WORKING
PAPER

Quality Indicators for the Management of Diabetes Mellitus for Vulnerable Older Persons

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WR-187

August 2004

HEALTH

QUALITY INDICATORS FOR THE MANAGEMENT OF DIABETES MELLITUS FOR VULNERABLE OLDER PERSONS

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This study was supported by a contract from Pfizer Inc to RAND.

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Word Count: 4,830

Number of tables: 4

INTRODUCTION

Diabetes mellitus is one of the most important causes of morbidity and mortality in the United States. It has been among the top ten causes of death for several decades, and it is the leading cause of end stage renal disease and visual loss among individuals under age 65. In 1997, diabetes was responsible for approximately 2.3 million hospital admissions, 14 million hospital days, and 70 million nursing home days. Direct medical expenditures on diabetic care were estimated at $44 million.[1,2] At Northern California Kaiser, a matched cohort analysis indicated that the annual *excess* expenditures for diabetic patients totaled $3,500 per person.[3]

The prevalence of diabetes rises dramatically with age: More than 10% of persons over age 65 have clinical diabetes. Almost all of these older patients have type II diabetes. Elderly patients are still at risk for the long term complications of diabetes, having an approximately two-fold increased risk for myocardial infarction, stroke, and renal insufficiency, when compared with persons of the same age without diabetes.[4]

To date, there has been considerable high quality research on the prevention and management of complications of diabetes. However, most of these data are not specific to elderly patients, and none are specific to individuals age 80 or older. Thus, extrapolation of published data to the vulnerable elderly population is a major challenge for developing quality indicators for this group. A related challenge pertains to the time frame required in order to benefit from the proposed indicators. Many testing and management strategies require a minimum of two to three years (and in some cases, much longer) in order to accrue significant benefits. Therefore, except where noted, all of the quality indicators in this paper are intended for persons who have a life expectancy of at least two to three years.

METHODS

The generic methods for developing the quality indicators are detailed in a preceding paper.(2) The following explicates specifics as they apply to this condition, diabetes mellitus.

The literature search began with the author's own files from a previous review to generate diabetes quality indicators for primary care in the United Kingdom (Campbell SM, Roland MO, Shekelle, PG, et al.; Qual in Health Care, 1999; 8:6-15). This review was updated from 1997 by searching major general interest and specialty journals as shown in Table 1. In addition, practice guidelines and quality indicators from other sources wee examined (Table 2).

These searches identified a total of 339 titles. Review of titles, abstracts, and reference lists identified 75 articles for further review.

On the basis of the literature and author's expertise, 15 potential quality indicators were proposed. As outlined in more detail in the accompanying methods article (2), these potential quality indicators were assessed for validity by a 12-member group of clinical experts representing diverse disciplines. The panel process used was a modification of the RAND/UCLA Appropriateness Method. This method involved two sets of ratings of each indicator by each panelist for validity in a 1-9 scale with 1 = "definitely not valid" and 9 = "definitely valid." A face-to-face meeting of the panel is used to discuss each indicator and the evidence and opinion supporting or refuting the validity as a measure of quality. Indicators that received a median rating in the highest tertile (7, 8 or 9) without panel disagreement were accepted as valid.

RESULTS

Of the 15 potential quality indicators, 10 were judged valid by the expert panel process (Table 3). When considering these indicators, they must be interpreted in the context of their purpose. Quality indicators are not the same as practice guidelines. Quality indicators, typically, set a standard which, if it is not met, almost certainly identifies poor quality care. By necessity, the sensitivity of identifying poor quality care is suborned to the specificity that any care so identified is substandard. The literature summaries that support each of the indicators judged to be valid by the expert panel process are described below.

Quality Indicator #1

Measurement of Glycated Hemoglobin

IF a vulnerable elder has diabetes, **THEN** his or her glycosylated hemoglobin level should be measured at least every 12 months, **BECAUSE** monitoring of glycemic control is a necessary prerequisite for improvement of glycemic control, which has been shown to reduce the risk of diabetic complications.

Supporting evidence: There are no randomized clinical trials of the effect of routinely measuring glycated hemoglobin levels on patients with type II diabetes either in the elderly or the non-elderly population. We did identify one randomized clinical trial that addressed this issue in patients with type I diabetes, and we identified another study that examined the effects of tight glycemic control on patients with type II diabetes.

A randomized clinical trial conducted through an outpatient clinic of a university hospital in Denmark examined the effects of glycated hemoglobin monitoring on patients under age 60 with type I diabetes mellitus. Study participants were randomized to either regular hemoglobin A_{1C} monitoring (n = 115) or to no monitoring (n = 107).[1] Patients in the intervention group had their hemoglobin A_{1C} level measured and recorded at each clinic visit, which occurred at least four times during the twelve month duration of the study. The main outcome measures were glycemic control (as measured by hemoglobin A_{1C} level) and the number of hospital admissions. At the one year follow-up point, the mean hemoglobin A_{1C} level in the intervention group had decreased from 10.1% to 9.5%, compared to no change in the control group ($p < 0.005$). Hospitalization for hypoglycemic or hyperglycemic episodes was less frequent among the monitored patients (12 events out of 115 patients, or 10%) than among the controls (23 events out of 107 patients, or 21%).

A second study, the Diabetes Clinic and Complication Trial (DCCT), established that for patients with type I diabetes mellitus, over a five-year period the tight control of glucose leads to moderate to substantial reductions in the microvascular complications of diabetes.[2] The United Kingdom Prospective Diabetes Study 33 (UKPDS 33), a randomized clinical trial, extended these findings to patients with type II diabetes mellitus.[3] The UKPDS 33 study randomly assigned 3,876 patients newly diagnosed with type

II diabetes mellitus (median age = 54 years) to either intensive therapy or to conventional therapy. Follow up time was for ten years. Hemoglobin A_{1C} levels averaged 7.0% in the intensive therapy group, compared with 7.9% in the conventional group. The intensive therapy group experienced a 12% lower risk for any diabetes-related endpoint, which was statistically significant. It also experienced a 10% lower risk for any diabetes-related death and 6% lower risk for all-cause mortality, neither of which reached statistical significance. Most of the risk reduction seen in the intensive therapy group was due to a reduction in the number of microvascular events, primarily diabetic retinopathy. As in the DCCT trial, patients in the intensive therapy group had a greater risk of hypoglycemic episodes: The risk increased from 0.7% per year in the conventional treatment group to between 1.4% and 1.8% in the intensive therapy group.

There are no data to support or refute any particular frequency for the routine measurement of glycated hemoglobin among patients with type II diabetes mellitus. The existing recommendations on monitoring frequency are thus based to some extent on the physiology of the red blood cell and on expert opinion.

Quality Indicator #2

Improving Glycemic Control

IF a vulnerable elder has an elevated glycosylated hemoglobin level, **THEN** he or she should be offered a therapeutic intervention aimed at improving glycemic control within 3 months if glycosylated hemoglobin is 9.0-10.9 and within 1 month if glycosylated hemoglobin is ≥ 11, **BECAUSE** good glycemic control has been shown to improve outcomes.

Supporting evidence: We identified two randomized clinical trials and two decision analyses that addressed the effects of tight glycemic control among patients with type II diabetes.

The United Kingdom Prospective Diabetes Study 33 (UKPDS 33), a large randomized controlled trial, established that tight control glycemic control in patients with type II diabetes mellitus (median age = 54 years) was associated with a statistically and clinically significant reduction in microvascular

complications and a borderline statistically significant reduction in macrovascular complications of diabetes.[1] Over the ten-year follow-up period of the study, the tight control group had a mean hemoglobin A_{1C} level of 7.0%, compared with 7.9% in the usual care group. The Kaplan-Meier curves published with UKPDS 33 indicate that at least two to three years of tight control are needed before its benefits become apparent. This level of control was associated with an increase from 0.7% to about 1.5% in the annual incidence in major hypoglycemic episodes. These results are in general agreement with a smaller randomized clinical trial from Japan.[2]

A decision analysis study employed a Markov model process to estimate the benefits of glycemic control on microvascular complications in type II diabetes.[3] The model used data extrapolated from the Diabetes Control and Complications Trial (DCCT) and epidemiologic data on complication rates among cohorts of patients with onset of type II diabetes at ages 45, 55, 65, and 75. The results indicated that most of the benefit of glucose control was achieved by decreasing very elevated levels of glucose (as measured by hemoglobin A_{1C}) to 9% and that relatively little was achieved by further reducing the hemoglobin A_{1C} level from 9% to 7%. For example, a person with diabetic onset at age 65 and a hemoglobin A_{1C} level of 11% had an estimated lifetime risk for blindness due to diabetic retinopathy of 1.9%. Decreasing the hemoglobin A_{1C} level to 9% decreased the lifetime risk of blindness to 0.5%, a change of 1.4 percentage points. However, further decreasing the hemoglobin A_{1C} level from 9% to 7% decreased the lifetime risk for blindness from 0.5% to just under 0.1%, a difference of 0.4 percentage point, or about one quarter of the benefit of decreasing hemoglobin A_{1C} from 11% to 9%.

A second decision analysis, using a different set of assumptions, concluded that tight control of non-insulin dependent diabetes was far less cost-effective for patients who developed diabetes at age 75 (> $200,00 per quality-adjusted life-year [QALY]) compared with patients who developed diabetes before age 50 ($20,000 per QALY).[4] This model also concluded that the cost per QALY increased greatly for hemoglobin A_{1C} values of less than 9%.

Very high levels of blood sugar have immediate physiologic consequences. In specific, hemoglobin A_{1C} values greater than 10% have been associated with poor white blood cell functioning and

wound healing.[5] However, other than the UKPDS 33 study and the Japanese study, there is no experimental evidence to support a benefit in terms of health outcomes for intervening at any particular hemoglobin A_{1C} threshold among patients with type II diabetes mellitus. Although the UKPDS patient population was primarily non-elderly, decision analysis suggests that elderly patients with type II diabetes may experience similar benefits from reductions in hemoglobin A_{1C} levels.

Quality Indicator #3

Routine Urine Examination

IF a diabetic, vulnerable elder does not have established renal disease and is not receiving an ACE inhibitor or ACE receptor blocker, **THEN** he or she should receive an annual test for proteinuria, **BECAUSE** this will detect early diabetic nephropathy, and treatment of early diabetic nephropathy will delay the development of renal complications.

Supporting evidence: There is good evidence that the presence of microalbuminuria predicts progression to diabetic nephropathy and is associated with fairly high mortality rates. In 1984, Mogensen reported on a prospective cohort with nine years of follow-up of diabetic patients, originally age 50 to 75, who had microalbuminuria on initial examination.[1] Progression to clinical proteinuria developed in four times as many patients with high levels of microalbuminuria at baseline as in patients with low levels. A similar association was shown with survival. A more recent, larger study, also from Denmark, confirmed that microalbuminuria was predictive of the development of diabetic nephropathy, although the prediction was not as strong as in the original Mogensen report.[2] In the recent Denmark study, about a third (31%) of patients who were microalbuminuric at baseline showed progressive increases in urinary albumin excretion rates over time.

There is good evidence that a urinary albumin concentration or a urinary albumin-to-creatinine ratio in a random urine sample provides a good screening test for microalbuminuria and macroalbuminuria for patients with type II diabetes mellitus.[3] Whether less expensive tests than either direct measurement of microalbuminuria or measurement of the urinary albumin concentration or urinary

albumin-to-creatinine ratio can be used to screen for nephropathy is not agreed upon. A review article concluded that the urinary albumin concentration or the urinary albumin-to-creatinine ratio should be used for screening.[4] A direct comparison of the simple dipstick (Chemstrip) in 221 patients attending primary care or diabetes clinics, using radioimmunoassay of albumin as the gold standard, reported that the sensitivity and specificity of the Chemstrip was 90% and 41%, respectively.[5] In this population, the negative predictive value of a negative Chemstrip was 96%.

There is no evidence to support or refute any recommended interval for performing screening for urinary microalbuminuria. By far, the most commonly recommended interval is one year.

Quality Indicator #4

Treatment of Proteinuria

IF a diabetic, vulnerable elder has proteinuria, **THEN** he or she should be offered therapy with an ACE inhibitor or ACE receptor blocker, **BECAUSE** such therapy can delay the development of renal complications.

Supporting evidence: There is no direct evidence demonstrating that treatment of diabetic patients with ACE inhibitors prevents the development of overt end stage renal failure. However, it is presumed by nearly all clinical authorities that this is the case because it is well established that treatment with ACE inhibitors delays the progression of microalbuminuria and macroalbuminuria to diabetic nephropathy, which itself is the cause of end stage renal failure in patients with diabetes. In one randomized clinical trial, patients with type II diabetes mellitus and normal blood pressure (mean age = 44 years) were randomized to enalapril (10mg/d) or to placebo.[1] After five years, 42% of patients in the placebo group had developed overt proteinuria (i.e., an albumin excretion rate > 300 mg/24 hr), compared with only 12% of patients in the enalapril group. Renal function remained stable in the enalapril group, but it decreased by 13% over five years in the placebo group. The difference in the rate of renal function decline was statistically significant by two years after initiation of treatment. This report was supported by the results of a similar trial of enalapril.[2]

Two meta-analyses, one published[3] and one presented in the Cochrane Database of Systematic Reviews,[4] also report that treatment of normotensive diabetes patients who have microalbuminuria with ACE inhibitors delays the progression of albumin excretion. Both meta-analyses included patients with type I and type II diabetes. In most cases, the studies pooled in the analysis were of one year's duration. Of note, though, is that none of these data are specific to elderly patients.

There are now reports that patients with type II diabetes mellitus and no evidence of microalbuminuria also receive some benefit from treatment with ACE inhibitors.[5]

Quality Indicator #5

Regular Mesaurement of Blood Pressure

IF a vulnerable elder has diabetes, **THEN** his or her blood pressure should be checked at each outpatient visit, **BECAUSE** measurement of blood pressure is a necessary prerequisite to control blood pressure, and control of blood pressure improves outcomes.

Supporting evidence: Good evidence from randomized clinical trials and meta-analyses of randomized clinical trials indicate that the control of blood pressure of diabetic patients is vitally important in improving long-term outcomes. To control blood pressure, it is necessary to first measure blood pressure. However, there are no experimental data to support or refute any recommended interval for the routine measurement of blood pressure in diabetic patients.

Quality Indicator #6

Diabetic Education

IF a diabetic, vulnerable elder has a glycosylated hemoglobin ≥ 10, **THEN** he or she should be referred for diabetic education, at least annually, **BECAUSE** such education may help the patient to better manage his or her diabetes.

Supporting evidence: A meta-analysis published in 1988 summarized the results of 93 studies that tested the effects of the following eight different interventions on 7,451 patients with diabetes mellitus:[1]

- Didactic education
- Enhanced education
- Diet instruction
- Exercise instruction
- Self-monitoring instruction
- Social learning and behavior modification
- Counseling
- Relaxation training.

About half of the studies assessed patients with insulin-dependent diabetes mellitus, about a quarter of them assessed patients with non-insulin-dependent diabetes mellitus, and the remaining quarter assessed patients with both. The overall mean effect size was 0.5 for all interventions combined, which was highly statistically significant. For the individual studies, more than 80% of the effect sizes were positive. Effect size for improvement on physical outcome measures, which included glycosylated hemoglobin and blood glucose levels, were statistically significantly positive for the following:

- Enhanced education (effect size = 0.36)
- Diet instruction (effect size = 0.62)
- Exercise instruction (effect size = 0.31)
- Social learning and behavior modification (effect size = 0.60)
- Counseling (effect size = 0.39).

In the subgroup of studies that measured both six-and twelve-month outcomes, the effect sizes were markedly attenuated at twelve months as compared to six months. This suggests that the effectiveness of these interventions diminishes some time between six and twelve months after they occur.

Quality Indicator #7

Control of Blood Pressure

IF a diabetic, vulnerable elder has elevated blood pressure, **THEN** he or she should be offered a therapeutic intervention to lower blood pressure:

- within 3 months if blood pressure 150-160/90-100 mmHg
- within 1 month if blood pressure > 160/100 mmHg

BECAUSE reducing blood pressure improves outcomes among patients with type II diabetes.

Supporting evidence: The United Kingdom Prospective Diabetes Study 38 (UKPDS 38), a randomized clinical trial, randomly assigned 1,148 hypertensive patients with type II diabetes (mean age = 56 years) and a mean blood pressure at entry of 160/94 mmHg to either tight control of blood pressure or less tight control.[1] Tight blood pressure control consisted of a target of < 150/85 mmHg using either an ACE inhibitor or a beta blocker; less tight control consisted of maintaining a blood pressure of < 180/105 mmHg. The mean blood pressure control in the group assigned to tight therapy was 144/82 mmHg, compared to a mean blood pressure of 154/87 mmHg in the group assigned to less tight control. Median follow-up time was 8.4 years. Patients assigned to tight control experienced the following effects:

- A 24% reduction in diabetes related endpoints
- A 32% decrease in deaths related to diabetes
- A 44% decrease in strokes
- A 37% decrease in microvascular endpoints

Examination of the Kaplan-Meier plots provided in the original article indicated in general that the curves for the tight control versus less tight control began to diverge between two or three years after initiation of therapy, and that they clearly diverged by five years after initiation of therapy. A cost-effectiveness analysis based on the same data reported that the cost per year of life free from any of the study endpoints was about $1,600, with costs and effects discounted at 6% per year.[2]

These data are supported by similar results from the Hypertension Optimal Treatment (HOT) trial. In the subgroup of 1501 patients with diabetes (mean age of overall population = 62 years), patients randomized to a target diastolic blood pressure of ≤ 80 mm Hg experienced half the number of major cardiovascular events over the four-year follow-up period that patients randomized to a target diastolic blood pressure of ≤ 90 mm Hg experienced.[3]

The efficacy of lowering isolated systolic hypertension among diabetic patients age 60 or older was established by a subgroup analysis of the Systolic Hypertension in the Elderly Program. In this report, the five-year major cardiovascular disease event rate was 34% lower among patients in the active therapy group relative to the placebo group.[4]

A meta-analysis in the Cochrane Database of Systematic Reviews that reported data from 15 trials, including studies of both primary prevention and secondary prevention, also concluded that blood pressure reduction was associated with significant or borderline significant improvements in cardiovascular mortality, all-cause mortality, and cardiovascular morbidity endpoints.[5] It should be noted that most of these data come from primarily non-elderly populations. Another meta-analysis in the Cochrane Database of Systematic Reviews concluded that the evidence supporting the efficacy of blood pressure control for persons under age 80 is clear and convincing.[6]

Despite relatively small differences in mean blood pressures, the treatment group (144/82 mmHg) and the control group (154/87 mmHg) in the UKPDS 38 study still experienced substantial differences in

outcomes. This suggests that a blood pressure target of 140/90 mmHg among middle-aged patients with type II diabetes may be inappropriately lenient.

Quality Indicator #8

Aspirin

ALL diabetic vulnerable elders should be offered daily aspirin therapy **BECAUSE** the regular use of aspirin among diabetic patients reduces the risk of myocardial infarction and mortality from cardiac causes.

Supporting evidence: The prophylactic use of aspirin therapy for high risk patients has been advocated to reduce the risk of myocardial infarction, stroke, and cardiac mortality. Substantial randomized clinical trial evidence and meta-analyses of randomized clinical trials support the use of aspirin for the general population of high risk patients (patients with current or past history of myocardial infarction, stroke, or other relevant vascular disease), but few such studies have addressed the diabetic patient population. One meta-analysis, published in 1992, reviewed 145 trials of antiplatelet therapy versus placebo and identified seven trials that contained data specific to diabetic patients.[1] These trials, in aggregate, included over 1300 patients. There was no clinically or statistically significant benefit for aspirin therapy in reducing the risk of myocardial infarction, stroke, or vascular death. However, the 95% confidence intervals were broad and included the point estimate of the overall pooled effect of aspirin in the other population of high risk patients, which consists of an odds reduction of about 25%.

A large randomized clinical trial published in 1994 reported the results of ingesting 650 mg per day of aspirin versus placebo for 3711 patients with both type I and type II diabetes mellitus.[2] At an average of five years of follow-up, all-cause mortality was 19.7% in the group treated with placebo and 18.3% in the group treated with aspirin, a difference that did not reach the predetermined threshold of 99% statistical significance. Similar results were seen for cardiovascular outcomes. While these risk reductions of 10% to 20% are consistent with the effects of aspirin observed in studies of other high risk populations, the results did not reach the 99% level of statistical significance.

A recent observational study of diabetic patients with known coronary artery disease (mean age = 60 years) reported that overall cardiac mortality at five years of follow-up was 10.9% among the 52% of diabetic patients taking aspirin compared with 15.9% in the non-aspirin group ($p < 0.001$).[3] The study reported similar differences in all-cause mortality. These results persisted after adjustment for possible confounders.

Quality Indicator #9

Treatment of Lipids

IF a diabetic, vulnerable elder has fasting total cholesterol >= 240 g/dl, **THEN** he or she should be offered an intervention to lower cholesterol, **BECAUSE** lowering cholesterol in diabetic patients will decrease major coronary heart disease events and possibly mortality.

Supporting evidence: The Scandinavian Simvastatin Survival Study (4S), a randomized controlled trial, randomly assigned 4,242 non-diabetic patients and 202 diabetic patients who had previous myocardial infarction or angina pectoris and total serum cholesterol ≥ 5.5 mmol/L to 20 mg simvastatin or to placebo.[1] The average age of diabetic patients was 60 years, and 17% of these patients already had established proteinuria. Follow-up was up to six years.

At follow up, 17.5% of placebo patients had died from coronary heart disease, compared to 11.4% of patients taking simvastatin. Death from all causes occurred in 24.7% of patients taking placebo versus 14.3% of patients taking simvastatin. Non-fatal, definite myocardial infarction occurred in 24.7% of patients receiving placebo, but only 6.7% of patients receiving simvastatin. Similar differences were seen in other cardiac and vascular outcomes.

Compared with the statistically significant risk reductions in the non-diabetic patients (which were reported for total mortality, coronary heart disease mortality, major coronary heart disease events, any coronary heart disease event, and any atherosclerotic event), the risk reductions for the diabetic patients were all consistently greater (i.e., more benefit). Not all of these additional reductions in risk

were statistically significant, though, possibly due to the smaller sample size of the diabetic patients. The relative risk of any of the events among diabetic patients treated with simvastatin was between 0.4 and 0.7.

There is no direct evidence that lowering lipid levels in diabetic patients without coronary heart disease is associated with improvements in outcomes. However, there is direct evidence in the non-diabetic population that this is so. Based on the observation that diabetic patients in the 4S study experienced an even greater benefit from lipid lowering than did patients without diabetes, an indirect argument can be made that the relative risk reduction due lowering lipid levels is likely to be equal or greater among patients with diabetes.

Quality Indicator #10

Routine Eye Examination

IF a diabetic, vulnerable elder is not blind, **THEN** he or she should receive an annual dilated eye examination performed by an ophthalmologist, optometrist or diabetes specialist, **BECAUSE** early identification of diabetic retinopathy can facilitate early treatment to prevent blindness.

Supporting evidence: Although diabetic retinopathy is one of the most common causes of blindness among American adults, early detection and treatment of this condition can minimize visual loss. In the Wisconsin Epidemiologic Study of Diabetic Retinopathy, the rate of proliferative diabetic retinopathy varied from 2% in persons who had diabetes for less than five years, to 15.5% in persons who had diabetes for 15 or more years.[1] Two randomized clinical trials, which included patients with type I and type II diabetes mellitus, have established that early treatment of diabetic retinopathy with photocoagulation is highly effective.[2,3] These two studies show that treatment with photocoagulation reduces the rate of developing visual loss in patients with proliferative retinopathy and macular edema by about 50%. Inspection of the Kaplan-Meier curves accompanying the original reports indicated that the two survival curves diverged as soon as six to eight months after initiation of therapy.

Other studies have assessed the sensitivity of various screening methods to detect early diabetic retinopathy. One review reported a wide range of sensitivities, based on both the method and the type of health care professional who performed the screening.[4] They varied from a low of 0% when dilated direct ophthalmoscopy was performed by a nurse, to 49% when dilated direct and indirect ophthalmoscopy was performed by internists, to 70% to 97% when dilated and non-dilated direct and indirect ophthalmoscopy was performed by diabetologists or ophthalmologists. In most cases, the gold standard for diagnosis is stereoscopic fundus photography.

Decision analytic models have concluded that screening for diabetic retinopathy is cost saving when the cost for disability due to blindness is considered.[5,6] The cost-savings are less or non-existent for older patients with type II diabetes mellitus, although screening is still highly cost-effective by usual standards. There are no experimental data to support any particular recommendation for the interval at which patients should be examined for diabetic retinopathy. Published decision analytic models have generally used yearly screening for their estimation of the benefits of routine examination. A recent decision analysis, published after the development of these indicators, suggests that Type II diabetic patients who are well controlled do wait 2 or even 3 years between regular eye examinations (Vijan S, Hofer TP, Hayward RA; JAMA; 2000 Feb; 16;283(7):889-96).

Five additional quality indicators were proposed but not accepted by the expert panel (Table 4). The summary of the evidence regarding these indicators can be obtained from the author. Failure to be accepted should not be construed as indicating that these indicators do not represent good care. In many cases, the expert panel felt the indicator did represent good care but that there were so many "exceptions to the rule" that failure to adhere to the indicator did not have sufficient specificity to warrant its acceptance. In other cases, the proposed indicator was judged not to have adequate scientific support to justify its use.

DISCUSSION

Diabetes imposes a significant burden on individuals with this disease state and on the health care system. Vulnerable elders are at especially increased risk of morbidity and mortality from diabetes. Elderly patients with diabetes, as in other patient populations, frequently experience significant variations in processes and outcomes of care. Improvements in processes of care for this high-risk population may lead to substantial reductions in disease burden and improvements in patient outcomes. This project investigated the relationship between processes and outcomes of care and aimed to develop explicit criteria to evaluate the quality of care of elderly individuals with diabetes. Fifteen indicators were judged sufficiently valid for use as measures of quality of diabetes care for vulnerable elders. These indicators can potentially serve as a basis to compare the care provided by different health care delivery systems and for comparing the change in care over time.

Table 1. Literature Search

Source	Time Period	Search Terms	Citations
Cochrane Database of Systematic Reviews		diabetes mellitus	46
Database of Abstracts of Reviews of Effectiveness (DARE)		diabetes mellitus	42
MEDLINE, Embase	1997-1998	[diabetes mellitus (exploded and major)] + [“clinical trial-“ (exploded) or document type “clinical trials” or document type “randomized controlled trial” or “costs and cost analysis” (exploded from MEDLINE) or “cost” (exploded from Embase) or “economic evaluation” (exploded from Embase) or “ meta analys-“ (truncated) or document type or “meta-analysis” or “decision making” (exploded from MEDLINE) or “decision support techniques” (exploded from MEDLINE) or “decision making” from Embase or “decision” within 2 words of “analys-“ or “support” from Embase] + [The following journals: JAMA, New England Journal of Medicine, Lancet, British Medical Journal, Annals of Internal Medicine, Archives of Internal Medicine, Diabetes Care, Diabetes] + [human only]	251

Table 2. Comprehensive Listing of Clinical Practice Guidelines and Quality Indicators

Guideline Name	Organization	Reference
Clinical Practice Recommendations 1998. J of Clinical and Applied Research and Education. 1998;21 (Suppl 1). www.diabetes.org/diabetescare/supplement198/default.htm	American Diabetes Association	1
AACE Guidelines for the Management of Diabetes Mellitus, 1995. www.aace.com/clin/guides/diabetes_guide.html	American Association of Clinical Endocrinologists	2
Matfin GM, Guven S. Diagnosing Diabetes Mellitus: Do We Need New Criteria? 1998. www.aace.com/clin/fcc/newcrit.html	American Association of Clinical Endocrinology	3
Diet and Exercise in Non-Insulin Dependent Diabetes Mellitus. NIH Consensus Development Conference Statement Online. December 8-10 1986;6(8):1-21. http://odp.od.nih.gov/consensus/cons/060/060_statement.htm	NIH	4
Sox HC. Tests of Glycemia in Diabetes Mellitus. Common Diagnostic Tests: Use and Interpretation. American College of Physicians - Clinical Efficacy Project, 2nd Edition, 1990.	American College of Physicians	5
Singer, DE, et al. "Screening for Diabetes Mellitus." Annals of Internal Medicine. 1988;109:639-649.	American College of Physicians	6
Working Group on Hypertension in Diabetes. Bethesda, MD. 1995.	NIH - National Heart, Lung, and Blood Institute	7
Management of Diabetes Mellitus. Jacksonville, FL. 1994.	American Association of Clinical Endocrinologists	8
Kelly DB, et al. Intensive Diabetes Management, 2nd Edition. Alexandria, VA: American Diabetes Association - Clinical Education Series, 1998.	American Diabetes Association	9
Lebovitz HE (ed.). Therapy for Diabetes Mellitus and Related Disorders, 3rd Edition. Alexandria, VA: American Diabetes Association - Clinical Education Series, 1998.	American Diabetes Association	10
Ruderman N and Devlin JT. The Health Professional's Guide to Diabetes and Exercise. Alexandria, VA: American Diabetes Association - Clinical Education Series, 1995.	American Diabetes Association	11
"Monitoring Quality of Primary Care: A Self-Assessment Workbook, DEMPAQ Record Review Criteria, Diabetes," in Palmer RH, Clark LE, Lawthers AG, Edwards JE, Fowles J, Garnick D, Weiner J. DEMPAQ: A Project to Develop and Evaluate Methods to Promote Ambulatory Care Quality, Final Report, Volume III. Boston, MA: Harvard School of Public Health, 1994.	Harvard School of Public Health	12
"Diabetes Profile," in Palmer RH, Clark LE, Lawthers AG, Edwards JE, Fowles J, Garnick D, Weiner J. DEMPAQ: A Project to Develop and Evaluate Methods to Promote Ambulatory Care Quality, Final Report, Volume III. Boston, MA: Harvard School of Public Health, 1994.	Harvard School of Public Health	13

"Monitoring Quality of Primary Care: A Self-Assessment Workbook, DEMPAQ Record Review Criteria, Glucose-Fasting and Random Blood Levels," in Palmer RH, Clark LE, Lawthers AG, Edwards JE, Fowles J, Garnick D, Weiner J. DEMPAQ: A Project to Develop and Evaluate Methods to Promote Ambulatory Care Quality, Final Report, Volume III. Boston, MA: Harvard School of Public Health, 1994.	Harvard School of Public Health	14
Quality Improvement/Clinical Guidelines: Management of Diabetes Mellitus in Adults. Humana, Inc. Quality Improvement/Clinical Guidelines: Management of Diabetes Mellitus in Adults. Humana, Inc. www.humana.com/providers/guidelines/mellitus.html	Humana, Inc.	15
Screening for Diabetes Mellitus. US Preventive Services Task Force. Guide to Clinical Preventive Services, 2nd Ed. Alexandria, VA: International Medical Publishing, 1996.	US Preventive Services Task Force	16
Diabetes Mellitus, Reference Guide, 6th Edition. Lexington, KY; 1997.	American Board of Family Practice	17
FACCT Quality Measures - Diabetes. Foundation for Accountability. www.faact.org/measures/existing_measures/diabetes.html	Foundation for Accountability	18

Table 3. Quality Indicators Judged by the Expert Panel as Valid for the Assessment of Care for Heart Failure in Vulnerable Elders

1.	**IF** a vulnerable elder has an elevated glycosylated hemoglobin level, **THEN** he or she should be offered a therapeutic intervention aimed at improving glycemic control within 3 months if glycosylated hemoglobin is 9.0-10.9 and within 1 month if glycosylated hemoglobin is ≥ 11.
2.	**IF** a vulnerable elder has an elevated glycosylated hemoglobin level, **THEN** he or she should be offered a therapeutic intervention aimed at improving glycemic control within 3 months if glycosylated hemoglobin is 9.0-10.9 and within 1 month if glycosylated hemoglobin is ≥ 11.
3.	**IF** a diabetic, vulnerable elder does not have established renal disease and is not receiving an ACE inhibitor or ACE receptor blocker, **THEN** he or she should receive an annual test for proteinuria.
4.	**IF** a diabetic, vulnerable elder has proteinuria, **THEN** he or she should be offered therapy with an ACE inhibitor or ACE receptor blocker.
5.	**IF** a vulnerable elder has diabetes, **THEN** his or her blood pressure should be checked at each outpatient visit.
6.	**IF** a diabetic, vulnerable elder has a glycosylated hemoglobin ≥ 10, **THEN** he or she should be referred for diabetic education, at least annually.
7.	**IF** a diabetic, vulnerable elder has elevated blood pressure, **THEN** he or she should be offered a therapeutic intervention to lower blood pressure: • within 3 months if blood pressure 150-160/90-100 mmHg • within 1 month if blood pressure > 160/100 mmHg
8.	**ALL** diabetic vulnerable elders should be offered daily aspirin therapy.
9.	**IF** a diabetic, vulnerable elder has fasting total cholesterol >= 240 g/dl, **THEN** he or she should be offered an intervention to lower cholesterol.
10.	**IF** a diabetic, vulnerable elder is not blind, **THEN** he or she should receive an annual dilated eye examination performed by an ophthalmologist, optometrist or diabetes specialist.

Table 4. Quality Indicators Not Judged by the Expert Panel as Valid for the Assessment of Care for Heart Failure in Vulnerable Elders

• **ALL** vulnerable elders over age 65 should be screened at least once for type II diabetes mellitus.
• **IF** a vulnerable elder has diabetes mellitus, **THEN** he or she should use some form of self-monitoring of blood glucose
• **IF** a vulnerable elder has diabetes, **THEN** he or she should have regular examinations of his or her feet
• **IF** a vulnerable elder has diabetes, **THEN** he or she should receive an annual test of fasting lipids, including low-density lipoprotein cholesterol and high-density lipoprotein cholesterol
• **IF** a diabetic, vulnerable elder with multivessel coronary disease is to undergo coronary revascularization, **THEN** he or she should have coronary artery bypass graft surgery rather than angioplasty

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