PREVENTING DIABETES-RELATED MORBIDITY AND MORTALITY IN THE PRIMARY CARE SETTING*

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Diabetes is the leading cause of blindness, end-stage renal failure, non-traumatic limb amputations, and cardiovascular morbidity and mortality. The vast majority of patients with diabetes receive routine care from primary care providers who are not endocrinologists. Primary care providers, including internists, family practice physicians, and physician extenders with advanced skills, face the important task of implementing standards of care recommendations for persons with diabetes. These recommendations draw upon an emerging body of compelling evidence regarding the prevention and management diabetes and its complications. The challenge of diabetes must be tackled on three fronts: Primary prevention, secondary prevention (of diabetes complications), and tertiary prevention (of morbidity and mortality from established complications). There is now abundant evidence that type 2 diabetes, which accounts for greater than 90% of diabetes world-wide, is preventable. Moreover, the complications of diabetes are preventable by a policy of tight glycemic control and comprehensive risk reduction. Even after complications have set in, intensive glucose control dramatically reduces the risk of progression of complications. The challenge, therefore, is the identification of strategies that enable translation of existing scientific data to pragmatic benefits. This article proposes 10 strategies for preventing or reducing diabetes-related morbidity and mortality at the primary care level. These strategies include provider education; patient empowerment through promotion of lifestyle and self-care practices; surveillance for microvascular complications; cardiovascular risk reduction; efficient use of medications; goal setting; and stratification of patients and triaging of those with poor glycemic control for more intensive management. (*J Natl Med Assoc.* 2002;94: 549–560.)

INTRODUCTION

Diabetes mellitus, which currently affects more than 16 million Americans, continues to be a major clinical challenge, both in terms of the undiagnosed disease burden and the obstacles to optimal glycemic control.[1–3] Diabetes is a public health problem, accounting for the majority of patients with adult-onset blindness, end-stage renal failure, and non-traumatic limb amputations. Furthermore, diabetes is the leading underlying cause of coronary heart disease, stroke and pe-

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Dr. Dagogo-Jack is supported in part by NIH Clinical Research Center Grant MO1 RR00211

*Presented in part at the Southern Medical Association 95th Scientific Assembly, Nashville, TN, November 8-10, 2001

ripheral vascular disease.[2–5] In fact, a diabetic patient without a prior history of myocardial infarction has a greater risk of suffering a heart attack than a nondiabetic subject with a prior myocardial infarction.[6]

Both the incidence and prevalence of diabetes are increasing worldwide. In the United States, there was a 33% increase in the prevalence of diabetes between 1990 and 1998.[7] Besides the human toll, the economic burden of diabetes is staggering. The total annual health care costs attributable to diabetes in the U.S. is in excess of $105 billion.[8,9] The increasing prevalence of diabetes is particularly marked in the southeastern region of the U.S., which appears to be the epicenter of the diabetes epidemic.[7] For instance, in the author's state of residence, Tennessee, approximately 206,042 adults (5.1% of the population) had a diagnosis of diabetes in 1997, and an additional 1,750, 245 persons were at risk for development of diabetes because of demographic and other predisposing factors.[10–12] Statewide health statistics analyzed in 1997 indicated a considerable burden of diabetes-related complications in Tennessee: There were 74,616 diabetes-related hospitalizations (including 23,583 admissions for cardiovascular disease), 315 new cases of blindness, 654 new cases of end-stage renal failure, and 1,441 lower extremity amputations. Furthermore, diabetes contributed to 4,054 deaths and accounted for a total health care expenditure of 2.7 billion in the state of Tennessee.[10–12] Remarkably, one year later, the 1998 data from the Centers for Disease Control showed that the prevalence of diabetes in Tennessee had risen to 6.6%, making Tennessee the 9th leading state in the hierarchy of diabetes prevalence (8). These disturbing trends in diabetes-related statistics are representative of the picture across the entire United States.[2,4–9,12]

There is a direct relationship between the degree of poor diabetic control and the development of long-term complications and the resultant prohibitive rise in health care costs. Nationally, the *per capita* health care cost in patients with diabetes is considerably higher than that incurred by patients without diabetes. In specific terms, the differences can be staggering. For example, the annual *per capita* cost of health care in Tennessee in 1997 was $13,000 for persons with diabetes compared with $2,700 for persons without diabetes.[12] Nationally, the quality of diabetes care is deemed to be very poor (hemoglobin {Hb}A1c >9%) in ~25% of patients, poor (HbA1c 8–9%) in ~15%, and suboptimal (HbA1c 7–8%) in ~20% of the remainder.[13] Thus, only about 40% of patients are in good metabolic control. The patients with the poorest state of glycemic control,~25% of the diabetes population, generate exponentially greater health care costs than those with better control.[14] Unquestionably, these poorly controlled patients present an opportunity for the application of focused, innovative, cost-containment strategies that are mediated through optimization of glycemic control and reduction of diabetes complications.

FOCUS ON ETHNIC MINORITIES

Measures of health care delivery, health care outcomes, and vital statistics indicate an emerging, if not fully established, health care crisis in urban America.[15] Urban America is inhabited by a disproportionate number of ethnic minorities as well as economically disadvantaged citizens from all ethnic and racial groups. From the 2000 census figures, ethnic minorities constitute approximately 25% of the overall U.S. population. The population of these minority groups has been increasing at a faster rate than the national average.

There are many reasons why special attention ought to be focused on ethnic minority populations in relation to diabetes. First, these populations suffer disproportionately from type 2 diabetes: Compared with caucasians, the prevalence of type 2 diabetes is 2–10 times higher in African Americans, Hispanic Americans, Asian Americans, and Native Americans.[16] In fact, type 2 diabetes is being diagnosed at alarming rates among ethnic minority subjects, including children and adolescents.[17,18]

Table 1. Schedule of surveillance for diabetic complications

Complications	Method	Frequency	Goal
Hyperglycemia	Hemoglobin A1c	2–4/yr	<7%
Retinopathy	Dilated funduscopy	Yearly	Normal retina
Nephropathy	Microalbuminuria*	Yearly	<30 mg/g creatinine
Neuropathy	Light touch sensation (Monofilament)	Every visit	Intact sensation
Hypertension	Sphygmomanometry	Every visit	<130/80mmHg
Dyslipidemia	Fasting lipid profile	Yearly	Normal lipids
Heart disease	Electrocardiogram**	Yearly	No ischemic changes
Diabetic foot	Clinical examination	Every visit	No ulceration

*24-hour urine (normal < 300 mg microalbumin per day) or spot urine (microalbumin:creatinine ratio).
**Stress cardiac testing is warranted in symptomatic patients and those with additional risk factors.

Second, virtually all of the long-term complications of diabetes, including premature death,[19] occur several-fold more frequently among minorities compared with non-Hispanic whites. Acute diabetic complications occur with varying frequencies in the different ethnic groups, but there are suggestions that the rate of hospitalization for diabetic ketoacidosis and nonketotic coma may be higher among certain minority groups, such as African Americans.[20]

Third, there are indications of disparities in access to care and quality of metabolic control among diabetic patients, as a function of their demographic and socioeconomic characteristics.[21,22] Finally, the demography of the southern states, the epicenter of the diabetes epidemic, is consistent with under-served patients from the African American and other minority populations bearing the brunt of the disease.[7,17,18]

STANDARDS OF CARE GUIDELINES

There is now compelling evidence that intensive treatment to control blood glucose levels in patients with type 1 and type 2 diabetes can dramatically reduce the risk of development of diabetes-related complications.[23–25] Concurrent management of co-morbid conditions (e.g., dyslipidemia, hypertension) reduces morbidity and mortality in patients with diabetes.[26,27] The Diabetes Control and Complications Trial (DCCT)[23] and the Kumamoto study[24] showed a nearly 60%–80% reduction of the risks for microvascular complications (retinopathy, neuropathy, nephropathy) in patients whose HbA1c was maintained at ~7%. The DCCT[23] and the United Kingdom Prospective Diabetes Study (UKPDS)[25] found that every 1% absolute decrease in HbA1c yields 35% – 45% reduction in the risk of development or progression of microvascular complications.

In the UKPDS, a 0.9% reduction in median HbA1c (7% in intensive group vs. 7.9% in controls) resulted in 74% reduction in the risk of doubling of serum creatinine levels (among other benefits), which could considerably delay the progression to end-stage renal failure. Furthermore, blood pressure control to 144/82 mmHg (vs. 154/87 mmHg in the comparison group) reduced the risks of development of any diabetes-related endpoint by 24%, diabetes-related death (32%), stroke (44%), microvascular complications (37%), and heart failure (56%).[26]

Based on these compelling data, the American Diabetes Association has reiterated existing guidelines that the goal of diabetes management should be the attainment and maintenance of an HbA1c level of <7%[28] numerous other tasks are called for in these guidelines (Table 1), including monitoring of HbA1c; methods and frequency of surveillance for renal, retinal, neuropathic, cardiac, and circulatory complications of diabetes; optimal blood pressure control; implementation of self-man-

agement and lifestyle recommendations, among others. The HbA1c goal of <7% is a minimal target, because updated data from the UKPDS indicate that the adjusted incidence of myocardial infarction decreased from ~25/1000 person-years to ~15/1000 person-years when HbA1c was lowered further from 7% to 6%.[29] In the same cohort, the incidence of microvascular complications decreased from 10/1000 to 5/1000 person-years with further reduction of HbA1c from 7% to 6%.[29]

Thus, the preferred policy of diabetes management is maintenance of blood glucose as close to the normal range as possible without intolerable hypoglycemia. The reason so many diabetic patients are poorly controlled can be attributed, at least in part, to the fact that diabetes care involves a series of specialized tasks that are difficult to implement satisfactorily in the generalist setting. Ironically, the states with the highest prevalence rates of diabetes also have the lowest quality indicators of diabetes care, such as HbA1c test ordering, annual eye examinations, and screening for dyslipidemia.[30]

INCREASING COMPLEXITY OF DIABETES PRACTICE

In keeping with enhanced awareness of the need to reduce the burden of diabetes and its complications, the pharmaceutical industry has been introducing new agents for the management of diabetes at an escalating rate since the mid-1990's. As a result, there are now different types of natural and recombinant human insulins with varying pharmacokinetic profiles, administered by traditional methods or via insulin pens, jet injectors, or pumps. The natural forms of insulin, which are extracted and purified from animal pancreata, are no longer available in the United States but are still in use in other countries. The complexity in the field of insulin delivery will escalate after ongoing clinical trials of nasal, oral and other novel forms of insulin, designed to bypass the traditional subcutaneous route, are completed in the near future.

With regard to oral antidiabetic agents (Table 2), there are now six chemically distinct classes (compared with only one or two up to a few years ago), and several others are under development. Each class has its unique properties conferred by chemical structure, mechanism of action, efficacy, adverse effect profile, and other pharmacokinetic and pharmacodynamic properties. As many as seven individual members may be found within a single oral antidiabetic drug class; oftentimes individual drugs within the same class may have unique dosing and toxicological considerations . In addition to developments in pharmacotherapy, numerous medical devices are being introduced to the diabetes care market at a brisk rate. Currently, more than 20 different brands of meters are on the market for home blood glucose monitoring: A new, bloodless device for transcutaneous monitoring of glucose levels is at an advanced stage of development and deployment. Increasingly, insulin-requiring diabetes patients are being treated with alternative delivery devices, such as insulin pens, pumps, and jet-injectors, as opposed to the traditional needles and syringes.

Current limitations

Because of a variety of reasons (including shortage of endocrinologists), most diabetic patients receive routine care from primary care providers. These primary care providers, including internists, family practice physicians, and physician extenders with advanced skills, are constrained to fit diabetes into a generalist practice that includes patients with a broad array of medical conditions, all competing for priority attention. Yet, today's internists and family physicians are expected to demonstrate fairly specialized skills and competencies across a more demanding spectrum of diabetes care tasks than was the case only a few years ago. Clearly, the burden of diabetes and the range of clinical tasks mandated by the existing standards of care recommendations constitute a

Table 2. Oral antidiabetic agents

Drug Classes	Mechanism of Action	HbA1c Fire Power*	Unique Features
Sulfonylureas		1–2%	Many generic forms; Relatively inexpensive
First generation	Insulin secretion		
Tolbutamide			
Acetohexamide			
Tolazamide			
Chlorpropamide			
Second generation	Insulin secretion		
Glyburide			
Glipizide			
Glimepiride			
Meglitinide		1–2%	
Repaglinide	Insulin secretion		Targets postprandial hyperglycemia
Amino acid derivative		~1%	
Nateglinide	Insulin secretion		Targets postprandial hyperglycemia
Biguanide		1–2%	
Metformin	Hepatic glucose output		No weight gain
Alpha-glucosidase inhibitors	Carbohydrate absorption	~0.5%	Target postprandial hyperglycemia
Acarbose			
Miglitol			
Thiazolidinediones	Insulin sensitivity	1–2%	Ancillary benefits on Syndrome X
Rosiglitazone			
Pioglitazone			

*"Fire power" refers to the expected decrease in HbA1c in full-dose monotherapy. Values are approximate and vary according to individual patient characteristics, clinical trial design, and other factors.

major clinical challenge in primary care. Indeed, surveys indicate inadequate compliance with such recommendations in primary care practice settings.[31,32]

ROLE OF PRIMARY CARE PHYSICIANS

The challenge of diabetes must be tackled on three fronts: Primary prevention, secondary prevention (of diabetes complications), and tertiary prevention (of morbidity and mortality from established complications). Primary prevention of type 2 diabetes can be accomplished in high-risk individuals with impaired glucose tolerance through lifestyle modification. Modest reduction (500–700 kcal/day) in caloric consumption together with regular physical activity (e.g., walking for 30 minutes five times per week) exerts a remarkably potent prophylactic effect against development of type 2 diabetes.[33,34] Primary care physicians should vigorously promote these primary preventive measures among relatives of their patients with diabetes. Once diabetes has developed, however, the priority shifts to secondary prevention, namely, avoidance of microvascular and macrovascular diabetic complications. The best prophylaxis against microvascular complications is tight glycemic control [23–25]. The best prophylaxis against macrovascular complications is a policy of comprehensive risk reduction (glycemic, lipid, blood pressure, smoking cessation, etc). Even after myocardial infarction has occurred, careful attention to blood glucose control reduces acute and chronic post-infarct mortality.[35]What is needed, therefore, is a more efficient model of integrated diabetes care delivery that achieves outstanding glycemic control, maintains updated fund of knowledge for providers, motivates self-management behaviors in patients, utilizes specialist referrals efficiently, and prevents morbidity and mortality from complications of diabetes.

The following are some suggestions toward attainment of these protean goals.

1. **Diabetes updates:** The primary care physician now, more than ever before, needs frequent updates of diabetes-specific knowledge base. Attendance at national or regional conferences is an effective mechanism for continuing education. Numerous dinner programs, sponsored by industry, are also available, to supplement learning opportunities. Although these latter programs are conceptually "promotional," they often provide quality diabetes education by outstanding experts in the field. Other avenues for updating fund of knowledge include journal subscription, affiliation with diabetes faculty, and involvement in continuing medical education programs at local tertiary care institutions. Clearly, there is need for innovative thinking in the design of training mechanisms in this area. One idea involves development of "mini-fellowships" that enable the generalist to perform at advanced levels in selected disease states (e.g., diabetes, dyslipidemia, hypertension) after completion of a series of brief, in-depth supervised experiences.
2. **HbA1c**: The testing frequency for HbA1c is suboptimal, nationally.[30] As the "gold standard" measure of diabetes control that has been linked to outcome, there is no excuse for not ordering the HbA1c test at the recommended frequency. The recommended testing frequency is 1− 4 times/year, depending on state of glycemic control. The minimal goal for prevention of long-term complications is <7%. From the updated UKPDS data, significant additional microvascular and macrovascular benefits accrued when HbA1c was lowered from 7% to 6%.[29] It is therefore of utmost priority for patients and their physicians to develop an interest in setting and reaching HbA1c targets. Patients need to be told that, since blood glucose levels fluctuate markedly in any given day, and from day to day, a convenient way of assessing average blood glucose over periods of 2–3 months is by measuring the HbA1c. Patients unable to grasp the full name of this test can be encouraged to remember it merely as the "A1c test." Every diabetic patient needs to know that keeping the HbA1c level below 7% (i.e, close to the upper normal range of 6%) is the best insurance against development of long-term complications. Finally, the good news from the DCCT data that every 1% absolute decrease in HbA1c level (e.g. from 9% to 8%) translates to a 45% reduction in the risk of retinopathy and other microvascular complications must be shared at every opportunity, as a motivational tool for patients with diabetes.
3. **Diabetes Education and Nutrition:** The core message to get across to patients is that control of blood sugar matters. A patient with average blood glucose levels of 200–250 mg/dl will have at least two-fold greater risk of developing retinopathy, neuropathy, and nephropathy than a patient with average glucose levels of 150–160 mg/dl, over the course of several years. cEffective internalization of this cardinal message requires that patients understand the identity and significance of the HbA1c test (as already elaborated in the preceding passage), and appreciate the role of self-monitoring of blood glucose (discussed later) as a valuable tool for optimization of care. These and other pertinent self-management tasks in diabetes education can be accomplished through referral to a certified diabetes educator. However, the primary care physician must remain engaged and must periodically monitor the efficacy of these referrals by assessing the patient's grasp of the aforementioned key concepts. Caloric restriction, avoidance of over-eating, and adoption of wholesome eating habits are other aspect of diabetes education that require emphasis and periodic reinforcement (through dietitian referrals).
4. **Lifestyle intervention**: Advice on diet and

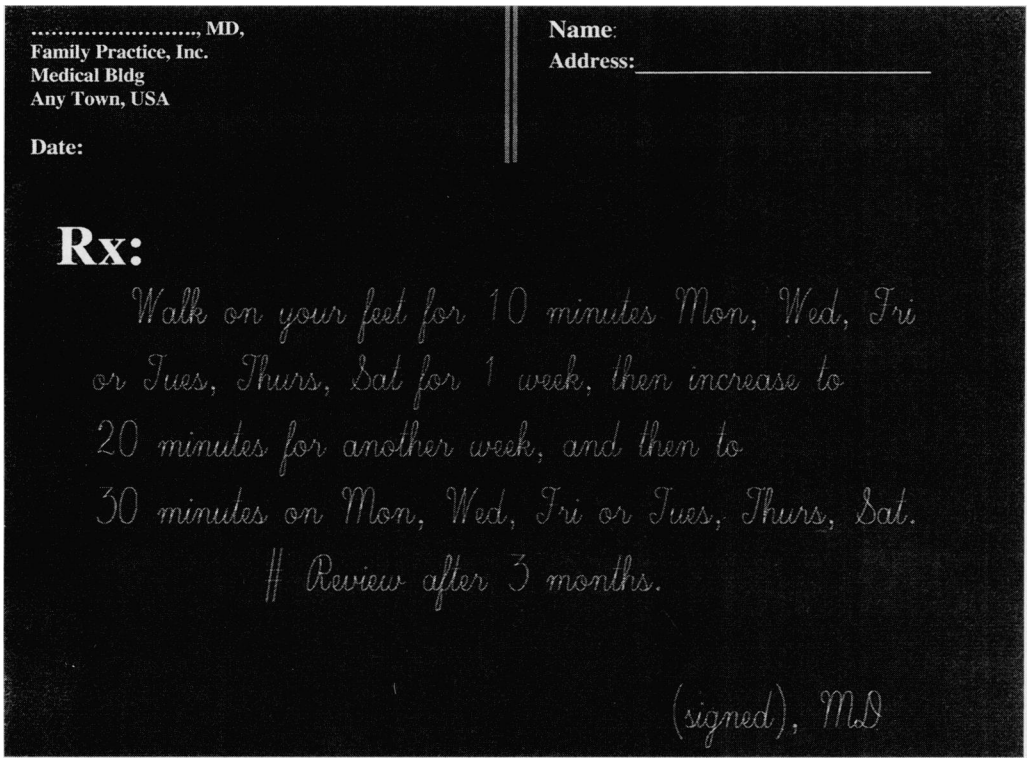

Figure 1. Sample prescription for exercise. An exercise prescription should be specific, gradually upgradable, and based on a clearly defined rationale. In previously sedentary patients, it may be prudent to progress more gradually, say, weekly increments of five minutes.

exercise should be delivered with the same conviction that accompanies prescription medicine. Referral to a dietitian often demonstrates such seriousness of purpose. Until Clinical Exercise Physiologists become routinely available, primary care physicians should undertake to actually issue written prescriptions for exercise. A good exercise prescription (Fig. 1) should have three elements: 1) a clear rationale – this can be established by briefly discussing the metabolic benefits of moderate exercise; 2) specificity – "walk for 10 min every Monday, Wednesday, Friday" is a better script than "exercise regularly", and 3) scalability – the exercise prescription should gradually be scaled up: For example, "Increase walks to 20 min on Monday, Wednesday, Friday after one week". A clear plan should be established for evaluation of adherence and efficacy of the program. Alternative modes of increasing physical activity should be considered if adherence and efficacy are suboptimal. A small investment in inexpensive home exercise equipment (e.g., stationary bike) may be necessary, if outdoor opportunities for exercise are limited or precarious. Of course, noninvasive cardiac screening before exercise is always prudent in patients who have not been physically active.

5. **Self-monitoring** : Self-monitoring of blood glucose (SMBG) predicts adherence to other medical recommendations and is associated with superior glycemic control. Patients who do not perform SMBG tend also to ignore other aspects of self-management. Thus, successful initiation of SMBG in any patient is a step toward better glycemic control. The standard recommendation for patients with type1diabetes is to perform self-testing of blood glucose three

to four times daily. The optimal frequency of self-testing for type 2 diabetes patients has not been determined, and can be negotiated with patients. Primary care physicians should encourage patients to perform and record SMBG results, and should review the home record with interest during office visits. It is especially important that patients be made to realize that the numbers are actually used to make changes in the treatment plan.

6. **Efficient use of medications:** The rational approach to type 1 diabetes is an optimized insulin replacement regimen that includes basal and bolus elements. Because of the pathophysiology of type 2 diabetes (combined insulin resistance, beta-cell insulin secretory defect, and excessive hepatic glucose production) and its progressive nature, achievement of optimal glycemic control often requires the use of more than one agent. As much as possible, drug combinations should be selected for their therapeutic "fire power," complementary mechanisms of action, ancillary benefits (especially on cardiovascular risk factors), safety, and tolerability (Table 2). Triple therapy with oral antidiabetic agents (e.g, sulfonylurea + biguanide + thiazolidinedione) is effective and may be an option in selected patients. Thus various combinations of the available oral agents are now conceivable, which should ensure adequate glycemic control in virtually every type 2 diabetes patient. Combination therapy will be most effective if initiated as part of a comprehensive diabetes care plan that includes lifestyle interventions. The decision to continue a combination regimen should be based on evidence of continuing efficacy, safety, and tolerability. There should be no reservation in adding insulin to the regimen, if glycemic control on oral agents remains suboptimal. Insulin can be started as bedtime NPH or glargine at a low initial dose (~10 units) and increased by 2–4 units every few days (while continuing oral agents) until a fasting blood glucose level of 130 mg/dl is achieved.[3] Once that target is achieved, a more stringent goal for fasting blood glucose (e.g., 110 mg/dl) can be pursued. Eventually, many patients will require multiple injections of short- and longer-acting insulin preparations for optimal control. Large daily doses of insulin (100 U/day) usually are required to maintain optimal glycemic control in patients with type 2 diabetes.
7. **Goal setting**: Goals are the therapeutic road maps that direct and concentrate all efforts. Without a clearly defined goal, the doctor and patient "are lost at sea." Achievable goals should be set, and strategies and tactics marshaled toward attainment of those goals. A typical goal in a patient with initial HbA1c of 11% could be to reduce that number by 1% by the time of follow-up visit in 2 months. The applicable strategies include review of current medication and adherence to lifestyle recommendations. The specific tactics include maximizing current drug doses, substitution or addition of an agent working by a differrent mechanism, formal referral to dietitian for reinforcement, and reinforcement of physical activity plan, including a written prescription for exercise (Fig. 1).
8. **Cardiovascular risk factors**: A comprehensive approach to modification of cardiovascular risk factors is mandatory. Targets include smoking cessation, lipids (LDL-cholesterol goal in diabetes is <100 mg/dl), blood pressure (goal <130/80), asprin prophylaxis, etc. Macrovascular disease accounts for the majority of deaths in diabetes. Coronary artery disease and myocardial infarction present in atypical ways in diabetes, so symptoms are unreliable. A high index of suspicion and a low threshold for ordering stress cardiac testing is appropriate in diabetes patients. Intensive glucose control in patients with acute myocardial infarction has been demonstrated to reduce short-term and long-term mortality in

diabetic patients.[35] Thus, intensification of glycemic control in the peri-infarct period and beyond should be standard practice in diabetic patients with acute myocardial infarction.

9. **Surveillance for microvascular complications (see Table 1):** The microvascular complications (retinopathy, nephropathy, and neuropathy) develop after several years of uncontrolled diabetes. The usually gradual time course of these complications affords an opportunity for early detection and tertiary prevention (i.e., prevention of morbidity and mortality from progression of diabetic complications).
   a. **Preemptive strike at kidney disease.** Both microalbuminuria, the earliest (and reversible) stage of kidney disease, and gross proteinuria precede end-stage renal failure by variable but lengthy intervals. The limited availability of organs for transplantation means that thousands of patients spend several years on dialysis without a chance of receiving kidney transplants. Thus the emphasis should be on prevention of kidney disease, since cure cannot be offered to all affected persons. The initial observation that microalbuminuria precedes more advanced stages of kidney disease by several years is important information. This knowledge creates a window of opportunity to intervene and prevent further decline in renal function. The decline in kidney function can be slowed down considerably if blood pressure is controlled (130/80 or lower) in persons who have both diabetes and hypertension. It has now been established that angiotensin converting enzyme (ACE) inhibitors[36] and angiotensin receptor blockers (ARB)[37,38] are effective in preserving renal function in diabetes patients with microalbuminuria and with more advanced forms of nephropathy. ACE inhibitors are well tolerated by normotensive patients. Thus the approach to diabetic kidney disease should focus on prevention. Persons who have had type 1 diabetes for 5 years or longer and all persons with type 2 diabetes are screened annually for microalbuminuria. The screening test consists of either a timed urine collection or a random spot urine for measurement of microalbumin-to-creatinine ratio. In patients with microalbuminuria treated with ACE inhibitors, follow-up urine test should be obtained and the dose of ACE inhibitor adjusted for maximum nephroprotective effect.
   b. **Zero tolerance for amputations:** Diabetes accounts for 50% of cases of non traumatic lower extremity amputations in the U.S. There should be zero tolerance for limb loss in modern diabetes practice. The risk factors for lower extremity amputation in persons with diabetes include peripheral neuropathy, peripheral vascular disease, deformities, trauma and deep tissue infections. With the possible exception of trauma, most of these risk factors are impacted by the state of metabolic control. Poor control of blood glucose is associated with increased risk of infections, impaired wound healing, and development of long-term diabetic complications, such as neuropathy and peripheral vascular disease. Additional risk factors for peripheral vascular disease include hypertension, cigarette smoking and elevated blood cholesterol levels. Strategies for limb preservation include: 1) tight control of blood glucose (and of blood pressure), 2) smoking cessation (patients should be given every assistance, including special counseling and prescription for bupriopion), 3) daily foot inspection by patients, 4) appropriate foot wear, and 5) regular physical examinations by physician, including an assessment of arterial pulses and skin sensation (using a 5.07/10 gm monofilament). Referral for

Table 3. Strengths of the Clinical Trials Model

1. Common Protocol and Manual of Operations
2. Goal setting/Incentives
3. Frequent contacts with patients
4. Close monitoring of endpoints
5. Team approach among multi-professionals
6. Shared responsibility with enrolled patients
7. Accountability to higher authority
8. Case manager and patients feel peer pressure to excel
9. Willingness of staff to go beyond the call of duty

routine podiatric evaluation before the development of limb threatening lesions has been demonstrated to reduce amputation rates. Clinics can obtain the popular *"Feet Can Last A Lifetime"* kit from the NIH by calling 1-800-GET-LEVEL.

10. **Practice-Within-a-Practice :** The primary care physician's role in preventing morbidity and mortality from diabetes requires a paradigm shift from the existing clinical traditions. Diabetes care needs to be isolated as a "Practice-Within-a-Practice", using methods that enable ready identification of affected patients (e.g., color-coded charts, special chart stickers, electronic medical record identifiers, etc.). Once so isolated as a *Practice-Within-a-Practice,* it should be feasible to categorize diabetes patients by quartiles of HbA1c (<7%, 7–7.9%, 8–8.9%, >9%) and to triage those in the top 2 quartiles for more intensive, focused attention and joint management with endocrinologists. A "Clinical Trials Model" wherein poorly controlled patients are identified and tracked closely by a nurse, nurse practitioner, or other appointed "Case Manager" within the practice is strongly proposed. This adaptation of the Clinical Trials Model can be an efficient mechanism for achieving excellence in diabetes management in the primary care setting, because of the inherent strengths of such a model. (Table 3).

CONCLUSION

Effective diabetes management entails a multi-modality approach that utilizes lifestyle and pharmacological interventions. The mnemonic *MEDEM* (Monitoring, Education, Diet, Exercise, Medications) can be used to recall the key modalities of care. Genuine commitment to the patient's overall well being promotes adherence to the multiple behavioral and self-care tasks expected of the diabetic patient. Excellence in diabetes care requires frequent patient contacts, especially during the "down time" between office visits. These contacts may be accomplished by means of telephone, facsimile, or via the Internet. Such contacts enable the diabetes care team to respond promptly to laboratory test results, review self-monitored blood glucose data, adjust medications, and assess adherence to lifestyle and pharmacological interventions. These interactions also have a heuristic impact on patients, build trust between the patient and caregivers, and may help modify behavior.[39,40] Patients with chronically poorly controlled diabetes (HbA1c > 8%) will benefit from joint evaluation and care by a specialist. Referral to an endocrinologist should have clear goals and reasonable time course (or number of visits) for attaining such goals. A reduction in HbA1c of approximately 1–2% from baseline within 2 visits should be set as the minimal justification for the specialist endocrinologist's intervention. Subjective symptoms suggestive of hypoglycemia occur frequently when patients with poorly controlled diabetes experience improved glycemic control. These symptoms occur at blood glucose levels that are usually within the physiological range or even higher, and are attributable to altered glycemic threshold for release of counterregulatory hormones.[41] No specific treatment other than reassurance is indicated for patients with such episodes of "pseudohypoglycemia." Referrals to other specialists (cardiac, podiatry, ophthalmology, etc.) should be implemented as necessary.

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