Several recent reviews provided the core references in developing quality indicators for diabetes (Singer et al., 1991; Bergenstal, 1993; Gerich, 1989; Nathan, 1993b; Garnick et al., 1994; ECDCDM, 1997). Where these core references cited studies to support individual indicators, we have included the original references. We also performed focused MEDLINE searches of the medical literature from 1985 through 1997 to supplement these references for particular indicators.

**IMPORTANCE**

Diabetes is a heterogeneous, often serious, and common chronic condition. The American Diabetes Association (ADA) estimated the number of diabetics in 1997 at 16 million. The prevalence of diabetes is 26.1 per 1,000 people of all ages, and 6.8 per 1,000 in people under the age of 44. Each day, approximately 1,700 people are diagnosed with diabetes. It is the fourth leading cause of death in the United States. Diabetes occurs more frequently among women than men, and among non-whites than whites (ADA, 1997).

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 cardiovascular effects of diabetes cause heart attacks, strokes, and, together with diabetic neuropathy, amputations (Garcia et al., 1974). About half of insulin-dependent diabetics eventually develop kidney failure (Bergenstal et al., 1993). All of these complications taken together result in much higher death rates among diabetics than the rest of the population (Palumbo et al., 1976).

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1 This chapter is a revision of one written for an earlier project on quality of care for women and children (Q1). The expert panel for the current project was asked to review all of the indicators, but only rated new or revised indicators.
Death rates from diabetes itself (excluding complications) 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). Much of the benefit of high quality care will accrue many years after the prevention of morbidity and mortality from the above-mentioned complications.

The treatment of diabetes is resource intensive, with total annual economic costs estimated at $91.8 billion in 1992 (ADA, 1997). For 1992, diabetes accounted for one of every seven dollars spent on health care (Rubin et al., 1994), and was the eighth most common reason for a patient visiting a physician’s office (NCHS, 1994b).

**SCREENING**

This section covers screening patients who are not yet diagnosed as diabetic. Indicators for screening diabetics for complications are covered below under Diagnosis. 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) have recommended that asymptomatic patients not undergo screening for diabetes, because of the poor evidence that treatment of patients so identified would prevent complications. Although many persons have asymptomatic hyperglycemia, most complications of diabetes occur late in the course of the disease, which limits the benefits of early identification. Since the publication of the ACP and CTF recommendations, the Diabetes Control and Complication Trial (DCCT) has added evidence for the efficacy of tight control in known insulin-dependent diabetics in preventing complications (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). In 1997, the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus recommended that testing for diabetes should be considered in all individuals 45 years of age or older and, if normal, it should be repeated at three year intervals (ECDCDM). Undiagnosed Type 2 diabetes may affect 8 million individuals. The committee
reasoned that such patients are at increased risk for coronary heart disease, stroke and peripheral vascular disease, and so might benefit from early detection (ECDCDM). No other expert bodies have made similar recommendations.

**DIAGNOSIS**

According to the criteria of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (ECDCDM), the initial diagnosis of diabetes depends on the measurement of a fasting blood sugar greater than 126 mg/dl or a postprandial blood sugar of greater than 200 mg/dl (ECDCDM, 1997). If a recorded blood sugar meets the above criteria, we recommend as a quality indicator that the provider be required to note the diagnosis of diabetes in the progress notes or problem list (Indicator 1).

Guidelines 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 testing sample and the difficulty of defining the time of initial diagnosis.

The Meta-analysis Research Group on the Diagnosis of Diabetes Using Glycated Hemoglobin Levels concluded that measurement of hemoglobin Alc levels may represent a reasonable approach to the diagnosis of treatment-requiring diabetics (Peters et al., 1996). However, because there are many different methods for measuring glycosylated hemoglobins and because nationwide standardization of the test has just begun, the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus does not currently recommend the hemoglobin Alc test for the diagnosis of diabetes (ECDCDM, 1997). Therefore, we do not propose its use as a diagnostic quality indicator at this time.

Instead, we have concentrated 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 glycosylated hemoglobin to monitor glycemic control. A randomized controlled trial
of 240 patients found that measuring hemoglobin A1c every three months led to changes in diabetic treatment and improvement in metabolic control, indicated by a lowering of average hemoglobin A1c values (Larsen et al., 1990). The landmark DCCT followed 1,441 insulin-dependent diabetics for nine years and found that tight glycemic control and lower hemoglobin A1c values decreased rates of diabetic complications (DCCT, 1993a; see under Treatment below). 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 that a hemoglobin A1c test be done for all diabetics at six-month intervals, which is the longest recommended interval (Indicators 2 and 3).

Home blood glucose monitoring has been shown to aid glycemic control in diabetics taking insulin. Because moderate hyperglycemia (<180 mg/dl) may not cause glycosuria, the DCCT employed home blood glucose monitoring for its population of insulin-dependent diabetics monitoring to achieve tight control, rather than the more easily tolerated urine glucose. At least one small randomized trial (n=23) has shown home blood glucose monitoring to improve glycemic control in obese insulin-dependent diabetics. The optimal frequency of monitoring has not yet been determined, although 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). 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), and observational data have failed to find any strong relationship between home blood glucose monitoring and glycemic control (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) (Indicator 4).

Because of the frequency of vision, cardiovascular, and renal complications among diabetics, many of which may be asymptomatic, the
ADA (1989) has recommended the following annual screening tests: eye exam, tests of triglycerides, total cholesterol, HDL cholesterol, urinalysis, and total urinary protein excretion (Indicators 2 and 3). An annual eye and vision exam conducted by an ophthalmologist, beginning at 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) (Indicators 2 and 3). Generalists detect retinopathy at an early treatable stage much less effectively than specialists (Reenders et al., 1992). The other screening recommendations have never been evaluated in controlled trials, but the conditions that are screened -- hyperlipidemia, nephropathy, and end-stage renal disease -- 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 (Indicators 2 and 3), 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 concerning diabetic treatment hinges on the utility of tight glycemic control. The goals of tight control and prevention of long-term complications through aggressive treatment are supported by the 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 five 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 1 diabetes (complete pancreatic deficiency of insulin) and Type 2 diabetes (abnormal secretion of insulin and resistance to insulin action). In Type 1 diabetes, emphasis is placed on avoidance of diabetic ketoacidosis and tight control of blood sugar levels through the judicious use of insulin. In Type 2 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 2 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 relied on dieticians and revealed that greater adherence to dietary instructions resulted in better control (1993b). Exercise also improves glucose tolerance and may reduce or even eliminate the need for drug therapy (Raz et al., 1994). Thus, the ADA and the American Board of Family Practice (ABFP) 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 as a quality indicator evaluating the medical record for evidence that all diabetics have received dietary and exercise counseling and that Type 2 diabetics have undergone a trial of this conservative therapy prior to pharmaceutical intervention (Indicator 5 and 6).

Randomized controlled trials have shown that oral hypoglycemic agents improve glycemic control and prevent hyperglycemic coma. However, the effectiveness of these agents in preventing longer-term complications of Type 2 diabetes has been questioned, particularly in
the controversial UGDP Trial of the 1970s (Gerich, 1989; Kilo et al.,
1980; Knatterud, 1978). The effectiveness of oral hypoglycemic agents is
under study in the UK Prospective Diabetes Study (USPDS), but results
are not currently available (Turner, 1995).

The biguanide metformin is a relatively new (in the U.S.)
antihyperglycemic drug used in patients with noninsulin-dependent
diabetes mellitus. Its efficacy in lowering blood glucose is similar to
that achieved with a sulfonylurea. Unlike sulfonylurea, it does not
cause weight gain and, when used as monotherapy, does not cause
hypoglycemia. It can be used either as initial therapy or as an
additional drug when sulfonylurea therapy is inadequate. (Campbell et

At present, we recommend evaluating the medical record to determine
if oral hypoglycemic therapy has been offered to symptomatic Type 2
diabetics who have already received a trial of dietary therapy
(Indicator 6).

Insulin treatment is essential for Type 1 diabetics and a treatment
of last resort for Type 2 diabetics. The literature contains varied
recommendations on 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. We recommend as a quality
indicator that Type 2 diabetics who have failed oral hypoglycemics be
offered insulin (Indicator 7).

Although quality indicators for treatment of hypertension are
covered elsewhere, 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 and proteinuria receive ACE inhibitors or
calcium channel blockers as first-line pharmacotherapy if diet has
failed to control blood pressure (Indicator 8).
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 propose as a quality indicator that diabetics should visit the provider every six months (Indicator 9).
REFERENCES


RECOMMENDED QUALITY INDICATORS FOR DIABETES MELLITUS

These indicators apply to men and women age 18 and older. Only the indicators in bold type were rated by this panel; the remaining indicators were endorsed by a prior panel.

<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>Diagnosis</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>1. Patients with fasting blood sugar &gt;126 or postprandial blood sugar &gt;200 should have a diagnosis of diabetes noted in progress notes or problem list.</td>
<td>III</td>
<td>ADA, 1989 ECDCDM, 1997</td>
<td>Prevent diabetic complications.¹</td>
<td>This definition of diabetes is accepted worldwide. Blood sugar tests are often ordered as part of panels.</td>
</tr>
<tr>
<td>2. Patients with the diagnosis of Type 1 diabetes should have all of the following: a. Glycosylated hemoglobin or fructosamine every 6 months. b. Eye and visual exam (annual). c. Total serum cholesterol and HDL cholesterol tests (annual). d. Measurement of urine protein (annual). e. Examination of feet at least twice a year. f. Measurement of blood pressure at every visit.</td>
<td>I, III</td>
<td>ADA, 1989; Larsen et al., 1990; ACP, ADA, and AAO, 1992</td>
<td>Prevent diabetic complications.¹ Prevent retinopathy, hyperlipidemia, atherosclerotic complications, and renal disease.</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. Eye and visual exams are shown to detect retinopathy at an earlier treatable stage. Other recommendations are 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>Indicator</td>
<td>Quality of Evidence</td>
<td>Literature</td>
<td>Benefits</td>
<td>Comments</td>
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<tr>
<td>3. Patients with the diagnosis of Type 2 diabetes should have all of the following: a. Glycosylated hemoglobin or fructosamine every 6 months; b. Eye and visual exam (annual); c. Total serum cholesterol and HDL cholesterol tests (annual); d. Measurement of urine protein (annual); e. Examination of feet at least twice a year; f. Measurement of blood pressure at every visit.</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. Reduce morbidity from foot infections.</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. Eye and visual exam are shown to detect retinopathy at an earlier treatable stage. Other recommendations are 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. Types 1 and 2 patients taking insulin should monitor their glucose at home unless documented to be unable or unwilling.</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>5. Newly diagnosed 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 dietitians 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>6. Type 2 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>Indicator</td>
<td>Quality of Evidence</td>
<td>Literature</td>
<td>Benefits</td>
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<tr>
<td>7. Type 2 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.¹</td>
<td>Recommended by the ADA and ABFP.</td>
</tr>
<tr>
<td>8. Hypertensive diabetics with proteinuria should be offered an ACE inhibitor or a calcium channel blocker within 3 months of the notation of proteinuria.</td>
<td>I</td>
<td>Lederle, 1992; Anderson, 1990</td>
<td>Reduce diabetic complications.¹</td>
<td>May reduce progression to diabetic nephropathy.</td>
</tr>
</tbody>
</table>

**Follow-up**

<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>9. All 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.¹</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>

**Definitions and Examples**

¹Diabetic complications include visual loss and dysfunction of the heart, peripheral vasculature, peripheral nerves, and kidneys.

Synonyms for types 1 and 2 diabetes are listed below:

<table>
<thead>
<tr>
<th>Type 1 diabetes</th>
<th>Type 2 diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDDM - Insulin-dependent diabetes</td>
<td>AODM - Adult-onset diabetes</td>
</tr>
<tr>
<td>Juvenile diabetes</td>
<td>MODM - Maturity-onset diabetes</td>
</tr>
<tr>
<td>Juvenile-onset diabetes</td>
<td>NIDDM - Non-insulin dependent diabetes mellitus</td>
</tr>
<tr>
<td>Ketosis-prone diabetes</td>
<td>Nonketosis-prone diabetes</td>
</tr>
</tbody>
</table>

**Quality of Evidence Codes**

<table>
<thead>
<tr>
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<th>Description</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>RCT</td>
</tr>
<tr>
<td>II-1</td>
<td>Nonrandomized controlled trials</td>
</tr>
<tr>
<td>II-2</td>
<td>Cohort or case analysis</td>
</tr>
<tr>
<td>II-3</td>
<td>Multiple time series</td>
</tr>
<tr>
<td>III</td>
<td>Opinions or descriptive studies</td>
</tr>
</tbody>
</table>