

# Improving Outcomes in Diabetes: A Review of the Outpatient Care of NIDDM Patients

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This article is a critical review of the recent medical literature on the outpatient care of patients with non-insulin-dependent diabetes mellitus (type II). The 1989 consensus statement of the American Diabetes Association, "Standards of Medical Care for Patients with Diabetes Mellitus," has been selected as an initial point of departure. The author's goal is to present an evidence-based approach to the outpatient care of patients with type II diabetes in a way that is practical, strategically fo-

cused, and consistent with the basic philosophy of family practice. This article sets forth a detailed flow sheet for the implementation of this approach by the nurse and physician working as a team.

*Key words.* Diabetes mellitus; patient care management; progressive patient care; ambulatory care; family practice; primary health care.

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Despite numerous technical advances, diabetes care remains a challenging problem for primary care physicians. With a nationwide prevalence of 2.78%,<sup>1</sup> type II, or non-insulin-dependent diabetes mellitus (NIDDM), is present in as many as 18% of persons over age 65, comprising 70% of all diabetics.<sup>2</sup> Diabetes is the seventh leading cause of visits to a primary care physician,<sup>3</sup> and of the top 10 reasons for visits, it is the one that has the most significant impact on community mortality rates. Diabetes is the most complicated disease managed in primary care. In 1986, NIDDM was responsible for \$11.6 billion in health care expenditures and accounted for 6.8% of total US mortality: 144,000 deaths.<sup>4</sup> Diabetes mortality increased by 17.3% in the years between 1979 and 1989, and by 15% in the period between 1988 and 1990.<sup>1</sup>

In 1989, partly in response to these statistics and partly because of a perceived lack of standardization in the "routine" quality of care given to diabetic outpatients, the American Diabetes Association (ADA) published a position statement. "Standards of Medical Care for Patients with Diabetes Mellitus" is an attempt to establish

uniform standards for the primary outpatient care of these patients.<sup>6</sup> The ADA's standards of medical care are divided into two sets of criteria: those for the initial assessment of patients with newly diagnosed diabetes, and those for the continuing care of patients with established diabetes (Tables 1 and 2). These recommendations were based on expert consensus rather than a formal analysis of the published medical literature of the kind that has been modeled for general medicine by the United States Preventive Services Task Force (USPSTF) report<sup>7</sup> and by Smith et al<sup>8</sup> in the family practice literature. In the years since the publication of this article, however, there has been little physician awareness of these standards and no published evidence of any impact of these standards on physician practice or diabetes mortality. The most apparent obstacle to systematic implementation of these standards is their sheer number and the lack of any convenient instrument for tracking them. For these reasons, the standards are impractical in the usual busy office setting, where it is common for new patients to be allotted visits of only 20 to 30 minutes and established patients to be allotted visits of 10 to 15 minutes.

## Evaluating the Standards

This evidence-based review of the literature has two principal objectives. The first is to reduce the voluminous

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Table 1. American Diabetes Association Standards of Care at the Initial Visit of a Patient with Previously Unrecognized Diabetes Mellitus

- A. History
  1. Symptoms and laboratory results related to diagnosis
  2. Dietary habits, nutritional status, weight history
  3. Details of previous treatment and diabetes education
  4. Current treatment, diet, and results of glucose monitoring
  5. Exercise history
  6. Frequency and severity of complications, such as hypoglycemia
  7. History of infections
  8. Course of any chronic diabetic complications
  9. Medication history
  10. Cardiac risk profile
  11. Psychosocial and economic factors
  12. Family history
- B. Physical examination
  1. Height and weight
  2. Blood pressure (with orthostatic measurements)
  3. Ophthalmoscopic examination
  4. Thyroid palpation
  5. Cardiac examination
  6. Evaluation of pulses (with auscultation)
  7. Foot examination
  8. Skin examination
  9. Neurologic examination
  10. Dental and periodontal examination
- C. Laboratory evaluation
  1. Fasting plasma glucose
  2. Glycosylated hemoglobin
  3. Fasting lipid profile
  4. Serum creatinine
  5. Urinalysis
  6. Urine culture (if indicated)
  7. Thyroid function tests
  8. Electrocardiogram
- D. Management plan
  1. Statement of goals
  2. Medication instructions
  3. Individualized nutrition recommendations (may be from a dietitian)
  4. Recommendation for appropriate lifestyle changes
  5. Patient and family education
  6. Glucose and blood pressure monitoring instructions
  7. Annual referral to ophthalmologist
  8. Specialty consultations (as indicated)
  9. Agreement on ongoing support and follow-up

literature and overly numerous recommendations to two simple lists: what is worth doing, and what is not. The second is to create a strategic focus for office-based care by prioritizing the list of worthwhile interventions by ranking them in order of their epidemiologic impact on overall diabetes morbidity and mortality.

From an epidemiological perspective, the prevention of heart disease among patients with diabetes mellitus warrants consideration as the primary focus, just as it does for the general adult population. Ischemic heart disease, the number one killer of diabetic patients, occurs at a far higher rate in these patients than among the general population.<sup>9</sup> The clear secondary goal is the prevention of

Table 2. American Diabetes Association Standards for Continuing Care of the Type II Diabetic Patient

- A. Visit frequency
  1. Daily availability for new initiation of insulin therapy, if not hospitalized
  2. Contact within 1 week if insulin regimen is changed
  3. Contact within 1 month after modification of oral hypoglycemic regimen
  4. Routine visits:
    - a. For patients on insulin: every 3 months
    - b. For other patients: every 6 months
- B. Patient education
  1. All patients should be taught some form of glucose monitoring
  2. Recognition of early symptoms of complications
- C. Physical examination
  1. Comprehensive physical examination: annually
  2. Complete eye examination by an ophthalmologist: annually
  3. Every visit
    - a. Weight
    - b. Blood pressure
    - c. Previous abnormalities on the physical exam
    - d. Feet
- D. Laboratory evaluation
  1. Glycosylated hemoglobin: at least semiannually
  2. Fasting plasma glucose (optional)
  3. Lipid panel: annually
  4. Urinalysis: annually
- E. Review of the management plan
  1. Each visit
    - a. Nutrition and weight evaluation
    - b. Exercise regimen
    - c. Glucose and lipid control
    - d. Frequency of hypoglycemia
    - e. Compliance with aspects of self-care
    - f. Assessment of complications
    - g. Follow-up of referrals
    - h. Psychological adjustment
  2. Annually
    - a. General knowledge of diabetes
    - b. Self-management skills

diabetic renal disease. Ancillary objectives are the prevention of the less commonly fatal problems, which nonetheless cause a major impairment in the quality of life: loss of limb, blindness, and stroke. Interventions that most directly influence these five clinical outcomes will be ranked ahead of all others.

For use in this critical review of the literature, the approach of Smith et al<sup>8</sup> was slightly modified. Each item in both lists of interventions is preceded by one to four stars:

- ★★★★ Four stars designates a recommendation for or against an intervention that is well supported by the existing literature. These are generally so well documented that they are not discussed in detail here, but referrals to a specific evidence-based analysis, meta-analysis, or major clinical review are provided.
- ★★★ Three stars indicates recommendations derived



from a few small clinical trials, case-control studies, or larger retrospective studies.

★★Two stars indicates that the recommendation is supported by one or more of the following kinds of evidence: (1) expert consensus (including ADA standards); (2) evidence-based reviews of recommendations for the general medical population that would reasonably be extrapolated to diabetic patients but for which there are no adequate data specifically derived from the type II diabetic population (the best example of this kind of evidence is the guidelines of the United States Preventive Services Task Force); and (3) evidence from well-conducted experimental or physiological studies that implies a benefit from an intervention that is as yet unproven.

★A single star refers to policies or procedures that have been judged by this author to be especially useful and in keeping with a family practice approach (eg, cost-effective, less invasive, and less technology-intensive). The recommendations themselves are categorized by headings (ie, history, physical examination, laboratory evaluation, or therapeutic intervention) to facilitate comparison with ADA standards.

## Which Interventions Are Worth Doing?

### ★★★★Direct Assessment of Cardiovascular Risks I

#### 1. HISTORY

★★★A. *Family history of premature coronary artery disease is effective in identifying persons at particularly high risk.* The sensitivity, specificity, and positive predictive value (PPV) of a reported family history of myocardial infarction are 67%, 97%, and 71%, respectively, among myocardial infarction (MI) survivors, and 69%, 98%, and 74%, respectively, among controls.<sup>10</sup>

★★★★B. *Tobacco use.*<sup>7(pp289-96)</sup> Smoking is a well-documented major risk factor for coronary artery disease. It is also a significant predictor of the risk of nephropathy.<sup>11</sup> It is a clearly proven risk factor for lower extremity amputation.<sup>12</sup> A potential common mechanism for all these effects is that smokers have significantly higher plasma insulin and steady state plasma glucose concentrations, total plasma triglycerides, and lower high-density lipoprotein (HDL) levels after an oral glucose load as compared with a nonsmoking control group.<sup>13</sup>

★C. *Initial direct inquiry about a history of angina or infarction and an intercurrent history of chest pain each visit.*

★★★★D. *Direct inquiry about regular physical exercise.* Increased physical activity is effective in preventing NIDDM, even after adjusting for body mass index, and the protective effect is especially pronounced for those at highest risk of developing NIDDM.<sup>14,15</sup> For men with IDDM who exercise regularly, a large retrospective study showed a significantly lower prevalence of nephropathy and neuropathy but not retinopathy. For women, the currently available data are inconclusive.<sup>16</sup>

#### 2. PHYSICAL EXAMINATION

★★★★A. *Blood pressure measurement at every visit, with treatment for systolic pressures >140 mm Hg and diastolic pressures >85 mm Hg.*<sup>17,18</sup>

★★B. *Weight.* Although the degree of insulin resistance and hyperglycemia is directly related to weight in the majority of type II diabetics, the author could find only one study directly relating weight loss to improved outcomes. In a retrospective study of all 263 patients with type II diabetes from a single clinic who died in 1985 or 1986, Lean et al<sup>19</sup> found that for the average patient, each 1 kg of weight loss was associated with 3 to 4 months' prolonged survival.

#### 3. LABORATORY EVALUATION

★★★★A. *Annual cholesterol measurement.*<sup>6,7(pp11-22),20</sup> Diabetic patients are classified as being at high risk for coronary artery disease. A total cholesterol >240 mg/dL (6.21 mmol/L), a low-density lipoprotein (LDL) cholesterol >160 mg/dL (4.14 mmol/L), and an HDL cholesterol <35 mg/dL (0.91 mmol/L) clearly increase this risk and merit intervention, primarily nutritional.<sup>20</sup> The efficacy of pharmacologic therapy to lower cholesterol-related mortality remains controversial but is a reasonable consideration for high-risk patients who have failed dietary modifications, fiber, and exercise interventions.<sup>21,22</sup> For screening, an option that may be equally cost-effective, depending on the pricing policy of local laboratories, is to order a complete lipid panel at annual intervals. Data have shown the independent prognostic value for serum HDL levels and serum LDL levels for the general population but not specifically for patients with diabetes; no significant independent effect of serum triglycerides has been demonstrated.<sup>23</sup>

★★B. *Annual electrocardiogram.* The United States Preventive Services Task Force (USPSTF) did not find sufficient evidence to support routine annual testing of well



adults but comments that it may be appropriate in high-risk patients,<sup>7(pp3-10)</sup> such as those with diabetes. As many as 20% of newly diagnosed NIDDM patients already have coronary artery disease.<sup>24</sup> One study found that type II diabetics with abnormal exercise test results had double the rate of significant stenosis at coronary arteriography and double the rate of silent ischemia as compared with a control group of nondiabetic patients with abnormal exercise test results.<sup>25</sup> An abnormal result consistent with ischemic disease warrants more aggressive management of coronary risk factors and compliance.

#### 4. THERAPEUTIC INTERVENTION

★★★★A. *Daily prophylactic dose of aspirin (75 to 325 mg)*. Report No. 14 of the Early Treatment Diabetic Retinopathy Study<sup>26</sup> concluded that prophylactic aspirin therapy for the prevention of coronary artery disease was as effective for diabetic patients (both type I and II) as for the general population. The recent report of the Antiplatelet Trialists' Collaboration confirms and extends this finding.<sup>27</sup> Taking all high-risk patients together (including those with diabetes, hypertension, and coronary artery disease), the authors showed reductions of about one third in nonfatal myocardial infarction, about one third in nonfatal stroke, and about one sixth in vascular death ( $P < .001$ ). There is no evidence that prophylactic aspirin use increases the risks associated with diabetic retinopathy.<sup>28</sup>

★★★★B. *Menopausal hormone replacement therapy for menopausal women*. The report of the 10-year follow-up from the Nurses' Health Study found that the overall relative risk of major coronary disease in women currently taking estrogen was 0.56.<sup>29</sup> In 1992, the American College of Physicians published clinical guidelines recommending that all women, regardless of race, should consider preventive hormone therapy; the guidelines specifically suggested that women who have coronary heart disease or are at increased risk for coronary heart disease are likely to benefit from hormone therapy (ie, there is extensive and consistent observational evidence that, among these women, hormone therapy reduced the risk of coronary heart disease by 35%.<sup>30,31</sup>) One decision analysis has estimated that hormone therapy has a greater beneficial effect (estimated life-expectancy gain of 0.86 years from combined estrogen and progestin therapy) than that of cholesterol reduction, smoking elimination (among women), blood pressure reduction, or weight reduction.<sup>32</sup>

The specific effect of such therapy among women with NIDDM has not been evaluated separately, but these patients are considered at high risk for coronary artery disease. There is some evidence suggesting that

menopausal hormone therapy is used less often among women with diabetes: a higher proportion of diabetics has been reported among the "never users" group.<sup>33</sup> This finding may be related to physician uncertainty about the effects of such hormone therapy on glucose metabolism. The available evidence, however, suggests that hormone therapy produces generally favorable effects: lower blood pressure and fasting blood glucose levels among users,<sup>34</sup> no evidence of adverse effects of oral contraceptive use among IDDM patients of reproductive age,<sup>34</sup> and higher levels of HDL with lower levels of LDL, fibrinogen, glucose, and insulin.<sup>35</sup> The authors of the latter report conclude: "If these associations are independent, additive, and causal, our observation in hormone users of a reduction of 16 mg/dL (0.41 mmol/L) in the LDL, an increase of 9 mg/dL (0.23 mmol/L) in the HDL, and a reduction of 16 mg/dL (0.16 g/L) in the fibrinogen level would represent a sizable reduction of 42% in the risk of coronary heart disease in users as compared with nonusers. The reduction in fasting levels of glucose and insulin would further reduce the risk in hormone users. The reduction of 10 mg/dL (0.11 mmol/L) in triglycerides would probably reduce the risk associated with the use of estrogen with progestin even more."

#### ★★★★*Detection and Management of Diabetic Renal Disease*

NIDDM now accounts for at least 60% of all treated end-stage renal disease (ESRD) caused by diabetes in the United States. When mortality from other factors is controlled for, the incidence of ESRD appears to be about the same for patients with NIDDM and IDDM. Ten percent to 16% of NIDDM patients die of renal disease.<sup>18</sup>

#### 1. LABORATORY EVALUATION

★★★★A. *Annual dipstick testing for albuminuria*. Both albuminuria and microalbuminuria are strong predictors of coronary artery disease in NIDDM patients.<sup>36,37</sup> Microalbuminuria is found in 13% to 41% of patients with NIDDM at the time of clinical diagnosis,<sup>38,39</sup> and at least 5% of patients have clinically detectable albuminuria. The prevalence of clinical nephropathy has been reported to be between 15% and 40% in persons with NIDDM of at least 10 years' duration.<sup>40,41</sup> More aggressive control of blood pressure and other coronary artery disease risk factors is indicated for such patients. Direct pharmacologic intervention to reduce or prevent proteinuria is now available (angiotensin-converting enzyme [ACE] inhibitor therapy), although there are currently no studies that demonstrate a survival advantage for such therapy.



★★B. *Annual serum creatinine.* Although there are no research data showing that the level of serum creatinine makes a difference in outcome, it is a subject of expert consensus. An abnormal result should trigger both a 24-hour urine protein collection and a referral for dietary education.

★C. *Annual determination of 24-hour protein and creatinine in patients with albuminuria or elevated serum creatinine.* If nephropathy is accepted as an important marker of poor outcomes in NIDDM, it makes sense to measure it accurately rather than to rely on single determinations of either serum creatinine or urinary protein.

## 2. HISTORY

★★A. *Asking the patient whether he or she has received dietary and nutrition instruction about renal failure diets if the urine is positive for protein, the serum creatinine is elevated, or the creatinine clearance is reduced.* It has been shown for IDDM but not yet for NIDDM that limiting dietary protein and phosphorus can slow the progression of diabetic nephropathy without compromising glycemic control.<sup>42</sup> There is increasing evidence that all forms of diabetic education improve compliance and outcomes in both type I and type II diabetes.

## 3. THERAPEUTIC INTERVENTION

★★★A. *ACE inhibitor therapy for hypertension or early nephropathy.* ACE inhibitor therapy both reduces the degree of proteinuria in patients who have proteinuria<sup>43-47</sup> and independently retards the progression of renal insufficiency.<sup>48-50</sup> Some small studies and expert opinion are even recommending the prophylactic initiation of ACE inhibitor therapy in normotensive diabetics specifically for this purpose.<sup>51</sup>

### ★★★★ Screening for Diabetic Eye Disease

Approximately 21% of patients with NIDDM have retinopathy at the time their diabetes is diagnosed. By 20 years after diagnosis, 60% will have some degree of retinopathy, and 10% to 20% will have proliferative retinopathy.<sup>52</sup>

## 1. HISTORY

★★★A. *History of referral or visit to an ophthalmologist within the year.* Although the ADA,<sup>53</sup> the Centers for Disease Control,<sup>54</sup> the American Academy of Ophthalmology,<sup>55</sup> and the American College of Physicians<sup>56</sup> have all recommended an annual dilated ophthalmoscopic examination for patients with diabetes, current data suggest that this occurs in less than 50% of cases.<sup>57</sup> Effective treat-

ment for diabetic retinopathy is available, and blindness resulting from diabetic eye disease can largely be prevented.<sup>58</sup>

★★B. *Patients should be asked, "Have you been told that the diabetes has affected the back of your eyes, that is, the retina?"* For NIDDM, the sensitivity of this question varied from 9.9% for persons with mild nonproliferative retinopathy to 68.7% for persons with proliferative retinopathy. The specificity was 93.3%. This question is a highly specific measure of prevalence of diabetic retinopathy and is most sensitive for proliferative retinopathy.<sup>59</sup> Furthermore, patients are likely to be more compliant with annual ophthalmological examinations if they understand the findings in their own eyes or have received specific diabetic education.<sup>57</sup>

### ★★★★ The Prevention of Peripheral Vascular Disease and Lower Extremity Amputation

Of all nontraumatic amputations of the lower extremity in the United States, 50% involve patients with diabetes: about 60 amputations for every 10,000 persons with diabetes. An estimated 44% to 85% of these are preventable.<sup>60-64</sup>

#### ★★★★1. PHYSICAL EXAMINATION

*Visual inspection of the patient's feet with socks off.*<sup>60-64</sup>

#### ★★★★2. THERAPEUTIC INTERVENTION

*Provide specific patient education about diabetic foot problems and care.*<sup>12,60-65</sup>

### ★★ Monitoring of Glycemic Control

#### ★★1. LABORATORY EVALUATION

*Measurement of hemoglobin A<sub>1C</sub> every 6 months.* Although there is no proven correlation between hemoglobin A<sub>1C</sub> concentrations and the macrovascular complications of diabetes (coronary artery disease, amputation, and stroke), there is a highly significant correlation for diabetic retinopathy in both type I and type II diabetes.<sup>66</sup> In a prospective study of type I diabetes, a hemoglobin A<sub>1C</sub> concentration >10% (normal range, 5.4% to 7.6%) was associated with an increased risk of retinopathy progression, whereas a value <8.7% was associated with a reduced risk.<sup>67</sup>

#### ★★2. THERAPEUTIC INTERVENTION

*Dietary education.* A recent randomized, controlled trial reported small but consistent differential changes in the consumption of dietary fat and fiber, demonstrating the



effectiveness of providing self-help dietary materials introduced to outpatients by a nurse in a primary care setting.<sup>68</sup> In another study, two 4-hour intervention programs (a minimum intervention with a 2-week follow-up and an intermediate intervention program with a 26-week follow-up) were both shown to produce significant reductions in fat and calorie intake and significant increases in fiber intake.<sup>69</sup> Dietary education should be the principal means of glycemic control in type II diabetes.

### ★ *Other Interventions*

★1. *The focused review of systems.* Rather than carry out an exhaustive review of symptoms yielding numerous positive findings, which often lack specific implications for management, the review of systems should be used to develop an inventory of diabetic complications. This information could be used for assessing the severity, or stage, of the patient's disease. This information is not always obvious or volunteered by the patient. The physician or nurse should specifically ask about each of the major endpoints. The initial and annual history should specifically inquire about or examine for:

- A. Hypertension (any diastolic pressures <90 mm Hg)<sup>70</sup>
- B. Visual impairment or blindness
- C. Dialysis or transplantation
- D. Loss of any part of a limb or a history of vascular surgery
- E. Stroke
- F. Myocardial infarction
- G. Retinopathy
- H. Hospitalizations within the last 12 months; hospitalization within 12 months is regarded as a complication of diabetes if, based on the physician's judgment, it is related to the diabetes
- I. Sexual dysfunction (men) or urinary incontinence (women)
- J. Chronic need for a daily medication (other than aspirin, estrogen replacement, or medications specifically for diabetes), as a marker of somewhat more complicated management (ie, prescribing decisions)

## 2. HISTORY

★★A. *Hypoglycemic episodes for patients receiving pharmacologic therapy.* There is expert consensus supporting this recommendation. Without specific inquiry, patients may not report all episodes to their physician. Specific intervention in the form of dosage adjustment is indicated.

★★B. *Assessment of compliance.* Several studies indicate that nonclinical factors, such as psychosocial, economic, patient education, and compliance, account for a major proportion

of hospitalizations among patients with diabetes.<sup>71-75</sup> In a recent study of difficult-to-control asthma,<sup>76</sup> routine supervision of medication administration technique and knowledge of medication regimen on every visit as a measure of compliance, resulted in significant improvement in disease control.

★(1) Use an objective measure: eg, check for notations of 2 or more "no shows" for any scheduled aspect of diabetes care, such as office visit, laboratory test, consultation, education session.

★(2) Use a subjective measure: eg, the physician's own clinical assessment of whether the patient has been "substantially compliant" with the management plan outlined during the last visit.

★(3) Address barriers to compliance: look for obstacles hindering compliance that are not within the patient's control. Ask directly, "Is there any social or economic factor that will hinder you from carrying out your diabetes care as we have discussed it today?" Patients answering yes would be assumed to carry an increased risk of diabetic complications.

★C. *Alcohol use.* A recent study used two questions, "Have you ever had a drinking problem?" or, "When was your last drink?" among a population of 395 diabetic patients (types I and II).<sup>77</sup> Patients who answered yes to the first question or who indicated that they had their last drink within 24 hours were considered to have a drinking problem. In this study, problem drinking did not predict the degree of glycemic control but was associated with other significant risk factors, specifically, smoking and less frequent glucose monitoring.

★★D. *Formal diabetes education.* An increasing number of studies document a relationship between various diabetic outcomes and patient education. For example, in one study measures of diabetes knowledge, among other factors, were shown to be significantly related to glycemic control.<sup>78</sup> In another study, 44% of 169 diabetic patients demonstrated 20% improvement in hemoglobin A<sub>1C</sub> 2 months after formal 4-day diabetes patient education program; this result was unrelated to the type of diabetes. As previously mentioned, having attended a patient education class is independently associated with having an annual dilated eye examination.<sup>57</sup>

★★E. *Psychosocial factors.* Family function, stress, and negative affect have a significant association with both objective and perceived glycemic control particularly for type II diabetic patients.<sup>79</sup>



### 3. THERAPEUTIC INTERVENTION

★A. *Implementation of a patient-recall (tickler) system for diabetic patients.* The author knows of no formal data measuring the impact of a tickler system on diabetes care or outcomes. Some recent data, however, clearly show that the degree of interest demonstrated by the physician and the organization of the care-delivery system are associated with better glycemic control.<sup>80</sup> In a disease characterized by lethal but largely silent progression in the absence of systematic care, the rationale is compelling for implementing some kind of automatic recall system (for missed appointments, missed consultations, laboratory tests, or merely lost-to-follow-up situations).

★B. *Use of a clinical data monitoring instrument for systematic care of NIDDM patients (Appendix).* The specific factors leading to the recent increases in diabetes mortality have not yet been identified. The ADA standards are an attempt to eliminate some of the variability of the clinical database used in the management of these patients, but this goal was achieved at the expense of time efficiency and practicality for an office setting. The clinical instrument proposed here is intended to be less inclusive and more time efficient. It provides a practical means of measuring compliance with the standards recommended in this paper. The educational objectives emphasized for both physicians and patients are the strategic importance of modifying coronary artery disease risk factors, monitoring of blood pressure and urinary protein, routine inspection of the feet, routine annual eye examinations by ophthalmologists, and diabetes-specific patient education.

This form has also been designed to provide a numerical scoring system for quantitating aspects of both the stage of diabetic disease severity and the process of diabetes care to allow comparisons between patients and at different times. This staging and scoring system is currently being tested in a pilot study. Beyond serving as a clinical protocol, the instrument is designed to accomplish two goals: first, to provide an objective measure of the progression of the disease so that the efficacy of therapeutic interventions can be assessed; and second, to provide a measure of the process of care by the physician's office team. Inherent in the generation of these scores is the testing of the fundamental hypothesis that higher process scores will correlate positively with lower disease-stage scores. It is also anticipated that the very act of using the instrument will enhance the process of care, a hypothesis that can be directly tested by the scores generated. The details of the scoring system for clinical staging and the scoring system for the process of care are available

from the author on request.\* Initial experience with this instrument in the author's practice and eight other local practices has shown that it requires about 5 to 10 minutes (primarily of nursing staff time) to complete.

## Interventions Not Worth Doing

All the interventions listed in this section have some merit. This article, however, represents a strategic approach to NIDDM patients. The principal objection to the majority of the interventions listed below is that the practitioner's time is too limited to be spent on the large number of interventions for which there are no data to clearly suggest that they make a difference in outcome. I also assume that aspects of screening not generally recognized as effective for the general population (by the USPSTF, for example) are similarly ineffective for diabetics unless specific data to the contrary exist.

### History

★1. *Routine review of systems.* Many expert groups, including the ADA, recommend an extensive review of systems, including items such as dental health, and history of infections, diet and weight, family, skin problems, neurologic symptoms, and glucose control. However, there are no studies that specifically demonstrate that a review of either any isolated part of the history or any combination of historical factors alters the outcome of the disease process in diabetes. This article takes the position that the review of systems should be strategically focused on heart disease, eye disease, renal disease, and major vascular disease. A substantial problem with any comprehensive review of systems, just as for complete physical examinations, is that there are likely to be numerous positive findings that lead to no specific change in management plan and thus might fairly be termed irrelevant.

### Physical Examination

★★1. *Annual comprehensive physical examination.* Although routine, this has never been shown to be of any specific value for either the general adult population or for persons with diabetes.<sup>81</sup>

★★2. *Dilated ophthalmoscopic examination by the pri-*

\*The author will provide unlimited copies of the instrument to any clinician who is willing to use it and share the results with the author in order to accelerate the validation and revision of this instrument. In addition, an MS-DOS software program to automate and record the results of the scoring process is available on request. Along with the request for the instrument and software, please send a high-density diskette and postage-paid mailer.



*mary care practitioner.* The primary care ophthalmoscopic examination should be abandoned because it is time-consuming, inadequate,<sup>82-84</sup> redundant if the patient is going to be referred to an ophthalmologist anyway, and takes valuable time away from the other more important aspects of the primary care of diabetic patients discussed in this article. Although a recent article in the family practice literature<sup>85</sup> reported favorable results when primary care fundoscopic examinations were compared with specialists' examinations, this finding held true only when the primary care physicians participated in a 2-hour training session conducted by a retinal specialist within the year. This condition does not pertain to most ordinary office practices.

★3. *Orthostatic blood pressure.* Although this intervention has been recommended as a proxy for autonomic neuropathy in diabetes, it is neither sensitive nor specific. Although definite abnormal signs of cardiovascular autonomic function tests occur in 2.1% to 7.3% of NIDDM patients,<sup>86</sup> there are insufficient data as yet to recommend any specific intervention. Two new drugs, tolrestat<sup>87</sup> and midodrine,<sup>88</sup> hold promise and may alter this recommendation.

★★4. *Thyroid palpation.* The USPSTF has not endorsed routine thyroid palpation as an effective preventive intervention. There are no specific data for diabetes that support a different conclusion. This examination is known to be both insensitive and nonspecific, even when conducted by experts.<sup>89</sup> The prevalence of thyroid disease is not any higher among NIDDM patients than among the general population. The principal finding of this examination generally is thyroid nodules, which occur in 4% to 7% of the general population<sup>90</sup> and are not managed any differently in persons with diabetes. Thyroid disease is not a major source of morbidity or mortality among diabetic patients.

★5. *Cardiac examination.* The USPSTF has not endorsed routine cardiac auscultation as an effective preventive intervention for the general population. Although coronary artery disease is a major focus of care for diabetics, there is no correlation between coronary artery disease and cardiac auscultation.

★★6. *Palpation of peripheral pulses.* The limited available data clearly suggest that this is an unreliable sign that is neither sensitive nor specific.<sup>91</sup> Good studies exist to support the use of simpler measures (ie, patient education and examination with socks off) to more effectively achieve the desired goal of reducing peripheral vascular complications of the extremities.

★7. *Skin examination.* The only aspect of the skin examination clearly associated with improved outcomes is the examination of the feet with socks off.

★8. *Neurologic examination.* The neurologic examination is time-consuming and may identify abnormal findings for which we cannot improve patient outcomes. For example, the prevalence of diabetic neuropathy ranges from 1.2% to 80%, depending on the clinical methods used for detection.<sup>92-94</sup> Testing of vibration or proprioception is time-consuming and no more effective than simple visual inspection with socks off. Furthermore, there are numerous other subtle abnormalities that may be detected by careful neurologic examination, for example, impairment of cognitive function,<sup>95</sup> the outcome of which we may not be able to improve.

★9. *Dental and periodontal examination.* Diabetics suffer from more periodontal and dental disease than the general population,<sup>96</sup> but there are no data to show that patients specifically benefit from receiving more than regular prophylactic and restorative care. The presence of advanced dental or periodontal disease may be more a reflection of economic barriers to prescribed care than a measure of disease severity.

### Laboratory Examination

★1. *Routine glucose monitoring.* Only timed specimens (fasting or 2-hour postprandial) are specifically useful and these reflect only a part of a single day. Expert opinion does not set routine glucose monitoring as a specific standard of care but leaves the frequency of glucose monitoring to the judgment of the physician. More useful and reliable information is obtained from periodic glycosylated hemoglobin measurements. One recent report demonstrates the phenomenon of "white coat" hyperglycemia, in which the blood glucose measured in the office was found to be significantly higher than that measured at home. This finding raises serious questions about the benefits of office monitoring.<sup>97</sup>

★★2. *Home glucose monitoring.* To date, benefits from rigorous control of blood glucose among diabetics have been shown only for pregnant and IDDM patients. A recent retrospective study among 229 veterans with NIDDM showed no overall difference in glycosylated hemoglobin concentrations between patients who use home glucose monitoring methods and those who did not.<sup>98</sup>

★3. *Screening for microalbuminuria.* Microalbuminuria is the earliest marker of diabetic nephropathy.<sup>99</sup> Screening for microalbuminuria cannot be routinely recommended at this time because it is not generally available, and it may



be irrelevant if a prophylactic ACE-inhibitor therapy becomes standard. More data are needed.

★4. *Thyroid function tests.* While recommending routine thyroid function testing, the ADA standards do not specify a frequency. There are no published data on improved outcomes among NIDDM patients from routine testing. The USPSTF does not recommend routine thyroid testing for the general population.<sup>7(pp105-10)</sup>

## ★★Therapeutic Intervention

★★1. *"Tight control" for NIDDM.* For IDDM, two major recent studies have shown significant benefits achieved by means of "tight control."<sup>100,101</sup> There are no data as yet, however, to inform us whether we can or should apply their results to patients with NIDDM, which has a different cause and is more heterogeneous in both pathogenesis and treatment. The Diabetes Control and Complications Trial (DCCT) investigators specifically urged caution in applying their results and the use of therapies other than diet to patients with NIDDM.<sup>101</sup> A Mayo Clinic article suggests that tight control might be beneficial in selected cases of NIDDM.<sup>102</sup> An ongoing prospective trial from the United Kingdom may soon provide a more definitive conclusion to alter this recommendation.<sup>103</sup> At the present time, there is no literature to support tight control for NIDDM. Until better data are available, a safer, easier, and more prudent approach may be to use the hemoglobin A<sub>1C</sub> concentration as a marker for low-risk and high-risk groups, as demonstrated by the Oslo study for IDDM and diabetic retinopathy.<sup>67</sup>

★★2. *Combined insulin plus oral agent therapy.* A recent meta-analysis of all studies performed between 1966 and 1991 to evaluate the efficacy of combination therapy concluded that only a modest benefit was achieved at a significant increase in cost and the risk of hypoglycemia.<sup>104</sup>

## Conclusions

Previously published standards for diabetes care represent a much-needed attempt to systematize the process of caring for diabetic patients. Unfortunately, these standards were not developed from the perspective of practicing office physicians, who deliver the bulk of care to diabetic patients. In this paper, I have reviewed the recent medical literature on non-insulin-dependent diabetes mellitus and cited it where it justifies departure from the "standards," in the form of both deletions and additions. This paper represents a major emphasis on structuring our clinical knowledge base in a practical and time-efficient

system for primary care physicians with the prime objective of reducing of heart disease and cardiovascular mortality among type II diabetic patients.

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DIABETES OFFICE FLOW SHEET

BASELINE DIABETES DATA (To be filled in by office staff *one time only*)

Patient I.D. #: \_\_\_\_\_ Date filled out: \_\_\_\_\_ Sex: \_\_\_\_\_ Age: \_\_\_\_\_ Initial Weight: \_\_\_\_\_ Height: \_\_\_\_\_

(Part of the INITIAL DATA may best be completed by a PATIENT INTERVIEW; the other part of it requires a REVIEW OF THE CHART. Please CIRCLE or FILL IN the best response. All lab values refer only to the last 12 months.)

(Circle 2 responses.) Is this patient a NEW or ESTABLISHED patient? Is the diagnosis of Diabetes NEW or ESTABLISHED?

DATA FROM PATIENT INTERVIEW

1. What method does the patient use to monitor his/her blood glucose?

NONE URINE CHEMSTRIP GLUCOMETER

2. Has this method been verified for accuracy by the office, a commercial lab, or the store where purchased within the last 12 months?  
N/A YES NO

3. Is the patient on dialysis?  
YES NO

4. Has the patient ever had a myocardial infarction?  
YES NO

5. Has the patient ever had any surgery for his circulation or an amputation of any part of a foot?  
YES NO

6. Has the patient been referred to an ophthalmologist within the last 12 months?  
YES NO

7. Is the patient legally blind?  
YES NO

8. Has the patient ever had a stroke?  
YES NO

9. Has anyone in the patient's family had a heart attack under the age of 55?  
YES NO

10. Has someone in the office reviewed the patient's diet in the last 12 months, or has the patient been referred to a dietitian or nutritionist for diet counseling?  
YES NO

11. Does the office have any kind of tickler or patient recall system to follow up with patients who miss appointments, tests, or referrals?  
YES NO

DATA FROM CHART REVIEW

1. Any diastolic blood pressure >90 mm Hg in last 12 months?  
YES NO

2. Last total serum cholesterol value:  
\_\_\_\_\_ or  
NOT AVAILABLE

3. Last total serum HDL value: \_\_\_\_\_ or  
NOT AVAILABLE

4. Last hemoglobin A1C (glycosylated hemoglobin): RESULT: \_\_\_\_\_  
Normal range: \_\_\_\_\_ to \_\_\_\_\_  
or NOT AVAILABLE

5. Amount of protein in urine (last urinalysis within 12 months):  
0 TRACE 1+ 2+ 3+ 4+  
or NOT AVAILABLE

6. If PROTEINURIA is  $\geq 1+$ , has a 24-hour urine for protein and creatinine been obtained in last 12 months?  
N/A YES NO

7. Was the last serum creatinine within 12 months above the upper limit of normal?  
N/A YES NO

8. If YES, has the patient been referred to a dietitian for specific renal failure diet counseling?  
N/A YES NO

9. Is a copy of an ECG for this patient from the last 12 months in the chart?  
YES NO

10. Year of last tetanus shot: \_\_\_\_\_  
(Enter 0, if unknown.) or PATIENT DECLINES TETANUS TOXOID

11. Has the patient received the pneumovax immunization ever?  
UNKNOWN TODAY YES NO,  
or PATIENT DECLINES PNEUMOVAX

12. Does the patient have a history of noncompliance (ie,  $\geq 2$  notations in chart about NO SHOWS or failed appointments for tests for referrals)?  
YES NO

NURSES' ROUTINE VISIT CHECK LIST (for EACH Visit)

1. Date and initials of Physician seeing the Patient today:				
2. Weight today (pounds)				
3. Blood pressure today (systolic/diastolic)				
4. SMOKING: Enter the number of packs per day (or 0)				
5. Has (or will) the serum glucose been (or be) checked today?	YES	NO		
6. If YES, please enter the serum glucose value:				
7. If YES, please state whether this was: RANDOM (R) FASTING (F) or 2-HR POST-PRANDIAL (P)				
8. Will someone in the office review the patient's diet today?	YES	NO		
9. Treatment method for this patient: DIET (D) ORAL AGENT (O) INSULIN (I) BOTH (B)				
10. Does the patient take ASPIRIN (any dose from 40 mg to 325 mg daily or every other day)?	YES	NO	N/A	
11. If the patient is menopausal, does she take menopausal estrogens?	YES	NO	N/A	
12. Does the patient take any daily medication other than for diabetes, or other than aspirin or estrogen?				



FOR THE PHYSICIAN TO FILL OUT (*one time only*):

1. For *MEN*, Is the patient able to participate in his usual **SEXUAL ACTIVITY**?  
 DID NOT ASK    DECLINED TO ANSWER    NO OPPORTUNITY    YES    NO
- For *WOMEN*, Does she have sufficient urinary incontinence that it bothers her socially or requires her to use a pad?  
 DID NOT ASK    DECLINED TO ANSWER    YES    NO
2. Does this patient have diabetic **RETINOPATHY**?  
 DON'T KNOW    NO    BACKGROUND ONLY    PROLIFERATIVE
3. Are there any signs of **ISCHEMIC HEART DISEASE** on the most recent ECG?  
 DON'T KNOW    NO ECG    YES    NO
4. If the patient was **AMITTED TO THE HOSPITAL** in the last 12 months, was it for diabetes or a diabetes-related complication?  
 DON'T KNOW    NOT ADMITTED    YES    NO
5. Can the patient correctly state the **DEGREE OF EYE DISEASE**?  
 DON'T KNOW    YES    NO
6. Give your clinical impression of the severity of this patient's diabetes using a scale from 1 (very mild glucose intolerance) to 10 (severe diabetes with multiple major organ complications). \_\_\_\_\_

PHYSICIAN ROUTINE CHECK LIST FOR *EACH VISIT*

	DATE				
1. If patient uses alcohol, is it a problem clinically? YES NO					
2. If on hypertensive therapy, is it an insulin-enhancing agent (ACE-inhibitor or peripheral alpha-blocker)? N/A YES NO					
3. Has the patient had any hypoglycemic episodes since the last visit? YES NO					
4. Exercise (# of times per week, aerobic, sufficient to induce a light sweat) (Enter a whole number.)					
5. Neuropathic symptoms (pain in both feet at rest) or intermittent claudication? YES NO					
6. Foot exam today (Socks off)? YES NO					
7. Ulcer or cellulitis today? YES NO					
8. Typical angina since last visit? YES NO					
9. Atypical chest pain symptoms sufficient to warrant a stress test? YES NO					
10. Number of minutes of patient education done by you (Enter a whole number.)					
11. Follow-up appointment to be scheduled? (Enter # of weeks.)					
12. Has the patient been substantially compliant with the management plan from the last visit? YES NO					
13. Has the patient been asked, "Is there any personal or financial reason that will make it difficult for you to carry out your diabetes care as we have discussed today?" YES NO					
14. Patient response: YES NO					
15. If YES, write in reason:					