical treatment requires proper refraction, low vision evaluation, optical aids, and other techniques and devices to enable the person to use even severely limited vision.

**Treatment**

Patients with high-risk proliferative diabetic retinopathy should receive immediate laser photocoagulation surgery. Some patients with diabetic macular edema are candidates for immediate macular laser surgery. If careful follow-up can be maintained, it is safe to defer treatment in those with severe nonproliferative diabetic retinopathy and non-high-risk proliferative retinopathy until it approaches or reaches the high-risk stage. Alternatively, in patients with bilateral non-high-risk proliferative retinopathy, one eye may be considered for laser surgery prior to the high-risk stage. Patients with functionally decreased visual acuity should be referred for low vision evaluation and appropriate visual, vocational, and psychosocial rehabilitation.

**References**


**Lesson 9. Cardiovascular Disease**

**Patient Education Principles:**

• Inform patients with diabetes that their risk of developing cardiovascular disease is higher than that of persons without diabetes.

• Inform patients of the absolute necessity of not smoking.

• Emphasize to patients the importance of following dietary principles appropriate for their conditions (such as hypertension or hyperlipidemia).

• Inform patients that hypertension and hyperlipidemia must be treated vigorously.

Tell patients to immediately report symptoms of cardiovascular disease (for example, transient ischemic attack, chest pain, and claudication) so that investigation and treatment can begin promptly.

Cardiovascular disease is the leading cause of morbidity and mortality among persons with diabetes. The annual risk for death from cardiovascular disease is two to three times greater for persons with diabetes than for persons without diabetes. For persons with diabetes, the risk for cerebrovascular disease and for coronary artery disease is two to three times greater, and the risk for peripheral vascular disease is five times greater. Among persons without diabetes, women have a lower rate of cardiovascular disease than men do; among persons with diabetes, women are not preferentially spared. **Risk factors.** In persons with diabetes, smoking is a powerful risk factor for cardiovascular disease, and the prevalence of smoking appears to be higher in young people (less than 21 years old) with diabetes than in young people without diabetes. Hypertension, also a strong risk factor for cardiovascular disease, occurs two to three times more often in persons with diabetes than in persons without diabetes. The risk for cardiovascular disease increases linearly with increases in blood pressure. The precise relationship between hyperglycemia and atherosclerosis is also unknown. Among persons with diabetes, several concomitant conditions may affect the etiology of atherosclerosis: obesity, inactivity, hyperinsulinemia, abnormalities in platelet function, and defects in blood coagulation and flow.

**Prevention**
Smoking cessation may be the most important modification in behavior that can be made to reduce the risk for cardiovascular disease. Stress to patients the importance of not smoking. Encourage those who smoke to quit, and remind those who do not smoke not to start.

Blood pressure should be closely monitored in patients with diabetes. When blood pressure is increased over 140/90 mm Hg, nonpharmacologic therapy should be instituted. Medication may need to be initiated early, depending on the blood pressure level. When selecting drugs for treating hypertension, consider their potential adverse effects on other risk factors for cardiovascular disease.

When the total cholesterol is more than 200 mg/dl and the LDL cholesterol is more than 130 mg/dl, nonpharmacologic therapy should be instituted.

The relationship between plasma glucose and the development of cardiovascular disease is less clear. However, poor glycemic control is often associated with hyperlipidemia. Improved glycemic control has been shown to lower the concentration of cholesterol and triglycerides in plasma and to raise the concentration of HDL cholesterol in persons with diabetes who are either hyperlipidemic or normolipidemic. Weight, exercise, and aspirin therapy. Additional recommendations for preventing cardiovascular disease in diabetic patients include weight loss (for obese persons) and an increased level of physical activity. For patients who have had cardiovascular events, aspirin therapy may help to prevent mortality or additional morbidity from cardiovascular disease.

**Detection**

At every office visit **at least 4 times a year**:
- Measure the patient's blood pressure with a cuff appropriate for the patient's size.
- Ask patients whether they have had symptoms of the following conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral vascular disease</td>
<td>Transient blindness, dysarthria, or unilateral weakness.</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>Chest pain or pressure, dyspnea, and orthopnea, paroxysmal nocturnal dyspnea, or edema. (Painless myocardial infarction is common among diabetic patients, and they may have angina or myocardial infarction with atypical symptoms.)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>Intermittent claudication or foot ulcers that do not heal.</td>
</tr>
</tbody>
</table>

At least once a year:
- Ask patients about their use of tobacco.
- Auscultate for bruits over all large arteries and palpate all peripheral pulses.
- Measure triglycerides (TG), total cholesterol (TC), and HDL cholesterol levels in the fasting state, and calculate the level of LDL cholesterol. For TG under 400 mg/dl, LDL = TC - HDL - (TG \(\div\) 5).
- Obtain a baseline electrocardiogram in all patients with diabetes and repeat the procedure yearly for those with clinically apparent cardiovascular disease.

**Treatment**

Strongly advise patients who smoke to quit. Work with each patient to set a quit date, and follow up after that date. If the patient's blood pressure exceeds 140/90 mm Hg at two visits, begin nonpharmacologic therapy, including a low-sodium, alcohol-restricted diet designed for weight reduction. Regular exercise has also been shown to have a beneficial effect on blood pressure. Blood pressure should be maintained below 140/90 mm Hg. For individual patients, consider earlier pharmacologic intervention when indicated by clinical conditions (for example, diastolic blood pressure greater than 110 mm Hg) and the presence of other risk factors (such as albuminuria).

After 3 months of nonpharmacologic therapy, if the diastolic blood pressure remains above 90 mmHg, begin pharmacologic treatment. Select drugs that do not worsen other risk factors for cardiovascular disease (including lipids) and that do not induce or worsen autonomic neuropathic complications of diabetes (including hypoglycemia unawareness, orthostatic hypotension, or impotence).

**Hyperlipidemia.** When the calculated LDL cholesterol level is greater than 130 mg/dl, consider the following guidelines for glycemic control, diet, and exercise.

**Glycemic control.** Glycemic control should be improved through diet, use of sulfonylureas, or insulin therapy. Weigh the benefits of improved glycemic control against the potential risk for hypoglycemia.

**Dietary therapy.** Dietary therapy should be instituted to reduce the weight of obese patients and to try to lower the LDL cholesterol level to below 130 mg/dl. Consider the following restrictions on diet:
- Calorie restrictions for weight reduction if obesity is present.
- Total fat less than 30% of total calories.
• Saturated fats less than 10% of total calories. Complex carbohydrates and fiber (especially soluble fiber) can be substituted for the usual intake of saturated fats. Preliminary studies suggest that some diabetic patients with hypertriglyceridemia may benefit by restricting carbohydrate intake to 40% to 45% of total calories. In those patients, monounsaturated fats may be used to maintain caloric balance.

• Cholesterol less than 300 mg per day.

Exercise causes a modest drop in the LDL cholesterol level, to weight loss and to have a beneficial effect on lipids, especially levels of triglycerides and HDL cholesterol. Before patients begin an exercise program, determine whether they have hypoglycemia unawareness, postural hypotension, proliferative retinopathy, painless myocardial ischemia, or insensitive feet. An exercise stress test is recommended for all diabetic patients over 40 years old who are considering an exercise program.

Reevaluation. After 6 months of therapy, if a patient's LDL cholesterol level is above 160 mg/Dl, consider drug therapy. Drugs used to treat patients with hypercholesterolemia include bile acid sequestrates (cholestyramine or colestipol), HMGCoA reductase inhibitors (lovastatin), fibric acid derivatives (gemfibrozil or clofibrate), nicotinic acid, and probucol. Drugs used to treat patients with hypertriglyceridemia include fibric acid derivatives (gemfibrozil or clofibrate) and nicotinic acid.

Cerebral vascular disease. Patients with signs or symptoms of cerebral vascular disease should be referred for specialized diagnostic tests, including noninvasive Doppler flow studies and, if necessary, carotid arteriography. Caution should be used with dye studies in patients with preexisting renal disease and/or dehydration. Patients with symptomatic cerebral vascular disease may be treated with aspirin and anticoagulants. If symptoms persist despite pharmacological treatment and if correctable vascular lesions are present, surgery may be considered.

Coronary artery disease. Heart disease due to coronary atherosclerosis is the most common cause of morbidity and mortality in patients with diabetes. Patients with signs or symptoms of coronary artery disease should receive a complete evaluation, including exercise testing and, if necessary, coronary arteriography. Contrast-dye studies should be used with caution because of the possible coexistence of diabetic nephropathy. Nitrates, calcium channel blockers, and beta blockers may be prescribed for patients with angina. Consider coronary angioplasty or bypass surgery for patients with appropriate coronary lesions or intractable angina. Unless contraindicated, aspirin should be given after acute myocardial infarction. Because of their ability to prevent reinfarction in nondiabetic subjects, beta blockers may be used in patients with diabetes after myocardial infarction—with attention to possible hypoglycemia and/or hyperlipidemia.

Peripheral vascular disease. Generally, no effective medical treatment is available for patients with peripheral vascular disease, although some patients may benefit from pentoxifylline. Patients who have incapacitating symptoms of peripheral vascular disease (such as rest pain) or who have foot lesions that are poorly healing require careful evaluation. To detect surgically correctable peripheral vascular disease, first use clinical examination of the pulses and then consider noninvasive means (Doppler flow study). Contrast-dye studies should be used with caution because of the possible coexistence of diabetic nephropathy. Refer patients for surgery, as appropriate.

Reference


Lesson 10. Amputation prevention

At least half of the amputations performed every year are due to complications of diabetes. And, nearly every one of those is preventable! By following a few simple foot care tips, people with diabetes can reduce their chances of having foot problems like sores, cuts and bruises that may lead to amputation. With proper care and attention, feet can last a lifetime!

Remember! You are at risk for foot ulcers and amputations if you have:
- Loss of feeling in your feet
- Pain in legs while walking
- Changes in the shape of your feet
Previous foot ulcers
Foot ulcers and amputations can be prevented. To prevent foot ulcers, persons with diabetes who have any one of these risk factors must actively look at and protect their feet each day.

Action steps
♦ Look at your feet every day for sores, cuts, bruises, and injury.
♦ If you know, or have been told, that you have less feeling in your feet, always protect your feet by wearing appropriate shoes.
♦ If you are not sure you have normal feeling in your feet, have your doctor check your feet carefully and test to determine if you have normal feeling.
♦ Look for any color change, swelling, warmth, or redness, calluses or changes in the shape of your feet.
♦ Check between toes, trying to use a mirror to see difficult areas.
♦ If necessary, ask a family member or friend to help.
♦ If you find any problem with your feet, call your doctor immediately.
♦ Protect your feet at all times.
♦ Protect your feet with proper footwear: bunions and other irregularities require shoes that are wide and deep.
♦ Always wear socks.
♦ Stop wearing shoes that cause irritations.
♦ Make sure all your shoes are wide and deep enough to accommodate your feet and any inserts.
♦ Avoid wearing high heels and shoes with pointed or open toes.
♦ Before you put on your shoes, check the inside for rough spots or loose objects, which don't belong in the shoe.
♦ Be careful not to use anything hot on your feet.
♦ Consult your doctor immediately if your feet have been injured by your shoes.
♦ Avoid heating pads, hot water bottles, hot bath or tub water.
♦ If you burn your feet and have blisters, do not break the blisters keep the area clean and consult your doctor immediately.
♦ It is important not to go barefoot even inside your home.
♦ Consult your doctor, if you feel that you have a foot infection.
♦ If you can see well enough to trim your own nails:
  1). trim straight across - use only a nail clipper; 2). don't cut into the corners of the nails;
  3). don't cut corns or calluses yourself;
  4) use a nail file or emery board to smooth or round rough edges.
♦ If you are unable to care for your own nails:
  1). have a family member or friend assist with the trimming; 2) see a foot care specialist on a regular basis; 3) ask your doctor or nurse for further guidance.
♦ Remember common signs of poor circulation in your legs:
  Pain in your legs when walking or lying down
  Ulcers that won't heal
  Feet that always feel cold to the touch
♦ Always dry your feet with a soft towel after bathing or showering.
♦ If your feet are dry or cracked, use the moisturizing cream recommended by your doctor.
♦ Trim your toenails carefully.
♦ Make sure your doctor examines your bare feet during each visit.
♦ Make sure your doctor checks the pulses (circulation) in your feet at least once a year.

Why
♦ Having less feeling is the single most important reason for injury to your feet.
♦ Painless injuries often can lead to foot ulcers and amputation.
♦ Poorly fitting shoes can quickly lead to injuries. These injuries often result in foot ulcers and amputation.
♦ Finding and quickly treating all foot problems will decrease the risk of future foot ulcers.
♦ Socks provide a protective barrier around your foot to decrease the chance for irritation.
♦ Rough or worn edges and things that accidentally find their way into your shoe can quickly cause irritation, injury, and foot ulcers.
♦ Persons with diabetes often have less feeling in their feet and may not feel something even slightly too hot.
♦ With less feeling, burns can occur without pain.
♦ Injuries occur frequently when your feet are not protected with shoes.
♦ Injuries while barefoot are the second most common cause of ulceration and amputation.
Wetness between toes may allow the growth of bacteria and fungus, which may lead to a more serious infection.

Injuries from cutting your toenails can lead to infection, foot ulcers, and amputation.

Doctors and nurses are trained to test for loss or feeling and will see even small areas of injury, irritation, and infection.

They will show you how to best care for your feet and check to see that your toenails are correctly trimmed.

Poor circulation is very common in persons with diabetes.

Sometimes poor circulation is confused with nerve damage from diabetes (Diabetic Neuropathy).

**Two important notes:**

* Preventing foot ulcers is the most important step in preventing amputation.
* Keeping your diabetes in the best control possible, not only prevents foot ulcers, but may delay other diabetes complications as well.

**Am I at risk for a foot ulcer?**

- The primary risk is loss of sensation, the ability to feel normal sensation in your feet as a result of diabetes. This is "protective sensation", the warning signals in your feet that protect you from injury.
- Diabetes more than 10 years and over age 60
- Poor diabetes control
- Previous foot ulcers
- Irregularly shaped feet due to bunions or deformities

**Action Plan for Diabetes Care Professionals**

Lower extremity ulcers and amputations are an increasing problem among individuals with diabetes. Lower-level amputations (toe, foot, and ankle) were more common in individuals with diabetes than without diabetes. Amputation rates are greater with increasing age, in males compared with females. 9% - 20% of diabetic individuals experienced a new (ipsilateral) or second leg (contralateral) amputation within 12 months after an amputation. 28% -51% of diabetic amputees had undergone a second leg amputation.

Potential risk factors for diabetic foot ulcers are poor glycemic control and longer diabetes duration, high foot pressure neuropathy in the lower extremities. The risk factors for LEA (low extremity amputation) are: lower extremity ischemia and peripheral neuropathy, elevated glycated hemoglobin levels, history of foot ulcers, and retinopathy.

**Prevention of foot ulcers can be accomplished in 4 simple steps**

* Look/Feel
* Identify
* Educate
* Treat/Refer

**Look at your patients' bare feet at each visit.**

- Identify who is at risk for foot ulcers and amputation.
- Testing for loss of protective sensation.
- Testing for impaired circulation.
- Educate patients at the level consistent with their risk for amputation.
- Treat or refer promptly after identifying specific problems that may ultimately lead to amputation.

**Grading Wound Severity in Diabetic Neuropathic Foot Ulcers**

- Grade 1: Partial thickness ulcer involving on dermis and epidermis
- Grade 2: Full thickness ulcer involving subcutaneous tissue only
- Grade 3: Full thickness involving tendon, bone, ligament and/or joint
- Grade 4: Full thickness involving tendon, bone, ligament and/or joint with abscess and/or osteomyelitis
- Grade 5: Full thickness involving tendon, bone, ligament and/or joint with necrotic tissue in wound
- Grade 6: Full thickness involving tendon, bone, ligament and/or joint with gangrene in wound, surrounding tissue

**Treatment of foot ulcers.** Carefully evaluate and vigorously debride foot ulcers to establish the depth of the ulcer. Use X-ray studies to help exclude the possibility of imbedded foreign objects or osteomyelitis. If osteomyelitis is suspected, use follow-up radiographs and appropriate scans to help establish the diagnosis. Where there is significant infection, use parenteral antibiotics. Since anaerobes frequently occur in the foot ulcers of diabetic patients, take both aerobic and anaerobic bacterial cultures to help select antibiotics.
Ulcers that occur in areas other than the usual plantar area, that cannot be explained by previous trauma or ill-fitting shoes, or that do not respond to aggressive treatment should be biopsied. Ensure that patients do not put weight on the affected foot. Patients who do not feel pain will likely continue to walk; the resulting pressure on the foot will prevent healing. Total bed rest or the use of crutches may be required. Total-contact casts have been shown to help patients with foot ulcers ambulate while ulcers heal; the casts redistribute pressure so that the area of the ulcer bears much less weight than it would otherwise.

Good glycemic control also may help the patient’s foot to heal. Topical use of hyperbaric oxygen, however, is not effective.

If foot ulcers do not respond to therapy, vascular surgery must be considered.

Calluses. Assess the shoes of patients who have calluses. Teach patients to manage calluses with an emery board, callus file, or pumice stone: but strongly caution patients against trying to perform “ho-me surgery” on calluses.

Deformities. If the foot is deformed, the patient will likely need consultation and should benefit from having specially molded shoes. Surgical correction should be considered for bunions, claw toes, or hammer toes: if the patient’s circulation is good.

Neuropathic ulcers. When a neuropathic ulcer is present, consultation may be necessary, and the patient may need to be hospitalized where resources for proper treatment are available. Whenever a patient is hospitalized for any reason or is put at bed rest, heel protection should be used; the heels must be checked daily for evidence of pressure injury.

Reference:

1. This part was developed, using the brochure of Boehringer Mannheim and Eli Lilly and Company. (Last Modified 26 June 97).
2. Grading developed by William J. Wishner, M.D. for Boehringer Mannheim-Lilly Amputation.
Appendix 3.

Table 2. The organization of the program content in curriculum.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Instructor’s Activities</th>
<th>Patient’s Activities</th>
<th>Time</th>
<th>Setting</th>
<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesson 1</td>
<td>a. Distributes syllabus and timetable.</td>
<td>a. Patients clarify the available changes for each individual in timetable.</td>
<td>5 min.</td>
<td>Seminar Room</td>
<td>Syllabus and timetable</td>
</tr>
<tr>
<td></td>
<td>b. Explains program’s objectives, content and organization of it, teaching methods and evaluation criteria, assessment method.</td>
<td></td>
<td>5 min.</td>
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<tr>
<td></td>
<td>c. Instructor explains the content of the first lesson in the form of lecturing.</td>
<td></td>
<td>30 min.</td>
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<tr>
<td></td>
<td>d. Instructor asks questions on lecture’s topic, answers them.</td>
<td>b. Patients listen and ask questions.</td>
<td>5 min.</td>
<td></td>
<td>Handouts</td>
</tr>
<tr>
<td></td>
<td>e. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises) and check them.</td>
<td></td>
<td>10 min.</td>
<td></td>
<td>Check list</td>
</tr>
<tr>
<td></td>
<td>f. Instructor gives home task to answer given questions on a given list.</td>
<td>c. Patients participate in discussing process.</td>
<td>5 min.</td>
<td></td>
<td>Home task</td>
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<tr>
<td></td>
<td>g. Gives sources of information for every topic. (in handouts)</td>
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<tr>
<td></td>
<td>h. Asks to identify at home desirable issues on this topic to discuss tomorrow.</td>
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</tr>
<tr>
<td>Lesson 2</td>
<td>a. Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>Patients listen and ask questions.</td>
<td>5 min.</td>
<td></td>
<td>Answer</td>
</tr>
<tr>
<td></td>
<td>b. Lectures on the content of lesson 2, asking questions and explaining each point.</td>
<td>Patients participate in discussing process.</td>
<td>35 min.</td>
<td></td>
<td>Handouts</td>
</tr>
<tr>
<td></td>
<td>c. Instructor asks questions on lecture, answers them.</td>
<td></td>
<td>5 min.</td>
<td>Seminar Room</td>
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<tr>
<td></td>
<td>d. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises).</td>
<td></td>
<td>10 min.</td>
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<tr>
<td></td>
<td>e. Answers to the tasks, clarifying for each patient.</td>
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<td>5 min.</td>
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<tr>
<td></td>
<td>f. Instructor gives home task to answer to given questions on a given list.</td>
<td></td>
<td></td>
<td>Seminar Room</td>
<td></td>
</tr>
<tr>
<td></td>
<td>g. Asks to put at home desirable issues on this topic to discuss tomorrow.</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesson 3</td>
<td>a. Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>Patients listen and ask questions.</td>
<td>5 min.</td>
<td></td>
<td>Answers</td>
</tr>
<tr>
<td></td>
<td>b. Lectures on the content of lesson, asking questions and explaining each point.</td>
<td></td>
<td>30 min.</td>
<td>Seminar Room</td>
<td>Handouts</td>
</tr>
<tr>
<td></td>
<td>c. Instructor asks questions on lecture, answers them.</td>
<td></td>
<td>5 min.</td>
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<tr>
<td></td>
<td>d. Distributes the written exercises on topic to do in the class.</td>
<td></td>
<td>10 min.</td>
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<tr>
<td>Lesson 4</td>
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</tr>
<tr>
<td>a. Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>Patients participate in discussing process.</td>
<td>Home task</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>b. Lectures on the content of lesson, asking questions.</td>
<td>10 min</td>
<td>Video tap</td>
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</tr>
<tr>
<td>c. Instructor checks the home task, distribute written answers, and explain the questions for each patient. Explaining each point.</td>
<td>Patients participate in discussing process.</td>
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</tr>
<tr>
<td>d. Instructor asks questions on lecture, answers them.</td>
<td>10 min</td>
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<tr>
<td>e. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises).</td>
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</tr>
<tr>
<td>f. Instructor gives home task to answer to given questions on a given list.</td>
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<tr>
<td>g. Asks to put at home desirable issues on this topic to discuss tomorrow</td>
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<tr>
<td>h. Videotapes on relevant topics</td>
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</table>

<table>
<thead>
<tr>
<th>Lesson 5</th>
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</tr>
</thead>
<tbody>
<tr>
<td>a. Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>Patients listen and ask questions.</td>
<td>Answers</td>
</tr>
<tr>
<td>b. Lectures on the content of lesson, asking questions and explaining each point.</td>
<td>Patients listen and ask questions.</td>
<td>Handouts</td>
</tr>
<tr>
<td>c. Instructor asks questions on lecture, answers them.</td>
<td>10 min.</td>
<td>Seminar Room</td>
</tr>
<tr>
<td>d. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises).</td>
<td>Patients listen and ask questions.</td>
<td></td>
</tr>
<tr>
<td>e. Instructor gives home task to answer to given questions on a given list.</td>
<td>10 min</td>
<td></td>
</tr>
<tr>
<td>f. Instructor asks questions on lecture, answers to them.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. Asks to put at home desirable issues on this topic to discuss tomorrow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. Videotapes on relevant topics</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesson 6</th>
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</thead>
<tbody>
<tr>
<td>a. Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>Patients listen and ask questions.</td>
<td>Answers</td>
</tr>
<tr>
<td>b. Lectures on the content of lesson, asking questions and explaining each point.</td>
<td>Patients listen and ask questions.</td>
<td>Handouts</td>
</tr>
<tr>
<td>c. Instructor asks questions on lecture, answers them.</td>
<td>10 min</td>
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</tr>
</tbody>
</table>

55
| Lesson 7 | 1. Instructor checks the home task, distributes written answers, and explains the questions for each patient. | Patients listen and ask questions. | 10 min. | Seminar Room | Check list |
|         | 2. Lectures on the content of lesson, asking questions and explaining each point. | Patients listen and ask questions. | 30 min. | Handouts     | Home task  |
|         | 3. Instructor asks questions on lecture, answers them. | Patients listen and ask questions. | 10 min. | Seminar Room | Home task  |
|         | 4. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises). | Patients participate in discussing process. | 10 min. | Video tap     |           |
|         | 5. Instructor gives home task to answer to given questions on a given list. | Patients participate in discussing process. | 10 min. |             |           |
|         | 6. Asks to put at home desirable issues on this topic to discuss tomorrow. | Patients participate in discussing process. | 10 min. |             |           |
|         | 7. Videotapes on relevant topics. | Patients participate in discussing process. | 10 min. |             |           |

| Lesson 8 | a. Instructor checks the home task, distributes written answers, and explains the questions for each patient. | Patients listen and ask questions. | 10 min. | Seminar Room | Answers    |
|         | b. Lectures on the content of lesson, asking questions and explaining each point. | Patients listen and ask questions. | 30 min. | Handouts     |           |
|         | c. Instructor asks questions on lecture, answers them. | Patients listen and ask questions. | 10 min. | Seminar Room | Check list |
|         | d. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises). | Patients listen and ask questions. | 10 min. | Home task    |           |
|         | e. Instructor gives home task to answer to given questions on a given list. | Patients listen and ask questions. | 10 min. |             |           |
|         | f. Asks to put at home desirable issues on this topic to discuss tomorrow. | Patients listen and ask questions. | 10 min. | Video tap     |           |
|         | g. Videotapes on relevant topics. | Patients listen and ask questions. | 10 min. |             |           |
|         | h. Quiz (after the lesson). | Patients listen and ask questions. | 10 min. |             |           |

<p>| Lesson 9 | a. Instructor checks the home task, distributes written answers, and explains the questions for each patient. | Patients listen and ask questions. | 10 min. | Seminar Room | Answers    |
|         | 1. Lectures on the content of lesson, asking questions and explaining each point. | Patients listen and ask questions. | 30 min. | Handouts     |           |
|         | 2. Instructor asks questions on lecture, answers them. | Patients listen and ask questions. | 10 min. | Seminar Room | Check list |
|         | 3. Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises). | Patients listen and ask questions. | 10 min. | Check list   |           |</p>
<table>
<thead>
<tr>
<th>Lesson 10</th>
<th>Patients participate in discussing process.</th>
<th>10 min.</th>
<th>Home task</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Instructor checks the home task, distributes written answers, and explains the questions for each patient.</td>
<td>10 min.</td>
<td>Videotape</td>
</tr>
<tr>
<td>b.</td>
<td>Lectures on the content of lesson, asking questions and explaining each point.</td>
<td>30 min.</td>
<td>Answers</td>
</tr>
<tr>
<td>c.</td>
<td>Instructor asks questions on lecture, answers them.</td>
<td>10 min.</td>
<td>Seminar Room</td>
</tr>
<tr>
<td>d.</td>
<td>Distributes the written exercises on topic to do in the class. (Do changes in diet or exercises).</td>
<td>10 min.</td>
<td>Handouts</td>
</tr>
<tr>
<td>e.</td>
<td>Instructor gives home task to answer to given questions on a given list.</td>
<td>10 min.</td>
<td>Check list</td>
</tr>
<tr>
<td>f.</td>
<td>Asks to put at home desirable issues on this topic to discuss tomorrow.</td>
<td>10 min.</td>
<td>Home task</td>
</tr>
<tr>
<td>g.</td>
<td>Videotapes on relevant topics.</td>
<td>10 min.</td>
<td>Videotape</td>
</tr>
<tr>
<td>h.</td>
<td><strong>Final examination. (after the lesson)</strong></td>
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</tbody>
</table>
APPENDIX 4. Questionnaire for patients with Non-Insulin Dependent Diabetes Mellitus (type 2), aged 40-45, living in Yerevan

Diabetes Knowledge and Behavior Assessment

How do you do! I am (introduce yourself). We are conducting a survey having the aim to assess diabetes self-controlling practice, knowledge and behaviors among diabetic patients in Yerevan. We appreciate your participation in this survey, which could make a valuable input in this investigation. I am calling for your patience and sincerity in answering the questions which I am going to ask you. The interview will take 15 minutes. Any information that you give will remain confidential. At any moment you can stop the interviewing process.

Patient Knowledge and Beliefs

1. Which of the following is False?
   - 1. Desserts such as ice cream should be avoided because of their great impact on blood glucose.
   - 2. Potatoes have a higher glycemic index than table sugar.

2. Which of the following foods have carbohydrate?
   - 1. Juice
   - 2. Eggs
   - 3. Cheese

3. What is the normal range of blood glucose?

4. What is the optimal level of blood glucose for diabetic patients?

5. Which of these two following statements is true?
   - 1. Long high levels of blood glucose lead to early onset of diabetic complications.
   - 2. Long high levels of blood glucose do not influence the onset of diabetic complications.

6. How many visits should a diabetic patient do at least during one year to an ophthalmologist?
   - 1. Once a year.
   - 2. Twice a year.
   - 3. Four times a year.

7. How many visits should a diabetic patient do at least during one year to a neuropathologist?
   - 1. Once a year.
   - 2. Twice a year.
   - 3. Four times a year.

8. Is the following statement true: “the control of blood glucose levels can prevent foot amputation”?
   - 1. Yes
   - 2. No

9. Is the following statement true: “the levels of blood glucose can be changed by physical exercises”?
   - 1. Yes
   - 2. No
10. Is the following statement true: "the levels of blood glucose can be controlled by changes in diet "?
   - 1. Yes
   - 2. No

11. List three symptoms of hypoglycemia (such condition when blood glucose is decreased).

12. List three symptoms of hyperglycemia (such condition when blood glucose is increased).

13. Describe how to calculate ideal body mass of a person?

14. What would you do first in a case of hypoglycemia?
   - 1. Insulin injection
   - 2. Use sugar

15. List three techniques to decrease blood glucose levels.

16. Can physical activity decrease the blood glucose?
   - 1. Yes
   - 2. No

17. List three complications of diabetes.

18. From what type of treatment will diabetic type-2 patient start his treatment?
   - 1. Insulinotherapy
   - 2. Use of oral medication
   - 3. Regulation of body mass by diabetic diet

19. In your opinion, what do you think is the main cause of foot amputations?
   - 1. Foot ulcer
   - 2. Age
   - 3. Duration of diabetes

20. In your opinion, what do you think is the effect of alcohol intake on blood glucose levels?
   - 1. Hyperglycemia (high blood glucose)
   - 2. Hypoglycemia (low blood glucose)

21. In your opinion, how would you evaluate the quality of your blood glucose control?
   - 1. Good
   - 2. Satisfactorily
   - 3. Bad

22. In your opinion, how would you evaluate the quality of your urine glucose control?
   - 1. Good
   - 2. Satisfactorily
   - 3. Bad

23. What is the result of Insulin deficiency?
   - 1. Decrease of blood glucose
   - 2. Increase of blood glucose

24. Carbohydrate should comprise how many percent of daily calories?
   - 1. 50-60%
25. Fat should comprise how many percent of daily calories?
- 1. 50-60%
- 2. 10-20%
- 3. 30%

26. If the desirable body weight is 140 pounds, then the basal caloric requirement is:
- 1. 1400 calories
- 2. 2000 calories
- 3. 1000 calories

27. For physical sedentary activity levels the desirable body weight will be multiplied by:
- 1. 13
- 2. 15
- 3. 10

**Current Practice**

28. When I need to decrease my weight by a pound a week, from the total caloric intake I subtract
- 1. 3500 calories for one week
- 2. 500 calories for one week

29. When I shift from a physically sedentary activity level to a very active job, I multiply the desirable body weight by:
- 1. 10
- 2. 20
- 3. 15

30. I am managing symptoms of high blood glucose by restriction of dietary__________
- 1. Carbohydrate
- 2. Fat

31. When I make changes in my diet:
- 1. I am testing blood glucose every day.
- 2. It is not necessary to test blood glucose

32. When I make changes in level of my physical activity
- 1. I am testing my blood glucose every day.
- 2. It is not necessary to test blood glucose.

33. Even if I have no compliance, I have to see the ophthalmologist for a retinal examination:
- 1. At least 4 times a year
- 2. At least 1 time a year
- 3. It is not necessary

34. At least how many times do you have to see the neuropathologist to check the sensation in your feet:
- 1. 1 time a year
- 2. 4 times a year
- 3. It is not necessary

**Background Information:**

1. Permanent Address: _________________________________

2. In what polyclinic are you registered? ______________________

3. What is your telephone number?  
   Home ___________________________  
   Work ___________________________  
   (Of tree relatives) ___________________________
4. What is your date of birth? _______/_______/________

5. Gender
   □ Female
   □ Male

6. What is the highest grade you completed?
   □ 1. School (up to 8 years)
   □ 2. School (10 years)
   □ 3. College (2 years)
   □ 4. Institute/university (5-6)
   □ 5. Incomplete higher
   □ 6. Post. Grad
   Total Years

7. What is your occupation?

8. Are you currently employed?
   □ 1. Yes
   □ 2. No

9. When was your Diabetes first diagnosed? ______/_________/__

10. How was your diabetes diagnosed?
    □ 1. During examination, accidentally
    □ 2. Applying to a physician with specific complains
    □ 3. Applying to a physician for screening test

11. What is your weight (in kilograms)?

12. What is your height (in centimeters)?

13. Do you smoke?
    □ 1. Yes
    □ 2. No

   *If Yes, A) then how many cigarettes do you smoke daily?*
    □ 1. 1-2 cigarettes
    □ 2. 3-20 cigarettes
    □ 3. 21-30
    □ 4. 31 and above

   *B) When did you start to smoke? /__year__/__month__*

14. On average, how much does your family spend monthly?
    □ 1. Less than 10,000 drams
    □ 2. 10,001-20,000 drams
    □ 3. 20,001-35,000 drams
    □ 4. 35,001-55,000 drams
    □ 5. 55,001-100,000 drams
    □ 6. More than 100,001 drams

15. How many people live in the family?

   *Thank you very much for your time and assistance!*

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