Several recent reviews provided the core references in developing quality indicators for diabetes (Singer et al., 1991, in Eddy, 1991; Bergenstal, 1993; Gerich, 1989; Nathan, 1993, in Rubenstein and Federman, 1993; Garnick et al., 1994). Where these core references cited studies to support individual indicators, we have included the original references. We also performed narrow MEDLINE searches of the medical literature from 1985 to 1995 to supplement these references for particular indicators. Indicators of quality of care for gestational diabetes are covered in Chapter 14.

IMPORTANCE

Diabetes is a heterogeneous, yet often serious, and common chronic condition prevalent throughout the world. In 1992, the number of diabetics in the United States alone was estimated to be 7.2 million. The prevalence was estimated at 26.1 per 1,000 population, including all ages, while the prevalence in people under 44 was 6.8. Diabetes occurs more frequently among women than men, and among nonwhites than whites (American Diabetes Association [ADA], 1993).

The complications of diabetes include visual loss and dysfunction of the heart, peripheral vasculature, peripheral nerves, and kidneys. Diabetes is the primary cause of blindness in the United States, and diabetics are at much higher risk of developing cataracts, glaucoma, and poor near vision. The deleterious effect of diabetes on the cardiovascular system contributes significantly to the risk of heart attacks, strokes, and, together with diabetic neuropathy, is the principal reason for amputations due to gangrene (Garcia et al., 1974). About half of insulin-dependent diabetics develop kidney failure (Bergenstal et al., 1993). All of these complications taken together result in much higher death rates among diabetics than the remainder of the population (Palumbo et al., 1976). Much of the benefit of high quality care will accrue years later from the prevention of morbidity
and mortality from such complications. Death rates from diabetes itself increase with age ranging from 0.2 per 100,000 for those between 15 and 19 years of age to 14.6 per 100,000 for those between 50 and 54 years; older patients experience even higher rates (National Center for Health Statistics [NCHS], 1994a).

The treatment of diabetes is resource intensive, with total costs estimated at $30-40 billion annually in 1992 (ADA, 1993), or one of every seven dollars spent on health care in 1992 (Rubin et al., 1994). Diabetes was the eighth most common reason for a patient visiting a physician’s office in 1992 (NCHS, 1994b).

**EFFICACY AND/OR EFFECTIVENESS OF INTERVENTIONS**

**Screening**

Indicators of the quality of screening diabetics for complications of diabetes are covered under diagnosis below. This section covers screening patients not known to be diabetic for the disease. Both the American College of Physicians (ACP) (Singer et al., 1991, in Eddy, 1991) and the Canadian Task Force (CTF) on the Periodic Health Examination (1979) recommended that asymptomatic patients need not undergo screening for diabetes. These recommendations were based on the poor evidence that treatment of patients so identified would prevent complications. Though many persons have asymptomatic hyperglycemia, most complications of diabetes occur late in the course of the disease, limiting the benefits of early identification. Since the publication of those recommendations, the Diabetes Control and Complication Trial (DCCT) (see below) has added evidence for the efficacy of tight control in known diabetics in preventing complications (DCCT, 1993a). However, we have found no subsequent studies directly evaluating the efficacy of screening asymptomatic patients in reducing morbidity or mortality from diabetes (Singer, 1988; CTF, 1979).

**Diagnosis**

The initial diagnosis of diabetes depends upon the measurement of a fasting blood sugar greater than 140/mg/dl or a postprandial blood sugar of greater than 200/mg/dl. If a recorded blood sugar meets the above
criteria, we recommend looking for notation of the diagnosis of diabetes in the progress notes or problem list. Most experts also recommend a complete history and physical examination, dietary evaluation, urinalysis for protein, measurement of blood creatinine, and a lipid panel at the time of initial diagnosis (ADA, 1989). We do not propose any of these as quality indicators for the initial diagnosis because of the small number of incident cases in our sample and the difficulty of defining the time of initial diagnosis.

We instead concentrate on the routine diagnostic tests that known diabetics should undergo regardless of their clinical status and stage of disease. The first of these is the measurement of glycated hemoglobin to monitor glycemic control. A randomized controlled trial of 240 patients found that measuring hemoglobin A_{1c} every three months led to changes in diabetic treatment and improvement in metabolic control, indicated by a lowering of average hemoglobin A_{1c} values (Larsen et al., 1990). The landmark DCCT followed 1,441 insulin-dependent diabetics for 9 years and found that tight glycemic control and lower hemoglobin A_{1c} values decreased rates of diabetic complications (DCCT, 1993a). Despite recommendations from a number of specialty and generalist physician societies, there is great variation in the use of this test (ADA, 1993; Bergenstal et al., 1993; Garnick et al., 1994; Goldstein et al., 1994). We propose as a quality indicator a hemoglobin A_{1c} test be done for all diabetics at six-month intervals, the longest recommended interval.

Home blood glucose monitoring has been shown to aid glycemic control in diabetics treated with insulin. The DCCT employed home blood glucose monitoring for its population of insulin-dependent diabetics, rather than the more easily tolerated urine glucose monitoring to achieve tight control, because moderate hyperglycemia (180 mg/dl) may not cause glycosuria. At least one small randomized trial (n=23) has shown home blood glucose monitoring to improve glycemic control in obese insulin-dependent diabetics (Allen et al., 1990). The optimal frequency of monitoring has not yet been determined, though some studies have questioned patients’ ability to comply with frequent measurement (Bergenstal et al., 1993; Health and Public Policy Committee, 1983;
Muchmore et al., 1994; Gordon, 1991). Observational data have failed to find any strong relationship between home blood glucose monitoring and glycemic control in noninsulin-dependent diabetics (Patrick, 1994; Allen et al., 1990). Specialty societies recommend that patients on insulin be offered training and equipment for home glucose monitoring, and we propose this as another indicator of diagnostic quality (ADA, 1993). For patients not taking insulin, randomized trials have not shown home blood glucose to be any more effective at maintaining glycemic control than urine testing (Allen et al., 1990).

Because of the frequency of vision, cardiovascular, and renal complications among diabetics, many of which may be asymptomatic, the ADA (1989) has recommended several screening tests on an annual basis: eye exam, tests of triglycerides, total cholesterol, HDL cholesterol, urinalysis, and total urinary protein excretion. An annual eye and vision exam conducted by an ophthalmologist, beginning five years after diagnosis, has also been recommended by the ACP, the ADA, and the American Academy of Ophthalmology (AAO) (ACP, ADA and AAO, 1992). Retinal examination by generalists has been shown to be much less effective in detecting retinopathy at an early treatable stage (Reenders et al., 1992). The routine evaluation of the other screening recommendations has never been tested in controlled trials, but the conditions screened for (hyperlipidemia, nephropathy, and ESRD) are both more common in diabetics and amenable to intervention (The Carter Center, 1985). Compliance with ADA screening recommendations has been estimated to vary from 20 to 50 percent (Garnick et al., 1994; Brechner et al., 1993).

Other common treatable complications of diabetes include hypertension, cellulitis, and osteomyelitis. The ADA recommends blood pressure measurement and examination of the feet at every visit to detect these complications early in their course as well as a careful history to elicit signs and symptoms of hypoglycemia and hyperglycemia. No controlled trials have examined the efficacy of a regular history and physical examination.
Treatment

Recent debate in the area of diabetic treatment hinges on the utility of tight glycemic control. The goal of tight control and prevention of long-term complications through aggressive treatment is supported by the DCCT (DCCT, 1993a). The DCCT randomized 1,441 insulin-dependent diabetics into conventional therapy or intensive therapy that included daily adjustments of insulin dosage, frequent home glucose monitoring, and nutritional advice. Under the optimal circumstances present in the DCCT trial, 44 percent of the intervention group achieved glycosolated hemoglobin values under the goal of 6.05 mg/dl percent at least once, but only 5 percent maintained average values in that range. The intervention group developed 76 percent less retinopathy, 57 percent less albuminuria, and 60 percent less clinical neuropathy, but this reduction in diabetic complications may come at the expense of quality of life (Nerenz et al., 1992). For example, the tight control group in DCCT experienced a two- to three-fold increase in hypoglycemic episodes. The efficiency of such methods in general practice has not received adequate evaluation. Nonetheless, the ADA recommends that all diabetics over the age of seven be offered similar aggressive therapy.

Treatment strategies are different for Type I diabetes (complete pancreatic deficiency of insulin) and Type II diabetes (abnormal secretion of insulin and resistance to insulin action). In Type I diabetes, emphasis is placed on avoidance of diabetic ketoacidosis and tight control of blood sugar levels through the judicious use of insulin. In Type II diabetes, the focus shifts to control of symptoms, usually with a combination of diet, exercise, and oral hypoglycemic agents. If these measures fail to maintain adequate control in Type II diabetics, then insulin therapy is warranted. We will review the evidence for quality indicators for each of these treatment modalities in turn.

Adherence to the ADA-recommended diet decreases insulin and oral hypoglycemic requirements and serum lipids (Bantle, 1988). The DCCT trial relied on dieticians and revealed that greater adherence to dietary instructions resulted in better control (DCCT, 1993b). Exercise improves glucose tolerance and may reduce or eliminate the need for drug
therapy (Raz et al., 1994). The ADA and the American Board of Family Practice recommend dietary and exercise counseling at both the initial diagnosis and before starting oral hypoglycemics or insulin (ADA, 1989; Bergenstal et al., 1993). We recommend evaluating the medical record for evidence that all diabetics have received dietary and exercise counseling and that Type II diabetics have undergone a trial of this conservative therapy prior to pharmaceutical intervention.

Randomized controlled trials have shown oral hypoglycemic agents to effectively improve glycemic control and prevent hyperglycemic coma. Although the effectiveness of these agents in preventing longer-term complications of Type II diabetes has been questioned, particularly in the controversial UGDP Trial of the 1970’s (Gerich, 1989; Kilo et al., 1980; Knatterud, 1978), we recommend evaluating the medical record to determine if oral hypoglycemic therapy has been offered to symptomatic Type II diabetics who have already received a trial of dietary therapy.

Insulin treatment is essential for Type I diabetics and a treatment of last resort for Type II diabetics. The literature contains varied recommendations as to the optimal timing and content of insulin injections (Gregerman, 1991, in Barker et al., 1991; Knatterud, 1978), and no single regimen has emerged as superior. However, the ADA recommends that all diabetics taking insulin receive formal instruction in the technique of injection (ADA, 1989; Bergenstal et al., 1993). We recommend evaluating the medical record for evidence that this has taken place. We also recommend that symptomatic Type II diabetics who have failed oral hypoglycemics be offered insulin.

Though quality indicators for treatment of hypertension are covered elsewhere (Chapter 12), the intersection of diabetes and hypertension poses special treatment challenges. Control of hypertension is perhaps the most crucial step in preventing diabetic nephropathy. In particular, ACE inhibitors and possibly calcium channel blockers have been shown to reduce hyperalbuminuria and delay the progression to diabetic nephropathy (Lederle, 1992; Anderson, 1990). Beta blockers on the other hand may block the symptoms of hypoglycemia, and thus may be contraindicated in treated diabetics (Hamilton, 1990). We propose that diabetics with hypertension receive ACE inhibitors or calcium channel
blockers as first-line pharmacotherapy if diet has failed to control blood pressure.

**Follow-up**

A study of internists and family practitioners using patient vignettes found wide variation in recommended follow-up intervals for diabetics (Petitti and Grumbach, 1993). The ADA (1989) guidelines recommend that regular visits be scheduled every three months for insulin-dependent diabetics and every six months for other diabetics. As a minimum standard of care for patients with diabetes, we suggest a visit every six months.
# Recommended Quality Indicators for Diabetes Mellitus

The following criteria apply to nonpregnant women age 18-50.

## Diagnosis

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Quality of evidence</th>
<th>Literature</th>
<th>Benefits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients with fasting blood sugar &gt;140 or postprandial blood sugar &gt;200 should have diabetes noted in progress notes or problem list.</td>
<td>III</td>
<td>ADA, 1989</td>
<td>Prevent diabetic complications.*</td>
<td>This definition of diabetes is accepted worldwide. Blood sugar tests are often ordered as part of panels; this indicator will test the timeliness of follow-up on an abnormal result.</td>
</tr>
<tr>
<td>2. Patients with the diagnosis of diabetes should have glycosylated hemoglobin every 6 months.</td>
<td>I, III</td>
<td>ADA, 1989; Larsen et al., 1990; ACP, ADA and AAO, 1992</td>
<td>Prevent diabetic complications.*</td>
<td>Randomized controlled trial of 240 patients indicated a significant decrease in hemoglobin A1c among those whose hemoglobin A1c was monitored. Time interval is that used in most clinical trials.</td>
</tr>
<tr>
<td>3. Patients with the diagnosis of diabetes should have each of the following at least once a year: a. Eye and visual exam; b. Triglycerides; c. Total cholesterol; d. HDL cholesterol; and e. Urinalysis.</td>
<td>I, III</td>
<td>ADA, 1989; Larsen et al., 1990; ACP, ADA and AAO, 1992</td>
<td>Prevent diabetic complications.* Prevent retinopathy, hyperlipidemia, atherosclerotic complications, and renal disease.</td>
<td>Eye and visual exam shown to detect retinopathy at an earlier treatable stage. Other recommendations based on expert opinion, though studies have shown conditions they screen for to be more common in diabetics and all are susceptible to treatment with improved outcomes resulting from earlier detection.</td>
</tr>
<tr>
<td>4. Patients with the diagnosis of diabetes should have each of the following at every visit: f. examination of feet; and g. measurement of blood pressure.</td>
<td>I, III</td>
<td>ADA, 1989; Larsen et al., 1990; ACP, ADA and AAO, 1992</td>
<td>Prevent diabetic complications.* Prevent lower renal disease, extremity amputation, reduced morbidity from foot infections.</td>
<td>These are ADA recommendations. Earlier detection of treatable disease reduces probability of developing serious complications. Exam provides an opportunity for patient education.</td>
</tr>
<tr>
<td>5. Patients taking insulin should monitor their glucose at home.</td>
<td>III</td>
<td>ADA, 1993</td>
<td>Prevent hypoglycemic episodes. Prevent diabetic complications.*</td>
<td>A small RCT found that home glucose monitoring increases glycemic control in insulin dependent diabetics. Another study found no difference in control by frequency of monitoring. Recommended by the ADA.</td>
</tr>
<tr>
<td>Indicator</td>
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<td>6. Diabetics should receive dietary and exercise counseling.</td>
<td>II</td>
<td>Raz et al., 1994; Delahanty and Halford, 1993; ADA, 1989; Bergenstal et al., 1993</td>
<td>Reduce diabetic complications.*</td>
<td>Adherence to ADA diet decreases insulin and oral hypoglycemic requirements and serum lipids. Exercise improves glucose tolerance and may reduce or eliminate need for drug therapy. DCCT used dieticians and found that adherence to diet improved control and the ADA and the ABFP recommend their use. No study has found that dietary counseling reduces diabetic complications.</td>
</tr>
<tr>
<td>7. Type II diabetics who have failed dietary therapy should receive oral hypoglycemic therapy.</td>
<td>III</td>
<td>ADA, 1989; Gerich, 1989; Bergenstal et al., 1993</td>
<td>Reduce diabetic complications.*</td>
<td>Observational trials have shown oral hypoglycemics to be effective in treating hyperglycemia and improving glycemic control. No studies have shown reduction of diabetic complications. Specialty societies and review articles widely recommend their use in mild to moderate disease before starting insulin.</td>
</tr>
<tr>
<td>8. Type II diabetics who have failed oral hypoglycemics should be offered insulin.</td>
<td>III</td>
<td>ADA, 1989; Bergenstal et al., 1993</td>
<td>Reduce diabetic complications.*</td>
<td>Recommended by the ADA and ABFP.</td>
</tr>
<tr>
<td>9. If patient is receiving other antihypertensive therapy in the absence of ACE inhibitors or calcium channel blockers, progress note should document failure of ACE inhibitors and calcium channel blockers to control blood pressure.</td>
<td>I</td>
<td>Lederle, 1992; Anderson, 1990</td>
<td>Reduce rate of renal failure.</td>
<td>Randomized controlled trials have demonstrated a reduction in albuminuria and progression of diabetic nephropathy in hypertensive patients treated with ACE inhibitors and possibly calcium channel blockers.</td>
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</table>
Follow-up

<table>
<thead>
<tr>
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<th>Literature</th>
<th>Benefits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Patients with diabetes should have a follow-up visit at least every 6 months.</td>
<td>III</td>
<td>Bergenstal et al., 1993; ADA, 1989</td>
<td>Reduce probability of severe diabetic complications.*</td>
<td>Visits for diabetic patients in control should be every 3-6 months (per ABFP). Routine monitoring facilitates early detection and treatment of complications.</td>
</tr>
</tbody>
</table>

*Diabetic complications include visual loss and dysfunction of the heart, peripheral vasculature, peripheral nerves, and kidneys.

Quality of Evidence Codes:

I: RCT
II-1: Nonrandomized controlled trials
II-2: Cohort or case analysis
II-3: Multiple time series
III: Opinions or descriptive studies
REFERENCES – DIABETES


The Diabetes Control and Complications Trial Research Group. 30 September 1993. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-


