The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management—2002 Update

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AACE Diabetes Guidelines

INTRODUCTION

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In 1994, the American Association of Clinical Endocrinologists (AACE) developed a System of Intensive Diabetes Self-Management. This system remains the centerpiece of the AACE Medical Guidelines for the Management of Diabetes Mellitus. A key component of the AACE system of care is a patient-physician contract, which maintains the preeminence of the patient's participation in personal care. As stated therein, the duties of the physician and the diabetes management team are to teach and to help direct the patient's own self-management.

The System of Intensive Diabetes Self-Management includes the concepts of care, the responsibilities of the patient and the physician, and the appropriate intervals of follow-up assessment. Also included are the timing of required laboratory testing, determined by evidence-based and consensus clinical experience. As indicated in the original publication of the guidelines, the intensive selfmanagement system applies to patients with type 1 and type 2 diabetes.

AACE brought these concepts directly to the public with two highly successful patient initiatives. These diabetes initiatives were called "Patients First" and "Patients First 1998." The names of these initiatives emphasize that the treatment of the patient should be the first priority for the patient, the physician, and all those providing healthcare coverage. Access to appropriate care and durable medical equipment should not be restricted. AACE emphasizes that the patient should demand access to appropriate care.

In addition, the patient, with a focus on self-management, must become a "Professor of Diabetes." The physician and the diabetes management team are responsible for helping the patient achieve this expertise, and the clinical endocrinologist is the physician best trained to make the initial diagnosis and to recommend optimal treatment of diabetes.

During the past 5 years, many published studies have confirmed the importance of intensive diabetes self-management, not only for type 1 but also for type 2 diabetes. There is now no doubt that control of diabetes is of utmost importance. Furthermore, many new pharmacologic agents have been developed, some with unique mechanisms of action. The use of combinations of older and new pharmacologic agents enables the patient to achieve nearnormalization of blood glucose levels.

Evidence continues to accumulate in support of the importance of intensive diabetes self-management early during the course of the disease as well as intensive control of comorbid states, such as hypertension, dyslipidemia, and obesity. The early control of comorbid states decreases the occurrence of complications of diabetes. Moreover, comorbid states can be precipitated or worsened by the occurrence of diabetes.

The 2000 revision of the AACE medical practice guidelines focuses on the system of care provided in the original guidelines but adds new evidence for management and treatment of type 1 and type 2 diabetes mellitus. The AACE System of Intensive Diabetes Self-Management remains intact. In this revision, we have emphasized type 2 diabetes because it is our conviction that type 2 diabetes is an underrecognized but very serious disease that must be treated as aggressively as type 1 diabetes mellitus.

As chairman, I wish to thank the Diabetes Medical Guidelines Task Force, Drs. Richard Hellman, Richard Dickey, Paul Jellinger, John Janick, Helena Rodbard, Rhoda Cobin, David Bell, Om Ganda, Eugene Davidson, and John Seibel, for their valuable contributions to these revised, expanded guidelines.

2002 UPDATE

The American College of Endocrinology (ACE) held a Diabetes Mellitus Consensus Conference, August 20-21, 2001. The outcome of this ground breaking conference included new guidelines for HbA1c levels. Pre and postprandial targets, and a universal term for hemoglobin A1c. These guidelines have been revised to reflect these outcomes. Also included in the 2002 version are changes in treatment that have occurred since the publication of the 2000 version.

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MISSION STATEMENT

The results of the Diabetes Control and Complications Trial (DCCT), announced in June 1993, confirmed that the near-normalization of blood glucose levels in patients with type 1 diabetes can significantly delay the onset and slow the progression of complications associated with this disease (1). Near-normalization of blood glucose can be achieved by intensive control of diabetes (1). It has been established that the complications of diabetes are related to abnormalities in blood glucose (1). Many endocrinologists contended that intensive control could also reduce the complications associated with type 2 diabetes (2). At that time, AACE agreed that a system of intensive control of diabetes mellitus would likely decrease the rate of complications, improve the patient's quality of life, and decrease the total cost of care associated with both type 1 and type 2 diabetes. Studies since that time, including the United Kingdom Prospective Diabetes Study (UKPDS) of 1998, have confirmed AACE's notion that the goal in type 2 diabetes must also be normalization or near-normalization of the blood glucose level in order to decrease associated complications (3-5).

A systematic multidisciplinary approach has been developed to help clinical endocrinologists and other physicians provide intensive therapy for patients with diabetes mellitus in an effort to achieve normal or near-normal blood glucose levels. The primary requirements for the successful implementation of this system of care are active patient participation, a committed health-care team, and adherence to the schedule of recommended interactions between the patient and the health-care team.

The health-care team should be managed by a clinical endocrinologist; ideally, the team should include a diabetes-trained nurse, a dietitian skilled in diabetes education, and, as needed, a pharmacist, psychologist, and exercise physiologist. The team should be led by a clinical endocrinologist or other physician who has expertise and experience in overseeing and directing this integrated system of care. Of course, notable improvement in patient care will be achieved when physicians of all specialties are more aware of the relationship between blood glucose control and diabetes-associated complications and are familiar with the steps for implementing a program of intensive diabetes treatment. These guidelines, which are intended to assist in those efforts, now include the scientific evidence of recent years to support the AACE System of Intensive Diabetes Self-Management.

SECTION 1: INTENSIVE THERAPY IN TYPE 1 AND TYPE 2 DIABETES

Mechanisms and Goals

Current strategies for optimal care of patients with diabetes mellitus include vigorous and persistent efforts to achieve physiologic control of blood glucose and other often associated conditions including hypertension, dyslipidemia, and excess weight. Abundant evidence is now available that long-term maintenance of near-normal blood glucose levels is protective of patients with diabetes and substantially reduces complications and mortality in both type 1 and type 2 diabetes (1,3-6). The term "intensive therapy" denotes a comprehensive program of diabetes care that includes, as two of its components, frequent self-monitoring of blood glucose levels and more complex and sophisticated regimens for maintaining near-normoglycemia—which, in the case of insulin treatment, often involves multiple insulin injections daily or subcutaneous insulin infusion therapy (insulin pump therapy).

The DCCT (1) showed that, for patients with type 1 diabetes, intensive insulin therapy including three or more insulin injections daily or use of an insulin pump was optimal management. This therapy also can be optimal for many patients with type 2 diabetes who may have insulin deficiency and therefore require insulin supplementation. Often included in this group are older patients, nonobese patients, and patients with diabetes of long duration.

With the recent development of five major classes of orally administered antidiabetic agents, modern patterns of intensive therapy in type 2 diabetes are now widely diverse. In addition to medical nutrition therapy, the clinician often uses a wide variety of therapeutic regimens at different times in the care of the patient with type 2 diabetes. The decision for use of a specific treatment option should be in the hands of the leader of the diabetes care team, the clinical endocrinologist, who should establish the targets and choose the therapeutic agents for control of blood glucose.

For each patient, therapy should be individualized to maximize the likelihood of attaining and maintaining the appropriate goal and reducing the frequency of side effects or adverse reactions. To date, several studies have found a significant advantage associated with a decrease in glycosylated hemoglobin levels to 7.0% (normal, 3.8 to 6%), or lower if possible (1,3-6). Both preprandial and postprandial blood glucose targets are useful. The ACE Diabetes Mellitus Consensus Conference in August 2001 established the following goals: HbA1c level of 6.5% or less; preprandial glucose of 110 mg/dL or less; and the post prandial glucose of 140 mg/dL or less.(6a)

Clearly, the method used to attain normoglycemia is less important than the fact that the goal is achieved. The threat of hypoglycemia seems to be much less serious in type 2 than in type 1 diabetes (3,4) and can often be minimized with more frequent blood glucose monitoring (6), more comprehensive educational intervention, and careful adjustment of medication.

Emerging evidence indicates that intensive therapy and careful control of blood glucose levels are particularly important in achieving better diabetes-related outcomes in the setting of acute conditions (7,8). Data from the DIGAMI (Diabetes Mellitus and Insulin-Glucose Infusion in Acute Myocardial Infarction) Study (7) indicate the value of intensive insulin therapy during and after acute myocardial infarction in patients with diabetes. Other studies have also shown the importance of maintaining normoglycemia during severe infections, cerebral ischemia, or perioperative periods. Therefore, the clinical endocrinologist serves an important role not only in the day-to-day care of the patient with diabetes but also in the acute-care setting.

Although the benefit of a more comprehensive and intensive approach for diabetes care is evident at any point in the course of patient care (6), it is particularly important early during the course of the disease (1). The greatest benefits have been noted in patients with less advanced disease (1,5,6). Thus, prompt initial care and early referral to a clinical endocrinologist for preventive care in both type 1 and type 2 diabetes are not only logical and appropriate but key to achieving the best clinical outcome possible.

Diabetes Management Team

The value of diabetes management teams is also becoming clearer. The concept of active involvement of the patient in a self-management program is important; excellent results have been achieved when the patient actively participates as a member of the diabetes care team. Adherence to complex regimens of care is considerably enhanced by this method. Of note, however, the patient's personal goals, particularly at the outset, may differ substantially from the physician's treatment goals. Nevertheless, with increased interactions with the physician, the goals can converge. The patient is often besieged by information and misinformation from various sources. As a result, an important component of continuing care is the opportunity to continue a dialogue with the physician so that the patient's questions, level of understanding of diabetes care, and misconceptions can be addressed in a way that would be beneficial to and protective of the patient. For achievement of optimal results, a close working relationship among the diabetes team members is most useful.

Where the arrangement is possible, a clinical endocrinologist is most effective as the head of a comprehensive diabetes care program. Two reports have concluded that an endocrinologist's involvement offers advantages in the care, cost-effectiveness, and outcomes for patients with diabetes (9,10). Educational programs alone have not been demonstrated to improve major clinical outcomes, but programs integrating both education and sophisticated, direct care of the patients have been effective. Optimally, the clinical endocrinologist should be the principal-care physician for patients with either type 1 or type 2 diabetes. Alternatively, the clinical endocrinologist and the primarycare physician can comanage a program for their patients with diabetes. Whatever the arrangement, the relationship between the patient's physicians should be collegial so that the particular roles of both specialist and generalist can be used to maximize the benefit to the patient.

Cost-Effective Comprehensive Care

Intensive therapy has been shown to be cost-effective in both type 1 and type 2 diabetes (9,10). Because twothirds of the costs of diabetes management are currently for inpatient care and complications of diabetes, clearly the beneficial effects of intensive therapy on reducing both the complications of diabetes and their progression provide strong support for the increased use of an intensive and comprehensive approach to diabetes care.

Although formidable barriers to the implementation of widespread, intensive programs of diabetes care still remain, the benefits may be even greater in higher risk groups, such as minority populations (6). It is reasonable to expect, and should be a goal, to have most patients with diabetes in a community setting participate in an intensive treatment program and achieve an excellent outcome (3,4,6).

SECTION 2: THE CLINICAL ENDOCRINOLOGIST IN CONTINUING CARE

Continuing Care

The patient with diabetes mellitus has a chronic but highly treatable disease, which can have devastating and costly complications. The health-care needs of such a patient are predicated on the control of the diabetes. A comprehensive diabetes team approach yields the best health-care outcomes. The team approach, however, requires continuity of care and management.

The care of diabetes mellitus has become progressively more complex and demanding of both the patient and the physician. Comprehensive and intensive care of diabetes has been confirmed to yield important benefits by delaying or preventing complications (1,3-5). For achievement of these benefits, complex pharmacotherapeutic regimens, as well as insulin pumps or even pancreas transplantation, may be needed. The clinical endocrinologist can best coordinate this complex continuing care to achieve the optimal outcome.

Thus, it is particularly critical for avoidance of complications that continuity of care be maintained for the development of long-term goals that can be shared and pursued by the patient, the physician, and other members of the diabetes care team. When patients regularly share information with the physician, the special training and knowledge of the clinical endocrinologist can help to identify factors that may improve or disrupt diabetes control. For example, identification of improper habits can lead to the formulation of solutions and the implementation of beneficial changes, such as alterations in diet and nutrition practices, physical activity or exercise patterns, and responses to stress in the environment; use and adjustment of medications; careful attention to foot care; and adherence to a system of intensive diabetes self-management (11).

Intercurrent Illness

When the patient with diabetes needs to be hospitalized or has an intercurrent illness, the management of the patient's diabetes and of its effect on the course of the intercurrent illness often is the most important determinant of the outcome of the intercurrent illness (for example, infection, renal impairment, or hypertension). Therefore, the clinical endocrinologist can provide the patient with the best care for the diabetes as well as ensure the most favorable outcome for the intercurrent illness (2).

Education and Preventive Measures

Diabetes care is best focused on the prevention of related complications and comorbid conditions, so that hospitalizations and cost of care are minimized. The most costly aspect of the care of diabetes is the hospitalizations that result from complications. The acute and chronic complications occur because of either the lack of understanding in long-term and short-term control of the blood glucose or the patient's refusal to control the blood glucose levels. The educational responsibilities are shared by many members of the diabetes care team, each of whom has been specifically trained to understand and impart to the patient the value of preventive measures (12). As a leader of the team, the clinical endocrinologist is able to educate and train not only the patient but also other team members, as well as other physicians and nonphysicians, to understand and keep in mind the special needs of the patient with diabetes and optimal management practices (12).

SECTION 3: NUTRITION AND EXERCISE

Nutrition and exercise are major interventions in the treatment of diabetes mellitus. Their importance and effect in both type 1 and type 2 diabetes, however, have been inadequately emphasized. The result has been unsatisfactory patient adherence.

With the introduction of an increasing number of orally administered drugs for the treatment of type 2 diabetes, the focus has shifted to the use of these drugs rather than tackling the difficult problem of helping the patient implement the necessary lifestyle changes for adherence to nutritional recommendations and exercise programs.

A recent study showed that newer pharmaceutical agents cost, on the average, \$1,700 per year per drug (13). In a recently completed survey of AACE member clinical endocrinologists about prescribing practices for type 2 diabetes, 90% of the 348 respondents reported prescribing three or more agents in combination to achieve control. Sixty-five percent used four agents in combination. Of the survey participants, 95% reported that the oral combinations currently available allow better glycemic control than was ever achievable in the past. The problems reported with use of drug combinations, however, included expense (75%), side effects (66%), monitoring difficulties (61%), hypoglycemia (54%), and aversion to polypharmacy (30%) (14).

The notion of achieving blood glucose levels as near normal as possible in patients with type 2 diabetes is the underlying prevailing goal for the clinical endocrinologist. The clinical endocrinologist views type 2 diabetes as a serious disease with potentially severe complications. In patients with type 2 diabetes, nutrition and exercise are extremely important and the most cost-effective therapeutic interventions. The AACE System of Intensive Diabetes Self-Management promotes the concept of the patient being in control and responsible for self-management. An important element in self-management of diabetes mellitus is the lifestyle changes necessary to adhere to nutrition and exercise programs.

In recent years, it has become clear that the prescriptions for diet and physical activity must be individualized in order to improve patient adherence. The control over dietary intake and the effort to engage in physical activity correlates with the achievement of more normal blood glucose levels. The principles and strategies of nutrition and exercise for type 1 diabetes differ from those for type 2 diabetes. Patients must understand and measure the effect of diet and physical activity in order to be expected to adhere to these necessary lifestyle changes. In type 2 diabetes, nutrition and exercise can help maintain near-normal blood glucose and optimal lipid levels, achieve desirable weight, and improve physical condition.

Diet in Type 1 Diabetes

With use of insulin therapy for control of blood glucose, the patient must understand the action and the duration of the insulin being used as well as the effect of the timing of the intake of food on the insulin action. It is unreasonable to expect the patient to maintain a constant meal plan and insulin regimen. Flexibility of insulin dosing and timing must be taught to the patient. This flexibility can be adapted by using the result of the blood glucose determination and the response to intake and timing of food. The DCCT demonstrated that patients who adjusted their food intake and insulin dosage in response to blood glucose levels achieved lower glycosylated hemoglobin values than did the control group (15). The flexibility empowered those patients to adhere more willingly. The use of carbohydrate counting to determine the appropriate bolus premeal dose of rapidly acting insulin has made the use of intensive insulin therapy regimens even easier.

Diet in Type 2 Diabetes

Weight loss and maintenance of weight loss result in a decrease in the insulin resistance that is the hallmark of most patients with type 2 diabetes. Simply, a negative caloric balance can decrease insulin resistance. The endpoint does not have to be weight loss. In the process of attaining a decrease in weight, blood glucose levels will improve. By monitoring the blood glucose levels and the caloric intake and output, the patient can understand the effect of a negative caloric balance on the blood glucose. These measurements and observations will help promote adherence. Patients do not have to achieve ideal body weight to improve control of blood glucose, control of hypertension, and lipid levels. Loss of as few as 10 to 20 lb (4.5 to 9 kg) will be helpful, but the weight loss must then be maintained and exercise programs must be continued (16-18).

Nutritional Composition of the Diet

No clear-cut formula exists for carbohydrate, fat, or protein intake in the patient with diabetes. The key is the caloric intake relative to the caloric output. The motivation for adherence to nutrition and exercise programs is the patient's understanding of the effect of these actions on blood glucose, blood lipids, and blood pressure (19).

Carbohydrate Intake

Currently, the average amount of carbohydrate recommended for patients with diabetes is 55 to 60% of the total caloric intake. Little evidence is available to support the belief that sugar should be avoided or that starches should be preferred. Starches mixed with or containing fiber may slow down glucose absorption. Recently, starches (complex carbohydrates) have been shown to have a higher glycemic index than such foods as milk, fruit, or sucrose (20).

Many starches are rapidly converted into 100% glucose during digestion. If the absorption is not slowed down by a mixed meal containing fiber, the glycemic index can be high. In contrast, sucrose is metabolized to glucose and fructose. Fructose has a lower glycemic index than does glucose because it has a slower rate of absorption and is stored in the liver as glycogen (21).

The total amount of carbohydrate per meal, rather than its source, seems to be the critical factor that determines its effect on blood glucose (22).

Fat Intake

Normal intake of fat should be limited to a maximum of 30% of the total caloric intake. In patients with type 2 diabetes, weight is usually a factor in developing a treatment program. Each gram of fat contains 9 calories, in contrast with 4 calories for each gram of carbohydrate or protein. In overweight persons or those with dyslipidemia, fat intake should be reduced to as low as 15% of the caloric intake. Again, an individualized approach, with the patient making the choices through education, is the most effective means to achieve adherence (23). In persons with dyslipidemia, a concentrated effort should be made to avoid saturated fat and to substitute unsaturated fat or monounsaturated fat. The content should be as low in calories and in fat as tolerated.

Ethnic, cultural, and financial barriers must be understood and considered by the physician and the diabetes self-management team as dietary plans are developed. In addition, careful monitoring of metabolic variables, including blood glucose, glycosylated hemoglobin, lipids, blood pressure, and body weight, and assessment of quality of life as outlined in these guidelines are important. Monitoring serves to improve the patient's ability to adhere to recommendations, maintain motivation, and solve problems. It also enables the physician and the diabetes self-management team to help the patient understand and adjust therapeutic interventions.

Protein Intake

Intake of protein should be 10 to 20% of the total daily caloric intake. No evidence has indicated that patients with diabetes need a lower than average intake of dietary protein to protect against the onset of renal disease (24). After the onset of microalbuminuria, every effort should be made to decrease animal protein in the diet and to keep protein intake between 10 and 15% (25-27).

Use of Alcohol

The effect of alcohol on blood glucose in diabetes has always been confusing. If possible, patients with diabetes should avoid or limit the use of alcohol because predicting or anticipating its effect on blood glucose is difficult.

The effect on blood glucose depends not only on the amount of alcohol ingested but also on the amount of alcohol ingested in relationship to food and the content of the food consumed. Alcohol is oxidized by the liver. It may impair gluconeogenesis and result in subsequent hypoglycemia. The hypoglycemia can be severe in persons receiving injections of insulin because both insulin and alcohol can inhibit gluconeogenesis. Triglycerides can increase in response to alcohol; thus, hyperlipidemia can worsen when alcohol is ingested (22,28).

In general, however, the effects of alcohol are not severe. Because insulin is not required to metabolize alcohol, no food group should be eliminated from the calculated intake. Nevertheless, calories are added. Alcohol is currently counted as a fat exchange.

Patients with pancreatitis, dyslipidemia, or neuropathy should especially avoid the use of alcohol (22).

Diet in Gestational Diabetes

The goal of therapy in patients with gestational diabetes is to maintain normal fasting blood glucose as well as normal postprandial blood glucose levels. No extensive studies have been performed on diet in gestational diabetes. Each diet must be individualized and altered during the progress of the pregnancy to ensure adequate caloric intake without inappropriate weight gain or weight loss and to avoid the development of ketonuria (29). Patients with gestational diabetes are often adherent if they are educated adequately by a clinical endocrinologist and the physician-led diabetes self-management team. They are particularly motivated by their perceived responsibility to their unborn child (30).

Physical Activity

Physical activity as a therapeutic modality in patients with diabetes mellitus is important. In type 1 diabetes, however, the effectiveness of exercise as therapy has not been proved by double-blind controlled studies (31,32). If the serum insulin level is high from exogenous intake of insulin during exercise in a patient with reasonably controlled type 1 diabetes, physical activity can lead to hypoglycemia. Patients with type 1 diabetes and with a blood glucose level of 250 mg/dL or higher at the time of exercise will experience a further increase in glycemia and development of ketosis.

The effects of exercise on the relationship of diet and insulin have been well studied in type 2 diabetes and must be understood by the patient and the physician (33). In type 2 diabetes, physical activity has been shown to help decrease peripheral insulin resistance, plasma triglyceride levels, and very-low-density lipoproteins (VLDL). Because cardiovascular risk is high in most patients with type 2 diabetes at the onset, the risk of cardiovascular complications with physical activity must be constantly considered (34). Therefore, exercise must be viewed differently in type 2 diabetes than in type 1 diabetes.

In patients with either type 1 or type 2 diabetes, exercise can create a general sense of well-being. Exercise is generally credited with promoting physical fitness, which in turn prevents or decreases the onset of cardiovascular disease. Unfortunately, no controlled studies have been conducted in patients with type 1 diabetes to prove this point (35). The Malmo study, however, demonstrated the value of intervention with physical activity and nutritional therapy in controlling the progression of type 2 diabetes (36). Exercise promotes flexibility and motor strength, which are also thought to promote a sense of well-being (37).

Principles of Exercise as Therapy in Type 2 Diabetes

Of all patients with diabetes, 90% have type 2 diabetes. The major complication of type 2 diabetes is macrovascular disease. There is now consensus that the macrovascular complications are attributable to the hyperglycemia and the accompanying comorbid conditions of hypertension and dyslipidemia (see Section 5).

Type 2 diabetes is usually the result of increased insulin resistance and eventual decrease in insulin secretion because of beta cell failure. Physical activity improves blood glucose levels, the result of a decrease in insulin resistance as well as weight loss. Insulin resistance has been shown to decrease even without loss of weight. The increased sensitivity to insulin that results in increased peripheral utilization of glucose occurs not only during physical activity but for up to 48 hours after exercise (38). Therefore, exercise should be repeated at least every 48 hours to maintain this effect.

Any therapy that will reduce insulin resistance has the potential to improve blood glucose control. Another beneficial effect of an exercise program is the promotion of self-discipline necessary for controlling a chronic disease. Furthermore, in an era of increasing treatment options and complexity of orally administered medications for type 2 diabetes, any therapeutic maneuver that decreases the complexity of treatment at low economic cost is costeffective.

Physical activity consistently decreases plasma triglyceride levels and VLDL levels in type 2 diabetes. High-density lipoprotein (HDL) effects have not been well studied; however, if triglycerides are significantly lowered, HDL increases because the relationship of VLDL to HDL has been shown to be reciprocal (34).

Exercise evaluation studies with a stress electrocardiogram should be done before a program of physical activity is prescribed for any patient with diabetes who is 40 years old or older or who has possible cardiovascular disease. Evaluation for autonomic neuropathy can reveal the value of calculating maximal heart rate, predicting the potential occurrence of exercise-induced hypertension and of orthostatic hypotension after exercise. If either occurs or the patient experiences discomfort during such studies, the possibility of continued adherence to an exercise program precipitously decreases. Anticipation and crafting an exercise program to avoid these complications can increase the possibility of successful adherence. Because of subtle autonomic dysfunction, the pulse rate should not be used as a measure of intensity of physical activity. Patients should exercise to perceived exertion only and not based on pulse rate percent of maximal exertion for age (37).

The goal should be to promote physical fitness with consistent use of an exercise program. The level of fitness may be more important than weight loss to decrease mortality. The timing of the onset of an exercise program might be important because postprandial physical activity seems to lower postprandial blood glucose levels (39).

Every exercise prescription should be tailored to the individual patient's capacity and coexistent conditions, such as hypertension or prior myocardial infarction or neuropathy. Flexibility exercises are important for helping patients to participate in conditioning exertion without pulling or tearing muscles. The duration of exercise should be a minimum of 20 minutes every 48 hours (39). At the start of the exercise program, the patient should not push to achieve ideal duration but should stop as soon as fatigue is experienced.

Principles of Exercise as Therapy in Type 1 Diabetes

In normal persons, physical activity causes insulin levels to decrease because of an increase in glucose uptake by peripheral muscles and an increase in glucagon output to defend a declining blood glucose level. The blood glucose then increases as a result of increased output of glucose from the liver (40). The increase in peripheral blood glucose is a function of the individual person's conditioning and is matched by the reciprocal hepatic glucose output.

In patients with type 1 diabetes, the glycemic response to exercise is dependent on the metabolic control of the blood glucose, the physical conditioning of the patient, the integrity of the autonomic nervous system, the prior physical activity and food intake, the intensity and duration of the activity, and the timing of the peak insulin action.

For example, if intermediate-acting insulin peaks at the time of exercise and there is an increase in glucose uptake by the muscle, the high plasma insulin level can neutralize the ability of the patient's counterregulatory mechanisms to respond and defend the declining blood glucose level with a surge of glucose output from the liver. The resulting hypoglycemia can be severe (40). If the patient has poorly controlled diabetes, is poorly conditioned, and is stressed by the exercise, counterregulatory hormonal output resulting from the stress induced by physical activity along with the high blood glucose level attributable to poor control of the diabetes can result in an even higher blood glucose level (33).

The clinical endocrinologist and the diabetes selfmanagement team can teach the patient all the variables that can result from exercise and, as part of the self-management process, teach the patient to use the therapy of physical activity and conditioning to control the blood glucose level more effectively (33,34).

Effective blood glucose control can occur when the patient learns to vary the dose of insulin appropriately, anticipate the need for intake of food before or after physical activity, and monitor the effect of the physical activity by appropriate blood glucose measurement after participation in exercise. This monitoring is the responsibility of the patient. The responsibility of the physician and the diabetes self-management team is to teach the patient the principles and effects of physical activity and help make the patient a diabetes expert. In general, 15 g of carbohydrate should be added before or after physical activity, depending on the blood glucose level. If the activity will be very strenuous, 30 g might be needed. The anticipated effect of exercise and the regulation of this effect can and should be learned by the patient in order to take advantage of the benefits of exercise (37). In addition, the short-term and long-term effects of physical activity could necessitate a decrease in insulin dosage. With the patient gaining the experience of the effect of exercise, adjustment of the insulin dosage can result in more effective control of the blood glucose level. The process of physical conditioning through exercise training can result in a 20 to 30% decrease in the daily subcutaneous insulin requirement (39).

Summary

Nutrition and exercise programs are important, costeffective therapeutic maneuvers to assist patients with both type 1 and type 2 diabetes achieve effective metabolic control. The patient must understand the effects and importance of these therapeutic modalities in order to be motivated to adhere to a beneficial nutrition and exercise plan. The patient must be empowered not only to monitor the blood glucose level but also to initiate the needed changes in medication. When the patient becomes an active participant in diabetes management, adherence to effective therapy will increase and diabetes-related complications will decrease.

SECTION 4: PHARMACOLOGIC THERAPY FOR TYPE 2 DIABETES

Major advances have occurred in the pharmacologic treatment of type 2 diabetes during the past 5 years in the

United States. Drugs in several new classes have been approved by the Food and Drug Administration, including the new biguanides, thiazolidinediones, meglitinides,

-glucosidase inhibitors, and new shorter acting insulin. In addition, new sulfonylureas and newer forms of available sulfonylureas have been developed and approved. All these agents have tissue-specific sites of action to improve glycemia. They can be used in combination to take advantage of the respective mechanisms of action to reverse the multifactorial pathophysiology of beta cell dysfunction, insulin resistance, increased hepatic glucose production, and decreased peripheral glucose utilization.

The increase in choice and enhanced effectiveness of these new therapeutic compounds make possible the improved control of blood glucose in patients with type 2 diabetes. With this array of options, however, treatment regimens have become increasingly complex and confusing. A trial-and-error approach is not acceptable. The use of these new drugs alone as monotherapy and in combination must be directed by the physician, preferably a clinical endocrinologist.

Type 2 diabetes is a serious disease in which severe complications may occur, even in relatively asymptomatic persons. Newly available drugs are quite effective. Ideally, to optimize the effect of these drugs, patients with diabetes taking them should become involved with the ongoing management of their disease rather than simply taking the drugs and assuming that they are "working." By measuring the blood glucose at various times of day, the effect of the drug in relationship to activities such as meals, exercise, and stress can be judged. This information can lead to intelligent variations in therapy. Intensive diabetes selfmanagement, as recommended by AACE, will improve blood glucose control and lower the glycosylated hemoglobin level. Only then will the risk of devastating and costly complications of diabetes be reduced.

The cornerstones of therapy for type 2 diabetes remain proper nutrition, exercise, and education. These components of care should be implemented at the outset of the diagnosis of type 2 diabetes. Many patients with type 2 diabetes are immediately given medications without initial optimal therapeutic use of a program of appropriate nutrition and physical activity. Frequently, this approach leads to a never-ending spiral of treatment with more and more medication but little resulting improvement.

The choices of oral drug therapy for type 2 diabetes have become extremely complex. The physician must be positioned to use clinical judgment about the best combinations of drugs for the patient with diabetes. This discretion is particularly important in the long-term treatment of a chronic disease that is unrelenting and progressive and in which the response to therapy changes over time.

The following material is a summary of information about pharmacologic options available for the treatment of type 2 diabetes mellitus. See the current *Physicians' Desk Reference* (41) and package inserts (42-48) for detailed information about specific drugs and for additional complete information.

Table 1 Commonly Used Sulfonylureas: Dosage Data						
Drug	Daily dose (mg)	Doses/ day				
Glimepiride (Amaryl) 1 mg 2 mg 4 mg	1-8	1				
Glipizide (Glucotrol) 5 mg 10 mg	2.5-40*	1-2				
Glipizide-GITS (Glucotrol XL)† 2.5 mg 5 mg 10 mg	2.5-20	1				
Glyburide (Micronase, Dia eta) 1.25 mg 2.5 mg 5 mg	2.5-20	1-2				
Glyburide micronized (Glynase) 3 mg 6 mg	3-12	1-2				

*No further hypoglycemic effect at doses greater than 20 mg/day.

†GITS = Gastrointestinal Therapeutic System (controlled release).

Adapted from DeFronzo RA. Current Management of Diabetes Mellitus. Mosby-Year Book, 1998.

Sulfonylureas: Profile

Sulfonylurea agents differ in potency, pharmacokinetics, and cost

Use as an adjunct to diet and exercise, not as a substitute May be used as monotherapy or in combination with other drugs for diabetes

May be most useful in thin patients with insulinopenia Not effective in type 1 diabetes

Not to be used during pregnancy

Not recommended for use in association with:

Major surgical procedures or general anesthesia Severe infection, stress, or trauma

Predisposition to severe hypoglycemia (for example, advanced liver or kidney disease)

Mode of Action

Primary effect: stimulate insulin secretion by blocking the $K^{\scriptscriptstyle +}$ channel of the beta cell

Secondary effects: decrease hepatic glucose production; may improve insulin sensitivity at the receptor and postreceptor levels

Contraindications

Known hypersensitivity to the drug Type 1 diabetes, diabetic ketoacidosis Sulfa allergy

Potential Adverse Effects

Hypoglycemia, hypersensitivity, weight gain

Table 2Metformin: Dosage Data						
Drug	Daily dose (mg)*	Doses/ day				
Metformin (Glucophage) 500 mg 850 mg 1,000 mg	500-2,550	2-3				
*Begin with lowest dose and titrate, as needed, to						

*Begin with lowest dose and titrate, as needed, to maximal dose (2,550 mg). Maximal benefit is usually seen at 2,000 mg.

Metformin: Profile

Metformin (Glucophage) is a biguanide that has insulinsensitizing properties

May be used as monotherapy or in combination with other classes of agents or insulin

May be most useful in obese patients with dyslipidemia Associated with no weight gain or mild weight loss

Mode of Action

Primary effect: decreases hepatic glucose production by improving insulin action at the liver

Secondary effect: enhances muscle glucose uptake and utilization

Contraindications

Patients prone to metabolic acidosis or hypoxic states, including renal failure, renal dysfunction with serum creatinine >1.5 mg/dL, liver failure, congestive heart failure requiring pharmacologic intervention, diabetic ketoacidosis, major surgical procedure, dye procedures (temporarily discontinue metformin therapy at time of intravascular administration of iodinated contrast agent), sepsis, alcoholism

Use with caution in patients >80 years old (age-related decline in renal function)

Potential Adverse Effects

Lactic acidosis—extremely rare in properly selected patients

Anorexia, nausea, diarrhea—often transient

Table 3 α-Glucosidase Inhibitors: Dosage Data					
Drug	Daily dose (mg)*	Doses/ day			
Acarbose (Precose) 50 mg 100 mg	75-300	3†			
Miglitol (Glyset) 25 mg 50 mg 100 mg	75-300	3†			

*Begin with lowest dose (25 mg three times a day with meals) and titrate at 2- to 4-week intervals, as needed, to maximal dose (100 mg three times a day with meals).

†Take with first bite of each meal.

α-Glucosidase Inhibitors: Profile

May be used as monotherapy or in combination with sulfonylureas

Effectiveness demonstrated with all agents and insulin High rate of discontinuation because of gastrointestinal effects but tolerated satisfactorily by some patients Proper titration of dosage is essential

May be most useful in patients with exaggerated postprandial increase in blood glucose

Mode of Action

Act locally in small intestine by inhibiting α -glucosidase enzymes; this action slows digestion of ingested carbohydrates, delays glucose absorption, and reduces the increase in postprandial blood glucose

Glucagon-like peptide is released because of delayed absorption

Slight improvement in fasting blood glucose Modest reduction in glycosylated hemoglobin

Contraindications

Major gastrointestinal disorders, including inflammatory bowel disease, chronic ulceration, malabsorption, or partial intestinal obstruction

Potential Adverse Effects

Flatulence, abdominal bloating—these effects may subside over time

Table 4					
Thiazolidinediones: Dosage Data					

Drug	Daily dose (mg)	Doses/ day
Rosiglitazone (Avandia)† 2 mg 4 mg 8 mg Pioglitazone (Actos)‡ 15 mg 30 mg	2-8 15-45	1 or 2

†Initiate therapy at 4 mg/day.

‡Initiate therapy at 15 mg/day.

Thiazolidinediones: Profile

Rosiglitazone (Avandia), and pioglitazone (Actos) have been approved for use. Troglitazone has been withdrawn for use by the FDA.

Rosiglitazone and pioglitazone can be used as monotherapy or in combination with sulfonylureas and metformin. Only pioglitazone is FDA approved for use in combination with insulin therapy.

May take several weeks for onset of action and several months for "peak" action

Require the presence of insulin for action

May be most useful in patients with insulin resistance or azotemia

Mode of Action

Primary effect: enhance tissue sensitivity to insulin in muscle through activation of intracellular receptors Secondary effect: suppress hepatic glucose production No stimulatory effect on insulin secretion

Contraindications

Known hypersensitivity or allergy to the drug or any of its components

Clinical evidence of active liver disease

Abnormal results of liver function tests:

Troglitazone—alanine transaminase >1.5 times the upper limit of normal Rosiglitazone—alanine transaminase >2.5 times the upper limit of normal Pioglitazone—alanine transaminase >2.5 times the upper limit of normal

Congestive heart failure (New York Heart Association class III and IV)—unless benefit outweighs risk of volume expansion

Potential Adverse Effects

Weight gain (variable degrees), possibly related to improvement in glycemic control and volume expansion With troglitazone therapy, rare cases of severe idiosyncratic hepatocellular injury and necrosis

Precautions

Serum transaminase levels must be assessed at start of therapy

For troglitazone therapy, monitor liver function monthly for 1 year and then quarterly thereafter—*discontinue drug if alanine transaminase is* >3 *times the upper limit of normal* For rosiglitazone therapy, monitor liver function every 2 months for the first 12 months and then periodically thereafter—*discontinue drug if alanine transaminase is* >3 *times the upper limit of normal on two samples*

For pioglitazone therapy, monitor liver function every 2 months for the first 12 months and then periodically thereafter—*discontinue drug if alanine transaminase is 2.5 times the upper limit of normal on two samples*

Table 5Meglitinides: Dosage Data					
Drug	Daily dose (mg)	Doses/ day			
Repaglinide (Prandin) 0.5 mg 1 mg 2 mg	0.5-16*	2-4†			
Nateglinide (Starlix) 120 mg	360mg*	2-4†			

†Based on number of meals.

Meglitinides: Profile

Repaglinide (Prandin), in the meglitinide class of benzoic acid derivatives, is an insulin secretagogue

Requires the presence of functioning beta cells

Can be used as monotherapy or in combination with metformin

Similarly, nateglinide is phenyladanine derivative, insuline secretion

Mode of Action

Primary effect: lowers blood glucose levels by stimulating release of insulin in response to a glucose load (meal) Lowers both fasting and postprandial blood glucose but has a greater effect postprandially

There are distinct beta cell binding sites for repaglinide/ nateglinide apart from the sulfonylurea binding site Repaglinide/nateglinide closes adenosine triphosphatedependent K⁺ channels in beta cell membrane; the resultant increased calcium influx induces insulin secretion

Contraindications

Diabetic ketoacidosis, with or without coma Type 1 diabetes Known hypersensitivity to the drug or its inactive ingredients

Table 6

uling. Available Types

Potential Adverse Effects

Hypoglycemia, hypersensitivity, weight gain

Precautions

Similar to those for sulfonylureas

and Duration of Action*								
Drug	Available strengths	Duration of action (h)						
Regular	U-100, 100 units/mL U-500, 500 units/mL (Lilly only)	3-6						
Humalog (lispro)	U-100, 100 units/mL	1-2						
Novolog	U-100, 100 units/mL	1-2						
(insulin as	part)							
NPH	U-100, 100 units/mL	18-24						
Lente	U-100, 100 units/mL	18-24						
Ultralente	U-100, 100 units/mL	24-36						
Lantus (glargine)	U-100, 100 units/mL	24						
50/50†	U-100, 100 units/mL							
70/30†	U-100, 100 units/mL							
75/25††	U-100, 100 units/mL							

*Daily dose and number of doses/day must be

individualized.

†NPH/regular mixture.

††Lispro protamine suspension (NPL)/lispro pen, taken
15 minutes before the meal.

Clinical Expectations

Table 7 Fasting and Postprandial Blood Glucose and Glycosylated Hemoglobin Responses to Pharmacologic Treatment in Patients With Type 2 Diabetes*								
Decrease in fasting BG1-hour PPBG (↓ from baseline)Drug(mg/dL)(↓ from baseline)Undl(mg/dL)(↓ from baseline)								
Sulfonylureas	40-60		1.0-2.0%					
Repaglinide/Nateglinide	30.3	56.5	1.1%					
Metformin	53		1.4%					
Rosiglitazone (across dose range)	25-55		0.1-0.7%					
Pioglitazone	20-55		0.3-0.9%					
-Glucosidase inhibitors	20-30	20-74	0.5-1.0%					

*BG = blood glucose; HbA_{1c} = glycosylated hemoglobin; PPBG = postprandial blood glucose.

Table 8Effect of Pharmacologic Treatment of Type 2 Diabetes onInsulin Secretion and Glucose Production and Uptake					
Drug	Insulin secretion	Hepatic glucose production	Peripheral glucose uptake		
Sulfonylureas or repaglinide	Increase	Slight decrease	Slight increase		
Metformin	No change	Decrease	Mild increase		
Pioglitazone or rosiglitazone	No change	Mild decrease	Increase		
-Glucosidase inhibitors	No change	No change	No change		
Insulin	Decrease	Decrease	Increase		

SECTION 5: INTENSIVE TREATMENT OF COMORBID CONDITIONS

Substantial evidence indicates that treatment of comorbid conditions is critically important for achieving optimal outcomes in patients with diabetes mellitus. Cardiovascular disease accounts for 80% of mortality in patients with diabetes mellitus. Therefore, control of other risk factors such as dyslipidemia, hypertension, renal disease, obesity, and smoking is essential.

Atherosclerosis

In many patients, the first symptom of type 2 diabetes is a myocardial infarction attributable to coronary artery atherosclerosis. Atherosclerosis is well known to be associated with high plasma concentrations of cholesterol, particularly low-density lipoprotein (LDL), whereas HDL cholesterol exerts a protective effect. Patients with uncontrolled type 2 diabetes have dyslipidemia, characterized by high triglyceride levels and VLDL, lowered HDL levels, and elevated LDL, especially small dense LDL. Because of the association of atherogenic small dense LDL with hypertriglyceridemia and the increase in atherosclerosis, patients with diabetes have an added risk that must be controlled. Additionally, lipid abnormalities and hypertension are accelerated with the advent of early renal disease (see discussion of lipids, obesity, and insulin resistance in Section 8 of these guidelines).

The lesions of atherosclerosis occur primarily in large and medium-sized elastic and muscular arteries. The result is insufficiency of the coronary, cerebrovascular, mesenteric, and peripheral circulations. Patients with diabetes have a high absolute risk for coronary mortality and morbidity and a worse prognosis than the general population. Furthermore, women with diabetes mellitus lose their relative protection against coronary artery disease. Aggressive treatment, in accordance with the National Cholesterol Education Program guidelines, is advised (23). Most myocardial infarctions may be caused by lesions that are considered hemodynamically insignificant. Therefore, additional maneuvers such as plaque stabilization (with use of aspirin or angiotensin-converting enzyme [ACE] inhibitors) may be important.

Dyslipidemia

Although numerous clinical studies have demonstrated the beneficial effects of lipid-lowering agents, no published clinical trials have assessed the protective effect of lipid-lowering agents on coronary artery disease exclusively in patients with diabetes. Analysis of subgroups of patients in several large studies, however, provides evidence of improved outcomes, especially in patients with diabetes. These investigations include the Helsinki Heart Study (49), the Scandinavian Simvastatin Survival Study ("4S") (50), the Cholesterol and Recurrent Events (CARE) Trial (51), and the Air Force/Texas Coronary Atherosclerosis Prevention Study (52). From these studies, one could extrapolate the conclusion that intensive therapy for dyslipidemia would be as protective as for the general population. AACE believes that intensive treatment of dyslipidemia in patients with diabetes is important and necessary for protection from the macrovascular complications of dyslipidemia.

Currently, four major classes of lipid-lowering drugs are available:

- 1. *Statins* (hydroxymethylglutaryl-coenzyme A reductase inhibitors): lovastatin, simvastatin, pravastatin, fluva-statin, and atorvastatin
- 2. Fibric acid derivatives: gemfibrozil, fenofibrate
- 3. Bile acid sequestrants: cholestyramine, colestipol
- 4. *Nicotinic acid* (which should be used with extreme caution, if at all, in patients with diabetes because of deleterious effects on glycemic control)

The most common lipid abnormality in patients with type 2 diabetes mellitus is hypertriglyceridemia (53). The relationship between hypertriglyceridemia and coronary artery disease is complex. A recent meta-analysis suggested that triglyceride levels are an independent risk factor for coronary artery disease (54). Triglyceride-rich lipoproteins tend to be associated with low HDL cholesterol levels and small dense LDL particles. This lipid triad is often associated with insulin resistance, hypertension, and prethrombotic states.

Hypertension

Recently, the UKPDS (55) demonstrated that intensive control of blood pressure in patients with hypertension reduced all diabetes complications by 24%, diabetesrelated deaths by 32%, strokes by 44%, heart failure by 56%, and microvascular complications by 37%. For achieving control of hypertension, -adrenergic blocking agents and ACE inhibitors were equally efficacious.

ACE inhibitors may confer an additional benefit. Studies have shown a specific effect of ACE inhibitors slowing the progression of diabetic nephropathy in patients with type 1 and type 2 diabetes (56). ACE inhibitors also may slow the progression of microalbuminemia to macroalbuminemia, even in normotensive patients with type 2 diabetes (57). Recently, another potential beneficial effect of ACE inhibitors has been reported. Endothelial dysfunction is common in patients with type 2 diabetes. ACE inhibitors have been shown to improve endothelial function in type 2 diabetes (58). Other renal protective measures include prevention and prompt treatment of urinary tract infections, institution of a low-protein diet, and avoiding or minimizing the use of radiographic contrast media.

In its sixth report, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (59) concluded that systolic blood pressure should be reduced below 130 mm Hg and diastolic blood pressure below 85 mm Hg to achieve optimal risk reduction.

Patients with type 2 diabetes and hypertension should monitor their blood pressure frequently with home blood pressure self-monitoring. Blood pressure can vary with food and salt intake, stress, and weight gain. Patients should be taught how to judge the effect lifestyle changes might have on the blood pressure and when to adjust their lifestyle in addition to their medication. The physician and the diabetes self-management team should empower the patient to be aware of these fluctuations. The team should teach the patient the significance of reducing the risk complications of hypertension and the importance of the data obtained with home blood pressure self-monitoring.

Cardiovascular Disorders

Antioxidants such as vitamin E have been shown to decrease the incidence of myocardial infarction. In contrast, -carotene has been ineffective in decreasing the incidence of myocardial infarction. Prevention of vascular events by the antiplatelet effect of daily low-dose aspirin (as low as 30 mg/day) has been well established. Daily low-dose aspirin therapy is important for both primary and secondary prevention of cerebral and cardiac events (60). Less well established is the proposal to use multivitamin preparations containing folate, vitamin B_{12} , and vitamin B_6 to reduce the blood level of homocysteine, a known atherogenic agent (61,62). Outcomes of myocardial infarction (7,63,64) and stroke improve with near-normalization of the blood glucose level.

Screening for asymptomatic coronary artery disease is an important consideration in patients with diabetes (65,66). An appropriate protocol for such screening has not been adequately tested. Increasing age, gender, cardiovascular risk factors, microalbuminuria, and retinopathy may identify high-risk groups for whom such testing is indicated.

Overall

Optimal care of the patient with diabetes must include intensive glycemic control, proper nutrition, a physical activity program, cessation of smoking, and weight control. Aggressive medical management of comorbid conditions, such as dyslipidemia, hypertension, and early renal disease, and use of antiplatelet therapy for prevention of vascular events are critical to improved outcomes and decreased cost of care for diabetes and its complications.

SECTION 6: COST AND COST-EFFECTIVENESS OF DIABETES CARE

The cost of diabetes mellitus is enormous, not only in terms of human morbidity and mortality but also relative to the economic burden it has imposed on the health-care system in the United States. Although patients with diabetes constitute only 3.1% of the total US population, they incur 11.9% of the total US health-care expenditures (67).

Factors Contributing to Costs

The economic costs of diabetes consist of direct health-care expenditures as well as the loss of productivity because of related disability and premature death. The direct medical costs of diabetes may be calculated as both medical expenses attributable to diabetes and total medical expenditures incurred among patients with diabetes. In 1997 in the United States, direct medical expenditures attributable to diabetes totaled \$44.1 billion. This overall amount consisted of \$7.7 billion for diabetes and acute glycemic care, \$11.8 billion due to the excess prevalence of related chronic complications, and \$24.6 billion due to the excess prevalence of general medical complications. Analysis of cost categories showed that 62% of costs were for inpatient care, 25% were for outpatient services, and 13% were for nursing home care. In addition, indirect costs included \$17 billion from premature mortality and \$37.1 billion from disability, a total of \$54.1 billion (68).

Comparative Medical Expenditures

In 1997, total medical expenditures in the United States for people with diabetes were \$77.7 billion or \$10,071 per capita, in comparison with \$2,669 per capita for those without diabetes (68). For 1992, Rubin and associates (69) reported similar figures of \$9,493 and \$2,604, respectively, and noted that 15% of the national health-care expenditures were spent on treating the 10.3 million people with overt diabetes. It has been estimated that another 5.4 million people have undiagnosed diabetes, a factor that would further increase the estimates of health-care costs for those with diabetes (70).

Effectiveness of Intensive Management

Since the publication of the findings of the DCCT (1) and, more recently, of the UKPDS (3,4), it has become clear that tighter control of blood glucose in both type 1 and type 2 diabetes can result in significant reduction in the development and progression of microvascular complications of diabetes. Furthermore, the frequency of macrovascular complications is decreased by near-normalization of the blood glucose levels. Multiple contributing causative factors of macrovascular complications, including dyslipidemia and hypertension, make the statistical correlation between blood glucose and macrovascular complications less definite; nonetheless, they are associated variables.

Although the intensive management of diabetes, which is necessary for achievement of tighter blood glucose control, is associated with higher "up-front costs" of labor, medications, and supplies, this investment has been shown to be effective in reducing morbidity and mortality as well as minimizing later expenditures for the most costly long-term complications (10,71,72). The cost benefit of tight glucose control is most pronounced in young patients who, in general, will have a longer subsequent duration of life during which the complications of diabetes could develop if normoglycemia is not achieved (10).

The cost of treating diabetes with "intensive" therapy within the DCCT (\$4,014/yr) was 2.4 times that of "conventional therapy" (\$1,666/yr). This cost was in a research setting. Inpatient initiation of treatment during the study accounted for more than 80% of the additional cost (73). Outside the DCCT study participants, in physician practices, however, intensive therapy was much less expensive—only \$2,337/yr (67). This difference was primarily due to less frequent and less prolonged use of hospital services and a lower cost for outpatient visits. Dedicated diabetes management teams led by an endocrinologist have been shown to maintain DCCT-level control of diabetes while using fewer inpatient and emergency department resources (74).

A simulation model of disease progression and costs (75) revealed that intensively treated patients with diabetes live 5.1 years longer than those given conventional therapy, with a lifetime increment in cost of only \$33,746 or \$6,616 per year of additional life. Therefore, the intensive treatment represented an extremely cost-effective investment. In addition, with further consideration of the reduction in complications (blindness, end-stage renal disease, and lower extremity amputation) that decrease the quality of life, the study noted that the incremental cost per "quality-adjusted life year" gained was only about \$20,000 for type 1 diabetes and \$16,000 for type 2 diabetes—relatively inexpensive in relationship to other commonly accepted medical therapies.

Short-term outcome analysis (76) has shown that improved glycemic control in patients with type 2 diabetes is associated with improved quality of life, higher retained employment, greater productive capacity, and less absenteeism. When these factors are considered, the cost of intensive therapy seems offset by even greater economic benefit, not only to the individual patient but to society as a whole.

In the UKPDS (55), tight control of blood pressure was shown to confer additional preventive benefit. Although this effort increased the average cost of drugs by £ 613 (\$977 US equivalent), a decrease in complications necessitating hospitalization accounted for a reduction of £ 700 (\$1,116 US equivalent). Tight control was estimated to cost less than £ 3,000 (\$4,784 US equivalent) per year of life gained. Thus, intensive diabetes management makes as much sense economically as it does medically. Numerous studies have documented the importance of a diabetes management team led by a clinical endocrinologist in achieving the tight blood glucose control necessary to yield the benefits of reduction in human pain and suffering. Such studies have demonstrated the cost efficiency of this approach to diabetes care in reducing the frequency of unnecessary visits to the emergency department and short hospital stays (74), in decreasing the duration of hospital stay for patients with diabetes (2), in treating diabetic ketoacidosis more efficiently (77-80), and in providing ongoing care to patients with diabetes that reduced both cardiovascular and renal morbidity and mortality (6).

SECTION 7: PATIENT AND PHYSICIAN RESPONSIBILITIES FOR EFFECTIVE DIABETES CARE

In any therapeutic situation, the physician and the patient have specific responsibilities. During the past 3 decades, this concept of shared responsibility has especially been emphasized in the management of chronic diseases, and type 1 diabetes mellitus is a notable example.

Until recently, type 2 diabetes mellitus had not been perceived as being a serious disease, perhaps because patients with type 2 diabetes may be relatively asymptomatic. The medical community now knows that even though the patient may be asymptomatic, a high blood glucose level will result in unrelenting development of both microvascular and macrovascular disease. The microvascular disease leads to ophthalmologic, neurologic, and renal complications. The comorbid conditions of dyslipidemia and hypertension have a complex relationship with diabetes. They may be worsened by poorly controlled diabetes or, in some settings, may be a direct result of lack of glycemic control. To achieve glycemic control, the asymptomatic patient with type 2 diabetes must become an active participant in the management of the blood glucose level. The physician and the diabetes management team must teach, nurture, and continually guide the patient toward self-management of the blood glucose.

The AACE Medical Guidelines for the Management of Diabetes Mellitus include a patient-physician contract. This contract outlines both the patient's and the physician's responsibilities in the management of this very serious and complicated disease. The summarized responsibilities of each stakeholder follow.

The Patient's Responsibilities

- 1. Perform monitoring of blood glucose consistently to help understand the dynamics of blood glucose changes relative to medication, diet, stress, and exercise.
- Understand the importance of smoking cessation in decreasing the risks of diabetes-related macrovascular and microvascular complications and, if a smoker, enroll in a program of smoking cessation.
- 3. Learn the importance of participation in a program of prescribed exercise for weight reduction and physical conditioning.
- 4. Know the importance of and reasons for the consistent use of aspirin in helping to reduce the risk of macro-

vascular complications. This knowledge will aid in increasing adherence to recommendations.

- 5. Monitor blood pressure consistently to help regulate the blood pressure and blood pressure medication. Understand the effects of medication and stress on blood pressure control and the risk of the lack of blood glucose control. This understanding will encourage adherence to blood pressure monitoring and control measures and decrease the risk of complications from hypertension, a serious comorbid complication of diabetes.
- 6. Recognize and understand the psychologic barriers that prevent adherence to the system of intensive self-management of diabetes. Learn how to express feelings and define the barriers to expressing feelings to the physician and the self-management team. This skill might help increase adherence with the system of intensive self-management of diabetes.
- 7. Learn the best techniques of foot care management and make a commitment to intensive foot care.
- 8. Understand the reasons for the onset of retinopathy, and recognize the signs and symptoms for early detection.
- 9. Understand the need for establishing goals for blood glucose, lipids, and blood pressure. Learn to participate in the development of these goals and in their modification, in consultation with the physician. After the goals have been established, develop a dedication to reaching those goals through intensive self-management of diabetes.
- 10. Actively participate in continuing diabetes education, such as support groups and physician and educator interactions, between regularly scheduled appointments. Share this valuable resource, becoming a teacher to other patients with diabetes and thereby learning from such interactions.
- 11. Adhere to proper nutrition and physical activity programs. Understand the physiologic rationale for their effectiveness. To improve adherence, discuss barriers with the physician and the diabetes management team.
- 12. Accurately document serial blood glucose and blood pressure measurements. Understand that the purpose of keeping such records is to help clarify blood glucose and blood pressure relationships to dietary aberrations, stress, exercise, and acute illnesses such as infections. This documentation will facilitate appropriate changes in treatment.
- 13. Understand the importance of keeping regularly scheduled appointments. Effective treatment of diabetes depends on a continuum of care, including periodic medical consultations.
- 14. Adhere to the proper use of medications. Understanding the mechanism of action of the medication will enhance adherence. If changes in the medication seem necessary, learn to communicate with the physician between appointments so that appropriate alterations can be made as a collaborative effort with the physician.
- 15. Understand the meaning of glycosylated hemoglobin, and know the results of personal glycosylated hemoglobin values.
- 16. Appreciate that the patient-physician contract is a tool to help both the patient and the physician uphold their commitments in the therapeutic plan.
- 17. Evaluate the compliance of the physician, and communicate this assessment to the physician.

The Physician's Responsibilities

For an effective diabetes self-management system, the physician must also fulfill the following responsibilities in the patient-physician contract.

- 1. Adhere to the protocol outlined in the AACE Medical Guidelines for the Management of Diabetes Mellitus: A System of Intensive Diabetes Self-Management.
- 2. Appropriately collect the patient data (details of the clinical course and the laboratory findings) so that clinical outcomes can be measured and related to economic outcomes.
- 3. Determine patient satisfaction and quality of life by use of questionnaires at yearly intervals.
- 4. Utilize a system of communication and documentation of the communication with the diabetes self-management team so that the team is truly an extension of the physician's care.
- 5. Utilize diabetes skill evaluation programs, and objectively evaluate the patient semiannually.
- 6. Define the frequency of patient visits, and assess the patient's ability and desire to adhere to the system of intensive diabetes self-management.
- 7. Document, evaluate, and rate the patient's concerns every 3 months in a utilizable data format. As the key element, the patient must feel comfortable describing barriers to intensive self-management. The patient should always be the focus of the diabetes self-management team.
- 8. Evaluate the effectiveness of the documentation of care of the patient. Pay particular attention to the quality of the documentation; continuous improvement in the quality of documentation should be an integral part of the system of care.

- 9. Supervise the education of the patient. The physician must be involved in discussing preventive methods and explaining risk reduction so that the patient gains expertise in diabetes management and is encouraged by the entire diabetes care team.
- 10. Ensure that the patient understands and adheres to preventive measures, including detailed instructions for foot care, diet, and physical activities, aimed at reducing the risk of complications.
- 11. Utilize a process to evaluate the patient's adherence to the system of intensive self-management. The assessment should be objective and amenable to evaluation in query format related to other variables. The program should include mechanisms to determine whether the patient is taking medicines and insulins safely and correctly. A continuing program should be undertaken to identify errors and misconceptions as well as to educate others in the system who help care for these patients. This effort will reduce the frequency of potential mistakes in the overall process.

The Patient-Physician Contract

In medical care, the social contract is between the patient and the physician. Both the physician and the patient have obligations in this therapeutic relationship. The fulfillment of those obligations and responsibilities by each party is critical to achieving near-normal blood glucose levels. In patients with type 1 or type 2 diabetes, decreasing the rate of complications, enhancing the quality of life, limiting the associated morbidity, and minimizing the economic costs can be achieved by increasing adherence and attaining near-normalization of the blood glucose levels.

Table 9 Summary of Patient and Physician Responsibilities in Intensive Diabetes Self-Management System

Patient responsibilities	Physician responsibilities
Exercise programAdherence to dietary guidelinesMBlood pressure monitoringLSmoking cessationMConsistent use of aspirinLOvercoming psychologic and other barriersHealthy expression of feelingsFoot and eye careLUnderstanding "targets" for control of blood glucoseand blood pressureLCommunication with physician and diabetes care teamKeeping appointmentsERecord keeping	Adherence to the system of intensive self-management of diabetes Measurement of outcomes Determination of patient satisfaction Maintenance of communication with team Development of evaluation programs; include safety in taking medication and identification of patient misconceptions Listening to patient concerns Establishing and maintaining follow-up schedule Documentation of patient care Supervision of the patient's diabetes education Encouragement of patient in use of preventive measures and risk reduction Supervision of proper foot care procedures

SECTION 8: THE INSULIN RESISTANCE SYNDROME

Characterization

The insulin resistance syndrome is characterized by glucose intolerance, hypertension, dyslipidemia, and visceral obesity (81,82). All of these findings are risk factors for ischemic heart disease, but insulin resistance, as assessed by the fasting insulin level, has itself been shown to be an independent risk factor for ischemic heart disease in investigations such as the Quebec Heart Study (83). In fact, in that study, insulin resistance was shown to be a more important risk factor than total apolipoprotein B or HDL cholesterol levels.

The dyslipidemia associated with insulin resistance is characterized by a high triglyceride level and a low HDL cholesterol level. In the atherogenicity of the dyslipidemia associated with insulin resistance, however, small dense LDL particles, postprandial hyperlipidemia, and increased remnant particles may be equally important factors (81,84).

Associated Conditions

Insulin resistance as a cause of hypertension is more prevalent in some ethnic minority groups than in others. The mechanism for the increased prevalence of hypertension is related to higher insulin levels acting on the renal tubule, increased reabsorption of sodium, and vasoconstriction through stimulation of the sympathetic system by insulin (85). In addition, the insulin resistance syndrome is associated with endothelial dysfunction (82,86), leading to a decrease in production of nitric oxide. The decreased production of nitric oxide, in turn, leads to vasoconstriction and stimulation of clotting factors, platelet aggregation, and decreased breakdown of fibrinogen through stimulation of plasminogen activator inhibitor. Endothelial dysfunction is also associated with increased endothelial permeability to molecules such as lipoproteins. In addition, activation of growth factors leads to accelerated atherosclerosis. Abnormal endothelial permeability is also present in the glomerulus, in reality an arteriole, leading to microalbuminuria and proteinuria. The level of proteinuria has been shown to be inversely proportional to the insulin sensitivity. In patients who are at high risk for diabetes because of insulin resistance, proteinuria will often be detected before fasting or postprandial blood glucose levels are found to be high.

Overt diabetes will develop when insulin production cannot be increased to overcome insulin resistance. In comparison with thin patients, many obese patients without diabetes produce 5 to 8 times more insulin—an amount that can be as much as 500 U/day—to overcome insulin resistance. Thus, type 2 diabetes can be attributed to a genetic failure of the pancreatic beta cells to compensate for insulin resistance (87). The presence of hyperuricemia, with or without clinical manifestations of gout, is also a feature of the metabolic syndrome which includes insulin resistance. Therefore, patients known to have hypertension, dyslipidemia, hyperuricemia, or gout at an early age should undergo periodic assessment for the presence of diabetes.

Some evidence suggests that breast cancer may be associated with insulin resistance-because of stimulation of tumor growth by high insulin levels or by decreased hepatic production of sex hormone-binding globulin and higher free estrogen levels (88). Moreover, many cases of polycystic ovary disease are associated with insulin resistance. High insulin levels stimulate the production of androgens from the ovaries and adrenal gland and luteinizing hormone from the pituitary gland (89). The decreased sex hormone-binding globulin further increases the free androgen levels and increases the likelihood of manifestations of the disease (acne, hirsutism, virilism, amenorrhea, and infertility). Women with polycystic ovaries, because of their underlying insulin resistance, are at high risk for subsequent development of the other manifestations of polycystic ovary disease including diabetes mellitus and vascular disease.

Causative Factors

Insulin resistance is a state in which insulin-sensitive tissues, such as skeletal muscle, have a reduced sensitivity to the effects of insulin on glucose uptake. At least 50% of any patient's insulin resistance is due to genetic factors. Insulin resistance is worsened by aging, inactivity leading to a loss of muscle mass, and the development of obesity. For obesity to be associated with insulin resistance, it must be of the android or male distribution (that is, with a high waist-to-hip ratio) and not the gynoid or female distribution, with most of the adipose tissue in the lower body (a decreased waist-to-hip ratio). Furthermore, subcutaneous adipose tissue is not associated with insulin resistance, whereas intraperitoneal or visceral adiposity is. The ratio of intraperitoneal to subcutaneous fat can be determined by computed tomographic scanning or magnetic resonance imaging. Increased intraperitoneal fat is suspected if the waist circumference is more than 37 inches (94 cm) or the waist-to-hip ratio exceeds 0.85 in women or 1.00 in men (82,90).

Other environmental factors that increase insulin resistance are cigarette smoking and a lack of exercise. Insulin resistance is lowered by a moderate alcohol intake (one to two drinks per day); however, AACE does not advocate the use of alcohol to achieve such a result. Pharmacologically, drugs such as nicotinic acid, -adrenergic blocking agents, thiazide diuretics, progesterones, and short-acting dihydropyridine calcium channel blockers increase insulin resistance, whereas ACE inhibitors, angiotensin II receptor blockers, and estrogen replacement therapy lower insulin resistance.

Because infections and cancers may exacerbate the insulin resistance syndrome, investigators have postulated that the final common pathway of the insulin resistance syndrome is through the action of cytokines. Although many cytokines have been shown to be increased in the insulin resistance syndrome, the cytokine that could most reasonably be the link among all the manifestations of the syndrome is tumor necrosis factor- .

Treatment

The key to nonpharmacologic therapy to reduce insulin resistance is increased physical activity and decreased caloric intake. Both the increase in physical activity and the decrease in caloric intake will increase insulin sensitivity, with or without weight loss (91).

As little activity as walking for 40 minutes four times per week is enough to lower insulin resistance. Likewise, as little physical activity as walking 5 miles per week can reduce the risk of developing diabetes by 6% (the reduction is even more in obese persons and those persons with a family history of diabetes) (36,92). Exercise increases the affinity of the insulin receptor for insulin, increases the mobilization of glucose transporters, and increases the activity of tyrosine kinase, each of which will lead to a decrease in insulin resistance in skeletal muscle. By preferentially decreasing intraperitoneal adiposity, increased activity also results in a decrease in free fatty acids and a further decrease in insulin resistance. Similarly, even as little as a 5% decrease in body weight will result in a substantial reduction in insulin resistance.

When the plasma glucose is high in the patient with diabetes, insulin resistance is increased. Irrespective of the method used to lower blood glucose levels, reversal of "glucotoxicity" will result in a decrease in insulin resistance as well as an increase in endogenous production of insulin.

SECTION 9: AACE SYSTEM OF INTENSIVE DIABETES SELF-MANAGEMENT

The AACE System of Intensive Diabetes Self-Management is divided into three phases. Phase I provides the opportunity for the initial patient assessment. Initial patient education and formulation of a customized therapeutic approach may require several outpatient visits during a period of a few weeks. Phase II, the follow-up phase, provides for interim assessments of the patient's physical condition, reaction to intensive therapy, and understanding of the tools for diabetes self-management. Phase III consists of the ongoing assessment of the complications of diabetes mellitus as well as reeducation of the patient and encouragement to maintain enthusiasm for the difficult task of intensively managing blood glucose levels.

In this ongoing system, the patient-intensive participation is the key to effective control of the diabetes. The clinical endocrinologist or other physician and all members of the health-care team must facilitate this participation by the patient.

Phase I: Initial Assessment

The primary goal of Phase I is the assessment of the patient's disease status and risk factors for complications of diabetes. This goal may be accomplished by a thorough elicitation of the patient history, performance of a complete physical examination by the physician, and appropriate laboratory evaluation. During Phase I, which may require multiple patient visits during an interval of 3 to 4 weeks, the physician will gather information, develop initial recommendations for the patient, and begin a diabetes self-management program with the help of the diabetes health-care team. The educational program should address appropriate nutrition, exercise, medication, record-keeping systems, and self-monitoring of blood glucose. As the patient begins to understand the rationale for intensive control of blood glucose, the regimen can be modified and the patient can be taught the reasons for modification. At this time, the clinical endocrinologist can schedule the appropriate evaluations or referrals for assessment of complications and specific risk factors.

Other goals during Phase I are to assess the patient's knowledge base about diabetes mellitus and to evaluate the ability of the patient to learn new skills and techniques. These assessments can be done by using a combination of objective knowledge tests, psychologic adjustment tests, and interview questions. After these assessments have been completed, the physician and other team members should be able to initiate the appropriate level of education regarding diabetes self-management skills.

During Phase I, the physician should evaluate the patient's commitment to a program of intensive treatment of diabetes and elicit the patient's written agreement to participate in the diabetes self-management system. The physician, patient, and health-care team should develop a set of individualized instructions for the patient's care.

Patient History

The patient's responses to the following areas of questioning should help the physician confirm the diagnosis and duration of diabetes mellitus, establish the success or failure of previous treatment regimens, evaluate the presence of existing complications of diabetes, and determine the patient's risk for the future development of complications (93).

- 1. What is the patient's chief complaint? How long has the patient had diabetes?
- 2. Did onset of diabetes include the following:
 - a. Polydipsia?
 - b. Polyuria?
 - c. Polyphagia?
 - d. Unexplained weight loss or gain?
- 3. Is there a family history of diabetes or other endocrine disorders?
- 4. Does the patient have a history of gestational diabetes?
 - a. Hyperglycemia?
 - b. Delivery of an infant weighing >9 lb (4.1 kg)?
 - c. Toxemia?
 - d. Stillbirth?
 - e. Other complications of pregnancy?
- 5. Has the patient lost or gained weight? What is the patient's current nutritional regimen?
- 6. What are the patient's exercise history and ability to exercise?
- 7. What are the patient's current non-diabetes-related medications?

- 8. What is the patient's alcohol intake?
- 9. Is there a history of recreational drug use?
- 10. Has the patient ever been hospitalized or undergone a surgical procedure?
- 11. If the patient has already been diagnosed as having diabetes mellitus:
 - a. When and how was the diabetes diagnosed?
 - b. Which medications have been used to treat the diabetes, and in which order? Establish the current treatment regimen, including nutrition and exercise programs.
 - c. How have the patient's blood glucose levels been monitored in the past? Has the patient monitored blood glucose at home? How frequently was the patient's glycosylated hemoglobin monitored? Were the results of these tests used to maximize the degree of control of diabetes?
- 12. Does the patient have symptoms of any of the following types of complications of diabetes?
 - a. Ophthalmologic (including retinopathy)?
 - b. Neuropathy?
 - c. Renal?
 - d. Vascular (cardiovascular, cerebrovascular, peripheral vascular system)?
 - e. Sexual dysfunction (men and women)?
 - f. Ketoacidosis?
 - g. Hypoglycemia?
 - h. Infections (for example, cutaneous, foot, gynecologic)?
- 13. Does the patient have any identifiable risk factors for complications of diabetes?
 - a. Family history of diabetes or coronary artery disease?
 - b. Hypertension (systolic, diastolic)?
 - c. Smoking history?
 - d. Lipid abnormalities?
 - e. Central obesity?

Physical Examination

Phase I should include a complete physical examination of each patient. Special attention should be directed to those aspects of the examination that focus on specific areas of risk for the patient with diabetes (93), including the following factors:

- 1. Height and weight measurements
- 2. Blood pressure determination, including orthostatic evaluation
- 3. Ophthalmoscopic examination
- 4. Thyroid palpation
- 5. Cardiac examination
- 6. Evaluation of pulses, including carotid pulses or bruit and respiratory variation
- 7. Foot examination
- 8. Skin examination
- 9. Neurologic examination, with particular attention to reflexes, vibratory sensation, touch, and proprioception

Laboratory Evaluation

Laboratory tests should be ordered to establish the diagnosis of diabetes and to determine the current level of glycemic control (93). In addition, Phase I laboratory testing should provide an evaluation of the patient's general medical condition and should identify associated risk factors. The following laboratory tests should be included in the Phase I assessment:

- 1. Fasting or random plasma glucose*
- 2. Glycosylated hemoglobin or fructosamine
- 3. Fasting lipid profile (cholesterol, triglycerides, HDL/LDL calculation)
- 4. Serum electrolytes*
- 5. Serum creatinine*
- 6. Urinalysis
- 7. Sensitive or ultrasensitive thyroid-stimulating hormone
- 8. Microalbuminuria and creatinine clearance
- 9. Electrocardiography, stress test, or both

*Commonly available as part of a serum chemistry profile.

Patient Knowledge Base and Motivation

The results of objective testing regarding the physiologic aspects and treatment of diabetes mellitus will help the clinical endocrinologist or other physician assess the level of diabetes education to be initiated (94). Psychologic tests and a subjective evaluation of the patient's psychologic support systems will help predict patient adherence to a system of intensive therapy. These evaluations will help determine which referrals are most necessary and will help establish priorities for educating the patient about diabetes self-management.

- 1. The following evaluation forms may be used to assess the patient's understanding of the physiologic aspects of diabetes mellitus:
 - a. Diabetes Assessment and Teaching Record (see Appendix)
 - b. AACE Knowledge Evaluation Forms (see Appendix)
- 2. The following psychologic tests may be used to evaluate the patient's motivation for participating in a diabetes self-management system:
 - Michigan Diabetes Research and Training Center Diabetes Care Profile (Available from MDRTC, University of Michigan Medical Center, G1111 Towsley Center, Ann Arbor, MI 48109-0201)
 - b. Millon Behavioral Health Inventory (Available to licensed professionals from National Computer Systems, PO Box 1294, Minneapolis, MN 55440)
- 3. The patient's resources and support systems should be evaluated in the following areas, to help assess the patient's motivation for adherence to intensive diabetes treatment:
 - a. Family
 - b. Financial (including medical insurance status)
 - c. Employment

4. The patient may be reassessed and reevaluated at 6 months to determine the level of knowledge retained after training and education

Diabetes Self-Management System

Patient empowerment is vital to a system of intensive diabetes therapy. For a successful system, the patient must understand and learn to manage the diabetes and its treatment (95). Traditional patient education is just one aspect of diabetes intensive self-management. In addition, the patient with diabetes must be taught to assume responsibility for the self-monitoring and problem solving that are critical to the successful implementation of a system of intensive diabetes therapy.

Although this educational process is initiated during Phase I, the information is so vital and the material is so extensive that the educational process should be continued during all phases of treatment.

Because each participating patient will have different educational needs, the members of the health-care team must individualize the program. The results of the initial patient assessment will help health-care team members establish a system of priorities for scheduling each topic to be covered. A series of ongoing patient assessments, undertaken during all subsequent phases of treatment, will help health-care team members revise these priorities as needed to ensure that the individual needs of each patient are being met and to facilitate patient adherence.

Topics to be addressed during the overall course of treatment of the patient with diabetes may be divided into the following categories (93):

- 1. Pathophysiologic features of diabetes
- 2. Rationale for the intensive treatment of diabetes mellitus
 - a. Potential complications associated with diabetes
 - b. Relationship between control and complications
- 3. Self-monitoring of blood glucose
 - a. Use of a blood glucose self-monitor
 - b. Schedule for use (minimum of twice daily)
 - c. Instructions for record keeping
- 4. Medication
 - a. Description
 - b. Dosing instructions
 - c. Dosage adjustment algorithms
 - d. Suggestions for record keeping
- 5. Nutrition
 - a. Importance
 - b. Prescribed meal plan
 - c. Dealing with nutrition-related fluctuations in blood glucose levels
 - d. Suggestions for record keeping
- 6. Exercise
 - a. Importance
 - b. Prescribed exercise plan
 - c. Dealing with activity-related fluctuations in blood glucose levels
 - d. Suggestions for record keeping

- 7. Recognizing and managing potentially dangerous complications
 - a. Hypoglycemia
 - b. Diabetic ketoacidosis
 - c. Hypoglycemia unawareness
 - d. Infection
 - e. Vascular disease
- 8. Instructions for special situations
 - a. Sick day rules
 - b. Travel instructions
 - c. Use of glucagon
- 9. Preventive care
 - a. Foot care
 - b. Skin care
- 10. Psychologic aspects
 - a. Effect on relationships and family dynamics
 - b. Effect on self-image
 - c. Importance of support
 - d. Denial
- 11. Instructions for family members

Patient-Physician Contract

For successful implementation of intensive diabetes management, the patient and the clinical endocrinologist or other physician must have mutual, frequently communicated treatment goals. This relationship necessitates regularly scheduled communication and frequent visits between the patient and members of the health-care team. The frequency of these interactions should be based on individual patient needs. Patients must be encouraged to adhere to the specified schedule. To achieve this goal, the physician may need to establish a follow-up system or, in some cases, the intervention of a third-party payer.

For optimal patient adherence to the System of Intensive Diabetes Self-Management, it may be helpful to elicit the patient's written commitment to participate. The document, which should be signed by both the patient and the physician, should specify the responsibilities of both parties and contain the prescribed schedule of follow-up visits and communications (see Appendix). The risks of assuming or declining the responsibility of intensive therapy need to be defined in the contract.

Phase II: Follow-Up Assessments

A goal of each follow-up assessment is to evaluate the patient's physical condition, level of blood glucose control, and degree of adherence to guidelines. Such an assessment should include an interim history, physical examination, laboratory evaluation, and review of the patient's results of self-monitoring of blood glucose. On the basis of the results of this evaluation, the physician and the patient may elect to revise any or all aspects of the patient's treatment plan or the schedule for the assessment of complications (see Phase III).

Because the patient with diabetes has a considerably increased risk of coronary artery and peripheral arterial disease, dyslipidemia, and hypertension, lipid levels and blood pressure must be rigidly monitored and controlled. The patient with diabetes should be viewed comparably to a nondiabetic patient who has had a coronary event. As has been substantiated, the reduction of high blood pressure in patients with diabetes significantly decreases the risk of nephropathy and retinopathy (55).

Other goals during Phase II are to assess the patient's understanding of diabetes mellitus and the rationale for intensive self-management and to determine the patient's self-management skills. This evaluation necessitates periodic administration of follow-up objective and psychologic tests and inquiry about the patient's support systems. Depending on the results of this interim assessment, the physician may reinstitute intensive diabetes education in any deficient areas.

Follow-up assessments should be scheduled at intervals of no longer than 3 months and may be combined with the modules for assessment of complications (see Phase III).

Interim Patient History

The patient's responses to the following areas of questioning should help in the development of a revised treatment plan, assessment of existing diabetes-associated complications, and reevaluation of the patient's risk for future complications.

- 1. Has the patient experienced any acute health problems?
- 2. Have any changes occurred in any chronic health problems?
- 3. Has the patient experienced any symptoms or signs suggestive of hypoglycemia?
- 4. Does the patient have any new symptoms or signs suggestive of diabetes-related complications?
- 5. Have any risk factors changed?

Physical Examination

Phase II includes an interim physical examination for each patient. The following elements may be included, depending on patient symptoms and signs and the results of the initial physical examination:

- 1. Height and weight measurements*
- 2. Blood pressure determination, including orthostatic evaluation*
- 3. Ophthalmoscopic examination
- 4. Thyroid palpation
- 5. Cardiac examination
- 6. Evaluation of pulses, including carotid pulses or bruit and respiratory variation
- 7. Foot examination*
- 8. Skin examination
- 9. Neurologic examination

*Should be included with every interim physical examination.

Every patient should undergo a complete physical examination at least once annually.

Laboratory Evaluation

During each follow-up assessment, the results of the patient's self-monitoring of blood glucose should be reviewed. In addition, laboratory tests should be ordered to confirm the patient's current level of glycemic control. These analyses should include the following:

- 1. Random plasma glucose
- 2. Glycosylated hemoglobin or fructosamine
- 3. Fasting lipid profile

On the basis of the results of the patient's self-monitoring of blood glucose and the laboratory testing, the physician may elect to revise the recommendations regarding nutrition, exercise, medication, self-monitoring, and follow-up communication. In addition, the physician may elect to revise the schedule for implementing any or all of the Phase III modules for assessment of complications.

Patient Knowledge Base and Self-Management Skills

To assess the patient's current level of understanding of the pathophysiologic features of diabetes mellitus and the rationale for self-management and to determine the current level of self-management skills, follow-up objective and psychologic tests should be administered. In addition, the patient's support systems should be reevaluated.

- 1. The following evaluation forms may be used to assess the patient's current understanding of the physiologic aspects of diabetes mellitus:
 - a. Diabetes Assessment and Teaching Record (see Appendix)
 - b. AACE Knowledge Evaluation Forms (see Appendix)
- 2. The following psychologic test may be used to evaluate the patient's motivation for participating in a diabetes self-management system:
 - a. Michigan Diabetes Research and Training Center Diabetes Care Profile (Available from MDRTC, University of Michigan Medical Center, G1111 Towsley Center, Ann Arbor, MI 48109-0201)
 - b. Millon Behavioral Health Inventory (Available to licensed professionals from National Computer Systems, PO Box 1294, Minneapolis, MN 55440)
- 3. The patient's resources and support systems should be reevaluated in the following areas:
 - a. Family
 - b. Financial (including medical insurance status)
 - c. Employment

Depending on the results of the interim assessment, the physician may reinstitute intensive education in the deficient areas or refer the patient to one or more members of the health-care team.

Phase III: Assessment of Complications

The goal of Phase III is to assess the presence and severity of the complications associated with diabetes mellitus. Each of the following four complications modules (93,96) should be performed in conjunction with a quarterly Phase II follow-up assessment:

- 1. Retinal
- 2. Cardiac-cerebrovascular-peripheral vascular
- 3. Renal
- 4. Neuropathy

Retinal Module

When performed in conjunction with the retinal module (96), the Phase II interim history and physical examination should include any questions relevant to the assessment of retinal complications. Additional diagnostic evaluations should include the following:

- 1. Test of visual acuity (Snellen chart)
- 2. Funduscopic examination
- 3. Intraocular pressure test

In addition to educating the patient about the retinal complications that may be associated with diabetes, the physician should determine—on the basis of the patient's history and findings on the current examination—the frequency of follow-up and the need for referral to an ophthalmologist or retinal specialist.

Cardiac-Cerebrovascular-Peripheral Vascular Module

Vascular risk factors should be assessed annually in adult patients with diabetes. When performed in conjunction with the cardiac-cerebrovascular-peripheral vascular module (93), the Phase II interim history and physical examination should include any questions relevant to the assessment of cardiac-cerebrovascular-peripheral vascular complications. Additional diagnostic evaluations should include the following:

- 1. Electrocardiography and rhythm strip, stress test, or both (based on the patient's age and symptoms)
- 2. Lipid profile (cholesterol, triglycerides, HDL/LDL calculation)
- 3. Evaluation of peripheral pulses by physical or objective testing (or both)

In addition to educating the patient about the vascular complications that may be associated with diabetes, the physician should determine—on the basis of the patient's history and findings on the current examination—the frequency of follow-up, the need for more intensive cardiac testing, and the need for referral to a cardiologist, neurologist, interventional radiologist, or vascular surgeon.

Renal Module

When performed in conjunction with the renal module (93), the Phase II interim history and physical examination should include any questions relevant to the assessment of renal complications. Additional diagnostic evaluations should include the following:

- 1. Test for microalbuminuria
- 2. Creatinine clearance
- 3. Automated serum chemistry analysis

In addition to educating the patient about the renal complications that may be associated with diabetes, the physician should determine—on the basis of the patient's history and findings on the current examination—the frequency of follow-up and the need for referral to a nephrologist.

Neuropathy Module

When performed in conjunction with the neuropathy module (93), the Phase II interim history and physical examination should include any questions relevant to the assessment of neuropathy. Additional diagnostic evaluations should include the following:

- 1. A review of symptoms relevant to peripheral nerve and autonomic dysfunction
- Module-specific testing (vibratory sensation, softtouch, pinprick, evaluation of autonomic dysfunction—for example, R-R interval variation with paced breathing)

In addition to educating the patient about neuropathy, the physician should determine—on the basis of the patient's history and findings on the current examination—the frequency of follow-up and the need for referral to a neurologist.

CONCLUSION

AACE has provided the recent scientific evidence that continues to support its Medical Guidelines for the Management of Diabetes Mellitus: A System of Intensive Diabetes Self-Management. A thriving patient-physician relationship and a partnership effort among the patient, the physician, and the diabetes management team remain critical to the success of intensive diabetes self-management. These coordinated efforts should result in normalization or near-normalization of the patient's glycosylated hemoglobin value and blood glucose level. The outcome will be an enhancement in the patient's quality of life, a decrease in morbidity, and a reduction in mortality.

The patient must be committed to learning diabetes self-management, and the physician and the diabetes selfmanagement team must be dedicated to teaching the patient the appropriate techniques and the rationale for them. AACE hopes that the use of these guidelines by physicians and patients will lead to improved care for patients with diabetes, an augmented quality of life for such patients, and decreased overall costs of diabetes care for the individual patients and society.

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Appendix

Diabetes Assessment and T eaching Record

Ι.	Name						Init	ial Visit Da	ate		
	Date Dx Diabetes						_ <u>0cci</u>	upation			
	Support System						Physician				
	Outside Referral						Lette	er Sent			
	Age	_ <u>Ht</u>		Wt			IBW		Sex	<u>Race</u>	
	Туре 1	Type 2		Gestatior	nal		AIM		Update		
∥.	Current Medi	cations									
	Oral Agent Therap	y:									
				Drug			Dos	e		<i>Tim</i>	e(s)
	Insulin Therapy:	A.M.	<i>P.M.</i>	Supper	- HS		_ Diet	Therapy Only			
	Allergies						Heal	th Status			
	Date	BP		Wt		HbA _{1C}		Chol	HDL		Trig
	Current Problems:										

III. Educational Objectives/Plan

Date	Objectives Met
1	
2.	
3.	

IVa. Nutrition Histor y

Breakfast:			
Snack:			
Lunch:			
Snack:			
Dinner:			
Snack:			

IVb. Meal Plan

Prescribed Total Daily Caloric Intake:

	Milk	Veg	Fruit	Starch	Lean Meat	Fat
Breakfast:						
Midmorning Snack:						
Lunch:						
Afternoon Snack:						
Dinner:						
Bedtime Snack:						

V. Previous Diabetes Education

			Date		Place	
Will anyone else a	ttend the educa	ation sessions?	Yes	No	Name	
Frequency of:						
DKA	Low BS	High BS		Diabetic	Hospitalizations	
Complications:						
Retinopathy	I BP	Nephropathy		Neuropathy	PVD	Other
Smoke	Amount			Drink Alcohol	Amount	Туре
Exercise:						
Туре		Times/Week		How Long		

VI. Teaching Record	Written Instr	Verbal Instr	Vrblz Undst	Demos Accrt Tchnq	Follow-up	Comments	Print Materials
A. Basic Pathophysiology Understands the basic pathophysiology of diabetes							
B. Psychologic Adjustment Has psychologically adjusted to diabetes and lifestyle modifications and understands effects of stress on management							
C. Family Involvement Family and/or significant other(s) are sufficiently involved in diabetes management S M W D							
D. Exercise Describes, understands, and incorporates effective exercise habits into diabetes management							
E. Medications Demonstrates and/or verbalizes correct use of 1. P.O. Type Dosage Frequency Action 2. Insulin Type/Dose Action Injection Techniques Mixing Storage Site Selection							
F. Relationship Among Nutrition/Exercise/Medication Understands interrelation of nutrition, exercise, medication, and lab values and incorporates this into diabetes management							
 G. Monitoring 1. Demonstrates accurate blood or urine glucose monitoring 2. Frequency 3. Type 4. Urine ketone testing 							
 Hypoglycemia Understands, describes, and appropriately reacts to and treats the signs and symptoms of hypoglycemia 							
I. Illness/Hyperglycemia Understands, describes, and appropriately responds to the signs and symptoms of illness and/or							

VI.	Teaching Record (continued)	Written Instr	Verbal Instr	Vrbiz Undst	Demos Accrt Tchnq	Follow-up	Comments	Print Materials
	Complications (Prevent, Treat, Rehabilitate) Understands the complications of diabetes and practices health-care measures to manage and assist in rehabilitation of those complications: Neuropathy Nephropathy Retinopathy Impotence BP Control							
	Care Benefits/Responsibilities Understands the benefits and responsibilities of appropriate diabetes management							
	Hygiene Understands the importance of and practices routine hygiene to prevent possible diabetes complications Foot care Eye care Dental Care General							
	Use of Health-Care Systems Is aware of and appropriately uses health-care systems (financial resources, health insurance) and knows how to reach health-care team and emergency care							
	Community Resources Is aware of and appropriately uses available community resources (ADA, MedicAlert [®] , support groups)							
VIIa.	Dietary Education							
A.	States that food is important for good nutrition and the control of glucose and lipid levels							
В.	States the necessity of eating meals and snacks at consistent times and in appropriate amounts							
	Lists the types and amounts of food to be included in meals and snacks as indicated on the meal plan							
D.	States that meal planning is a critical component in diabetes management							
E.	States the importance of maintaining normal body weight							

b. Follow-up/Continuing Education	Written Instr	Verbal Instr	Vrblz Undst	Demos Accrt Tchnq	Follow-up	Comments	Print Materials
A. Demonstrates how to plan appropriate meals from the meal plan							
B. States the caloric level of the meal plan and the percentages of carbohydrate, protein, and fat							
C. Lists food sources of dietary fiber and describes how to incorporate foods with fiber into the meal plan							
D. Demonstrates how to select foods in appropriate portion sizes							
E. Demonstrates how to select appropriate foods when dining out							
F. States the need to be consistent in daily caloric intake							
G. States the benefits of making permanent lifestyle changes in nutrition and activity levels							
Other:							

VIII. Evaluation Summary/Follow-up

Pretest Score:	Date:

Posttest Score: Date:

Signatures

_____ RN, CDE

RD/LD

AACE Knowledge Evaluation Forms

The AACE Knowledge Evaluation Forms are to be used to assess the patient's knowledge of diabetes before and after exposure to the system of intensive diabetes management in order to detect weaknesses in the patient's understanding and provide appropriate useful information. The educational process need not begin with basic elements in an already knowledgeable patient. The goals are to provide the information needed for self-management of diabetes and to encourage adherence.

Sample forms without the answers starred are available from the AACE office on request and may be photocopied.

Type 2 Diabetes: Patient Evaluation

What Is Diabetes?

- **1.** In type 2 diabetes, the body
 - **a.** cannot use insulin well*
 - **b.** makes no insulin at all
 - c. rejects insulin
 - **d.** destroys insulin
- **2.** Patients with type 2 diabetes
 - a. never need insulin injections
 - **b.** need insulin injections daily
 - c. may need insulin injections*
- 3. Insulin is made in the
 - **a.** liver
 - **b.** stomach
 - **c.** kidneys
 - d. pancreas*
- 4. Insulin helps the body
 - **a.** turn sugar into energy*
 - **b.** get rid of sugar
 - **c.** store sugar in the blood
 - **d.** make red blood cells
- **5.** "Blood glucose" refers to the level of sugar (glucose) in the blood.
 - a. true*
 - **b.** false
- 6. The target range for blood glucose before meals is
 - **a.** 50 to 70 mg/dL
 - **b.** 70 to 120 mg/dL*
 - **c.** 125 to 160 mg/dL
 - **d.** 160 to 200 mg/dL
- 7. "Hyperglycemia" means
 - **a.** high blood glucose*
 - **b.** low blood glucose

- **c.** high blood pressure
- **d.** low blood pressure
- 8. "Hypoglycemia" means
 - a. high blood pressure
 - **b.** low blood pressure
 - **c.** high blood glucose
 - **d.** low blood glucose*
- **9.** Which of the following is a symptom of hypoglycemia?
 - a. weakness
 - **b.** sweating
 - c. shakiness
 - d. all of the above*
- 10. The aim of intensive diabetes treatment is
 - **a.** to keep blood glucose as close to normal as possible
 - b. to avoid long-term complications
 - **c.** both of the above*
- 11. Complications of diabetes include
 - **a.** kidney disease
 - **b.** eye problems
 - c. foot problems
 - **d.** all of the above*
- **12.** Which of the following can affect blood glucose control?
 - a. stress
 - **b.** eating habits
 - **c.** exercise
 - **d.** all of the above*
- **13.** Patients with diabetes have no control over the development of complications.
 - a. true
 - **b.** false*
- 14. "Tight" control of diabetes means
 - **a.** keeping blood glucose as close to normal as possible
 - **b.** frequent self-monitoring
 - c. reduced complications
 - **d.** all of the above*
- **15.** Treatment of type 2 diabetes is usually initiated with **a.** insulin
 - **b.** diet and exercise programs*
 - **c.** diabetes pills
- **16.** The most important person on your health-care team is
 - a. you*
 - **b.** the doctor
 - **c.** the diabetes educator
 - **d.** the dietitian

Nutrition

- 1. In overweight patients with diabetes, losing weight may
 - **a.** help the body use insulin better
 - **b.** lower blood glucose
 - c. decrease the risk of heart disease
 - **d.** do all of the above*
- 2. Meals should generally be eaten
 - **a.** 1 to 2 hours apart
 - **b.** 4 to 5 hours apart*
 - c. every 6 hours
 - d. whenever you want
- **3.** Carbohydrates should make up what percent of your daily calories?
 - **a.** 5 to 10%
 - **b.** 15%
 - **c.** 25%
 - **d.** 55 to 60%*
- 4. A good source of complex carbohydrates is
 - **a.** eggs
 - **b.** mayonnaise
 - c. whole-grain bread*
 - **d.** roast beef
- **5.** Fat should constitute what percent of your daily calories?
 - **a.** less than 30%*
 - **b.** 45%
 - **c.** 55 to 60%
 - **d.** 75%
- 6. Which of the following foods is high in fat?
 - a. apples
 - **b.** lettuce
 - **c.** cheddar cheese*
 - **d.** oatmeal
- The fatty substance in food linked to heart disease is
 a. carbohydrates
 - **b.** protein
 - **c.** cholesterol*
 - d fibor
 - **d.** fiber
- **8.** To decrease dietary fat and cholesterol, which food is the best choice?
 - a. steak
 - **b.** fried eggs
 - c. broiled chicken without skin*
 - d. ham and cheese sandwich
- 9. How much cholesterol should you have a day?
 - **a.** 1,200 mg
 - **b.** 750 mg
 - **c.** 500 mg
 - **d.** no more than 300 mg*

- **10.** Which of the following foods contain cholesterol?
 - a. eggs
 - **b.** Swiss cheese**c.** red meat
 - c. red meatd. all of the abo
 - **d.** all of the above*
- 11. How much of your diet should be protein?
 - **a.** less than 10%
 - **b.** 15 to 20%*
 - **c.** 50%
 - **d.** 75%
- **12.** Which of the following foods provides low-fat protein?
 - a. broiled flounder*
 - b. Swiss cheese
 - **c.** carrots
 - **d.** saltines
- **13.** The maximum daily amount of salt (sodium) in your diet should be
 - **a.** less than $3 g^*$
 - **b.** 5 g
 - **c.** 10 g
 - **d.** 12 g
- 14. One serving of alcohol equals
 - **a.** 12 ounces of beer
 - **b.** 2 ounces of wine
 - **c.** 1.5 ounces of scotch
 - **d.** all of the above*
- 15. If alcohol is allowed, you should drink it
 - **a.** on an empty stomach
 - **b.** along with food*
- 16. If alcohol is allowed, which is *not* a good choice?
 - a. dry white wine
 - **b.** sweet liqueur*
 - c. scotch and water
 - **d.** beer
- 17. A "free food"
 - **a.** has no sugar
 - **b.** has fewer than 20 calories*
 - **c.** has no salt
 - d. can be eaten in unlimited quantities
- **18.** Patients with diabetes should never eat in restaurants.
 - a. true
 - **b.** false*
- **19.** Which of the following may help lower blood glucose?
 - a. fat
 - **b.** protein
 - **c.** soluble fiber*
 - **d.** all of the above

- 20. Which food provides soluble fiber?
 - **a.** lentils
 - **b.** oats
 - **c.** fruits
 - **d.** all of the above*
- **21.** Which of the following should *not* be used by patients with diabetes?
 - a. aspartame
 - **b.** honey*
 - c. saccharin
 - **d.** fructose
- **22.** People with diabetes need more vitamins and minerals than do people without diabetes.
 - a. true
 - **b.** false*
- **23.** The number of calories eaten should be
 - **a.** greatest at breakfast
 - **b.** greatest at lunch
 - c. greatest at dinner
 - **d.** evenly distributed among meals*
- **24.** All patients with diabetes follow the same meal plan.
 - a. true
 - **b.** false*
- **25.** "Exchange" refers to foods that
 - a. can be substituted for each other*
 - **b.** must be returned because they contain sugar
 - **c.** can be shared with friends
 - **d.** must be avoided

Exercise

- **1.** Regular exercise
 - a. improves lipid levels
 - **b.** strengthens the heart
 - **c.** gives a sense of well-being
 - **d.** does all of the above*
- 2. Regular exercise may
 - **a.** lower blood glucose
 - **b.** reduce the amount of insulin needed
 - c. reduce the amount of diabetes pills needed
 - **d.** do all of the above*
- **3.** Which exercise is best for patients with "insensitive" feet?
 - a. swimming*
 - b. jogging
 - **c.** running
 - **d.** tap dancing

- **4.** In general, fit patients with diabetes should exercise for
 - **a.** 15 minutes once a week
 - **b.** 1 hour once a week
 - c. 20 to 30 minutes 3 times a week*
 - **d.** 1 hour every day
- 5. Patients who need insulin should inject it into the thigh muscle before running.
 - a. true
 - b. false*
- **6.** If blood glucose is less than 80 mg/dL during exercise, you should
 - a. lie down
 - **b.** eat a snack*
 - c. call your doctor immediately
 - d. ignore it and keep exercising
- 7. If blood glucose is more than 300 mg/dL, insulin should be adjusted or exercise should be delayed.
 - a. true*
 - **b.** false
- **8.** For avoidance of hypoglycemia, the best time to exercise is
 - **a.** any time you are hungry
 - **b.** just before dinner
 - **c.** after meals*
 - d. just before breakfast

Monitoring

- **1.** Low blood glucose can be detected accurately by testing
 - a. urine
 - **b.** blood*
 - **c.** saliva
 - **d.** all of the above
- 2. Self-monitoring of blood glucose is
 - **a.** essential for intensive therapy
 - **b.** the key to determining the right amount of medication
 - **c.** useful even if diabetes is controlled with diet and exercise
 - **d.** all of the above*
- **3.** With intensive therapy, self-monitoring of blood glucose should be done
 - a. only before breakfast
 - **b.** only before lunch
 - c. only before dinner
 - d. several times a day*

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- 4. Monitoring should be done more often
 - a. on sick days
 - **b.** when traveling
 - c. when meal or exercise plans change
 - **d.** at all of the above times*
- 5. Patients with diabetes should undergo assessment by their clinical endocrinologist or another physician
 - **a.** every 3 months*
 - **b.** every year
 - **c.** every 2 years
 - **d.** only after complications develop
- **6.** A glycosylated hemoglobin test measures blood glucose over the past
 - a. hour
 - **b.** day
 - **c.** week
 - **d.** 8 to 12 weeks*
- 7. In people without diabetes, the normal glycosylated hemoglobin value is about
 - **a.** 8 to 10%
 - **b.** 3.8 to 6.0%*
 - **c.** 2.5 to 3.5%
 - **d.** 10.1 to 11.8%
- **8.** During illness, blood glucose should be monitored every
 - **a.** 1/2 hour
 - **b.** 3 to 4 hours*
 - **c.** 6 hours
 - **d.** 12 hours
- 9. To treat mild hypoglycemia, you could
 - **a.** take 3 glucose tablets
 - **b.** eat a few pieces of candy (*not* sugar-free)
 - **c.** eat 2 tablespoons of raisins
 - **d.** do any of the above*
- 10. Nighttime hypoglycemia should be treated with
 - **a.** carbohydrate
 - **b.** protein
 - **c.** fat
 - **d.** first carbohydrate, then carbohydrate plus protein*

Medications

- 1. Diabetes pills
 - **a.** lower blood glucose
 - **b.** increase the release of insulin
 - c. fight insulin resistance
 - **d.** do all of the above*
- **2.** For diabetes pills to work, the body must be able to make some insulin.
 - a. true*
 - b. false

- 3. Sources of insulin used for injections are
 - a. pigs
 - **b.** cows
 - c. synthesis by recombinant DNA
 - **d.** all of the above*
- 4. The insulin you are using should be stored in
 - **a.** the refrigerator
 - **b.** the freezer
 - **c.** the medicine cabinet
 - **d.** a cool, dry place*
- 5. The preferred site for an insulin injection is
 - a. the abdomen*
 - **b.** the hips
 - **c.** the buttocks
 - **d.** all of the above
- 6. Insulin should always be injected in the same site.
 - **a.** true
 - **b.** false*
- 7. When you travel, your medications and supplies should be
 - **a.** checked in your luggage
 - **b.** carried with you*
 - c. left at home
- **8.** During illness, you should stop taking your medications.
 - **a.** true
 - **b.** false*

Type 1 Diabetes: Patient Evaluation

What Is Diabetes?

- **1.** In type 1 diabetes mellitus, the body does not make enough
 - **a.** saliva
 - **b.** insulin*
 - c. glucose
 - d. cholesterol
- 2. Patients with type 1 diabetes
 - a. never need insulin injections
 - **b.** need insulin injections daily*
 - c. may occasionally need insulin injections
- **3.** Insulin is made in the
 - **a.** liver
 - **b.** stomach
 - c. kidneys
 - d. pancreas*
- **4.** Insulin helps the body
 - **a.** turn sugar into energy*
 - **b.** get rid of sugar
 - **c.** store sugar in the blood
 - **d.** make red blood cells

- 5. "Blood glucose" refers to the level of sugar (glucose) in the blood.
 - a. true*
 - **b.** false
- 6. The target range for blood glucose before meals is
 - **a.** 50 to 70 mg/dL
 - **b.** 70 to 120 mg/dL*
 - $\textbf{c.} \quad 125 \text{ to } 160 \text{ mg/dL}$
 - **d.** 160 to 200 mg/dL
- 7. "Hyperglycemia" means
 - a. high blood glucose*
 - **b.** low blood glucose
 - c. high blood pressure
 - **d.** low blood pressure
- **8.** "Hypoglycemia" means
 - **a.** high blood pressure
 - **b.** low blood pressure
 - **c.** high blood glucose
 - **d.** low blood glucose*
- **9.** Which of the following is a symptom of hypo-glycemia?
 - a. weakness
 - **b.** sweating
 - c. shakiness
 - **d.** all of the above*
- 10. The aim of intensive diabetes treatment is
 - **a.** to keep blood glucose as close to normal as possible
 - **b.** to avoid long-term complications
 - **c.** both of the above*
- 11. Complications of diabetes include
 - **a.** kidney disease
 - **b.** eye problems
 - **c.** foot problems
 - **d.** all of the above*
- **12.** Which of the following can affect blood glucose control?
 - a. stress
 - **b.** eating habits
 - c. exercise
 - **d.** all of the above*
- **13.** Patients with diabetes have no control over the development of complications.
 - **a.** true
 - **b.** false*
- 14. "Tight" control of diabetes means
 - **a.** keeping blood glucose as close to normal as possible
 - b. frequent self-monitoring
 - c. reduced complications
 - **d.** all of the above*

- **15.** The most important person on your health-care team is
 - a. you*
 - **b.** the doctor
 - c. the diabetes educator
 - **d.** the dietitian

Nutrition

- **1.** Carbohydrates should make up what percent of your daily calories?
 - **a.** 5 to 10%
 - **b.** 15%
 - **c.** 25%
 - **d.** 55 to 60%*
- 2. A good source of complex carbohydrates is
 - a. eggs
 - **b.** mayonnaise
 - c. whole-grain bread*
 - d. roast beef
- **3.** Fat should constitute what percent of your daily calories?
 - **a.** less than 30%*
 - **b.** 45%
 - **c.** 55 to 60%
 - **d.** 75%
- 4. Which of the following foods is high in fat?
 - **a.** apples
 - **b.** lettuce
 - **c.** cheddar cheese*
 - d. oatmeal
- 5. The fatty substance in food linked to heart disease is
 - a. carbohydrates
 - b. protein
 - c. cholesterol*
 - **d.** fiber
- **6.** Which of the following foods contain cholesterol?
 - a. eggs
 - **b.** Swiss cheese
 - **c.** red meat
 - **d.** all of the above*
- 7. To decrease dietary fat and cholesterol, which food is the best choice?
 - a. steak
 - b. fried eggs
 - **c.** broiled chicken without skin*
 - d. ham and cheese sandwich
- 8. How much of your diet should be protein?
 - **a.** less than 10%
 - **b.** 15 to 20%*
 - **c.** 50%
 - **d.** 75%

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- **9.** Which of the following foods provides low-fat protein?
 - a. broiled flounder*
 - b. Swiss cheese
 - c. carrots
 - **d.** saltines
- **10.** The maximum daily amount of salt (sodium) in your diet should be
 - **a.** less than 3 g*
 - **b.** 5 g
 - **c.** 10 g
 - **d.** 12 g
- **11.** One serving of alcohol equals
 - **a.** 12 ounces of beer
 - **b.** 2 ounces of wine
 - **c.** 1.5 ounces of scotch
 - **d.** all of the above*
- 12. If alcohol is allowed, you should drink it
 - **a.** on an empty stomach
 - **b.** along with food*
- **13.** If alcohol is allowed, which is *not* a good choice?
 - **a.** dry white wine
 - **b.** sweet liqueur*
 - **c.** scotch and water
 - **d.** beer
- **14.** A "free food"
 - **a.** has no sugar
 - **b.** has fewer than 20 calories*
 - c. has no salt
 - d. can be eaten in unlimited quantities
- **15.** Which one of the following should *not* be used by patients with diabetes?
 - a. aspartame
 - **b.** honey*
 - c. saccharin
 - **d.** fructose
- 16. "Exchange" refers to foods that
 - **a.** can be substituted for each other*
 - **b.** must be returned because they contain sugar
 - **c.** can be shared with friends
 - **d.** must be avoided

Exercise

- 1. Regular exercise
 - **a.** improves lipid levels
 - **b.** strengthens the heart
 - **c.** gives a sense of well-being
 - **d.** does all of the above*

- **2.** Which exercise is best for patients with "insensitive" feet?
 - **a.** swimming*
 - **b.** jogging
 - **c.** running
 - **d.** tap dancing
- **3.** In general, fit patients with diabetes should exercise for
 - **a.** 15 minutes once a week
 - **b.** 1 hour once a week
 - c. 20 to 30 minutes 3 times a week*
 - d. 1 hour every day
- **4.** Patients who need insulin should inject it into the thigh muscle before running.
 - a. true
 - **b.** false*
- 5. If blood glucose is less than 80 mg/dL during exercise, you should
 - a. lie down
 - **b.** eat a snack*
 - c. call your doctor immediately
 - d. ignore it and keep exercising
- 6. If blood glucose is more than 300 mg/dL, insulin should be adjusted or exercise should be delayed.
 a. true*
 - **b.** false
- **7.** For avoidance of hypoglycemia, the best time to exercise is
 - a. any time you are hungry
 - **b.** just before dinner
 - **c.** after meals*
 - d. just before breakfast

Monitoring

- **1.** Low blood glucose can be detected accurately by testing
 - a. urine
 - **b.** blood*
 - **c.** saliva
 - **d.** all of the above
- 2. Self-monitoring of blood glucose is
 - **a.** essential for intensive therapy
 - **b.** the key to determining the right amount of medication
 - c. important to see the effect of food intake
 - **d.** all of the above*
- **3.** With intensive therapy, self-monitoring of blood glucose should be done
 - **a.** only before breakfast
 - **b.** only before lunch
 - **c.** only before dinner
 - d. several times a day*

- 4. Monitoring should be done more often
 - **a.** on sick days
 - **b.** when traveling
 - c. when meal or exercise plans change
 - **d.** at all of the above times*
- 5. If your blood glucose is more than 240 mg/dL and your urine contains large ketones, you should
 - **a.** take a nap
 - **b.** take extra insulin, then call your doctor*
 - **c.** eat a large meal
 - **d.** exercise
- 6. Ketoacidosis may be caused by
 - **a.** very high blood glucose
 - **b.** very little insulin*
 - **c.** too much insulin
 - **d.** too much food
- 7. Patients with diabetes should undergo assessment by their clinical endocrinologist or another physician
 - a. every 2 years
 - **b.** every 5 years
 - c. every 3 months*
 - d. only after complications develop
- **8.** A glycosylated hemoglobin test measures blood glucose over the past
 - a. hour
 - **b.** day
 - c. week
 - **d.** 8 to 12 weeks*
- **9.** In people without diabetes, the normal glycosylated hemoglobin value is about
 - **a.** 8 to 10%
 - **b.** 3.8 to 6.0%*
 - **c.** 2.5 to 3.5%
 - **d.** 10.1 to 11.8%
- **10.** During illness, blood glucose should be monitored every
 - **a.** 1/2 hour
 - **b.** 3 to 4 hours*
 - **c.** 6 hours
 - **d.** 12 hours

- 11. To treat mild hypoglycemia, you could
 - **a.** take 3 glucose tablets
 - **b.** eat a few pieces of candy (*not* sugar-free)
 - **c.** eat 2 tablespoons of raisins
 - **d.** do any of the above*
- 12. Nighttime hypoglycemia should be treated with
 - a. carbohydrate
 - **b.** protein
 - **c.** fat
 - **d.** first carbohydrate, then carbohydrate plus protein*

Medications

- 1. Sources of insulin used for injections are
 - a. pigs
 - **b.** cows
 - c. synthesis by recombinant DNA
 - **d.** all of the above*
- 2. The insulin you are using should be stored in
 - **a.** the refrigerator
 - **b.** the freezer
 - **c.** the medicine cabinet
 - d. a cool, dry place*
- 3. The best site for an insulin injection is
 - a. the abdomen*
 - **b.** the hips
 - **c.** the buttocks
 - **d.** all of the above
- 4. Insulin should always be injected in the same site.
 - a. true
 - **b.** false*
- 5. When you travel, your medications and supplies should be
 - a. checked in your luggage
 - **b.** carried with you*
 - **c.** left at home
- **6.** During illness, you should stop taking your medications.
 - a. true
 - **b.** false*

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Sample Patient-Physician Contract

I understand that if I agree to participate in the System of Intensive Diabetes Self-Management, I will be expected to do the following:

- 1. Dedicate myself to getting my blood glucose level as close to normal as possible by following the instructions of the diabetes self-management team
- 2. Regularly visit the clinic for a physical examination, laboratory tests, and nutrition counseling; follow-up visits will be scheduled every 3 months or more frequently if deemed necessary by my physician or other members of my health-care team
- 3. Bring a detailed 1-day food record to each follow-up visit, provide necessary nutrition information for me and my dietitian, and adjust my eating habits to meet the nutrition goals established by my dietitian
- 4. Use medications as prescribed by my health-care team
- 5. Monitor my blood glucose levels at home as instructed and bring the results to each follow-up visit
- 6. Follow my prescribed exercise plan
- 7. Obtain identification as a patient with diabetes, for prompt assistance in case of an emergency
- 8. Ask my physician and other members of my health-care team to explain any aspect of my care that I do not entirely understand

I understand that if I do not monitor myself carefully, there is a risk of hypoglycemia.

I also understand that if I do not strive to normalize my blood glucose, I am at increased risk of developing the complications of diabetes mellitus.

My signature indicates that I have read and understand the above agreement.

Patient

Date

I agree to provide the leadership for the diabetes self-management team. Team members will be available to answer your questions and help you self-manage your diabetes. I will continue to encourage you to maintain the best possible control of your diabetes.

Physician

Date

Thase 1: Initial Assessment		Multiple visits over 5-4 weeks
Goals	Diagnostic tools	Action steps
Assess patient's disease	Complex history	Develop recommendations for
status and risk factors	 Medical (including chief complaint, 	•Nutrition
	duration of known disease)	•Exercise
	•Family, personal	•Medication
	•Gestational	 Blood glucose self-monitoring
	•Weight, nutrition	 Record keeping
	•Exercise	
	•Treatment	Schedule appropriate modular
	•Symptoms of complications	evaluation and referrals for
	•Risk factors	complications or risk factor modification
	Complex physical examination to be	
	done by clinical endocrinologist or	
	other physician	
	•Height, weight	
	•Blood pressure (including orthostatic)	
	•Ophthalmoscopy	
	 Thyroid palpation 	
	•Cardiac assessment	
	•Pulses	
	•Feet	
	•Skin	
	•Neurologic system	
	Complex laboratory tests to be done	
	and evaluated by clinical	
	endocrinologist or other physician	
	•Fasting or random plasma glucose	
	•Glycosylated hemoglobin	
	•Fasting lipid profile	
	•Serum electrolytes	
	•Serum creatinine	
	•Urinalysis	
	•Thyrotropin	
	•Microalbuminuria	
	•Creatinine clearance	
	•Electrocardiography, stress test	

Phase I: Initial Assessment

Schedule: Multiple visits over 3-4 weeks

Goals	Diagnostic tools	Action steps
Assess patient's knowledge base and motivation to learn	Objective tests •Diabetes Assessment and	Initiate discussion of diabetes self- management topics
	Teaching Record	management topies
Initiate appropriate level of	•AACE Knowledge Evaluation	Refer to
diabetes education	Forms	•Diabetes educator (1-2 hours ASAP •Dietitian (1-2 hours ASAP)
	Psychologic tests	•Exercise physiologist, if necessary
	•Michigan Diabetes Research and Training Center Diabetes Care Profile	•Psychologist, if necessary
	•Millon Behavioral Health Inventory	
	Support systems evaluation	
	•Family	
	•Financial	
	•Employment	
Obtain patient agreement	Patient-physician contract	Explain
to intensive diabetes		•Pathophysiologic features of diabete
treatment and initiate		•Rationale for intensive treatment •Patient role in diabetes self-
diabetes self-management		management
		Provide instructions regarding
		•Blood glucose self-monitoring
		 Medication (including dosage- adjustment algorithms)
		•Nutrition
		•Exercise
		•Complications
		•Special situations
		•Preventive care
		•Psychologic aspects
		Review schedule of follow-up
		communications (telephone, office
		visits) among patient, clinical
		endocrinologist, and health-care
		team

Phase I: Initial Assessment (continued)

Phase II: Follow-Up Assessme	ents (in	(in combination with complications modules)			
Goals	Diagnostic tools	Action steps			
Evaluate blood glucose control	Interim history	Revise recommendations for			
and disease complications	•Acute problems	•Nutrition			
	•Chronic problems	•Exercise			
	HypoglycemiaNew symptoms suggestive	 Medication (including dosage- adjustment algorithms) 			
	of complications	•Blood glucose self-monitoring			
	•Change in risk factors	•Follow-up communications between patient and health-care team			
	Laboratory tests				
	•Random plasma glucose	Make any necessary			
	 Glycosylated hemoglobin 	adjustments to scheduling of			
	•Lipids, if necessary	complications modules			
	Results of blood glucose	(see Phase III)			
	self-monitoring				
	Physical examination				
	•Height, weight				
	•Blood pressure (including orthostatic)				
	•Ophthalmoscopy				
	•Thyroid palpation				
	•Cardiac assessment				
	•Pulses				
	•Feet				
	•Skin				
	•Neurologic system				
6-month visit					
Evaluate patient's understanding	Objective tests	Initiate intensive education in areas			
of diabetes mellitus and rationale for self-management	Psychologic tests	of deficiency, if necessary			
	Support systems reevaluation	Refer (as needed) to			
		•Diabetes educator			
Assess patient's self-		•Dietitian			
management skills		•Exercise physiologist			
		 Psychologist 			

Schedule: 3-month intervals

Schedule: Each module to be performed annually Initiate at 9-month visit

	•				
Goals	Diagnostic tools	Action steps			
Retinal module	Module-specific follow-up assessment, including ophthalmoscopy	Educate patient about retinal complications			
	Test of visual acuity (Snellen chart)	Determine frequency of follow- up—on the basis of presence or absence of complications			
	Funduscopic examination and photographs (if indicated)	Refer to ophthalmologist—on the basis of age, duration of disease, and findings on current examination			
	Intraocular pressure test				
Cardiac-cerebrovascular- peripheral vascular module	Module-specific follow-up assessment, including pulses, orthostatic hypotension, and	Educate patient about vascular complications			
	cardiac risk factors Electrocardiography and rhythm	Determine frequency of follow-up—or the basis of presence or absence of complications and cardiac risk factor			
	strip (R-R variation)—on the basis of age and symptoms	Consider more intensive cardiac testing (such as stress test) or referra			
	Lipid profile (cholesterol, triglycerides, high-density and low-density lipoproteins)	to cardiologist—on the basis of findings on current examination			
Renal module	Module-specific follow-up assessment	Educate patient about renal complications			
	Laboratory tests •24-hour microalbuminuria •Creatinine clearance •Serum chemistry analysis	Determine frequency of follow-up—or the basis of presence or absence of complications			
	y	Refer to dietitian for instructions on modifications of protein intake, if needed			
Neuropathy module	Module-specific follow-up assessment, including thorough foot examination	Educate patient about neuropathologic complications			
	Review of symptoms relevant to peripheral nerve and autonomic dysfunction	Determine frequency of follow-up—or the basis of presence or absence of complications			
		Refer to neurologist, if needed			
	Module-specific testing •Vibratory sensation •Soft-touch				

Phase III: Assessment of Complications