Development of Evidence-Based Clinical Practice Guidelines for Diabetes

The Department of Veterans Affairs/Department of Defense Guidelines Initiative

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OBJECTIVE — To describe the Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guidelines for diabetes and contrast selected recommendations with those of the American Diabetes Association (ADA).

RESEARCH DESIGN AND METHODS — We summarize the general structure of the VA/DoD Guidelines and describe the rationale for recommendations issued in 2003 for glycemic control, management of hypertension, and retinopathy screening. We compare the synthesis of evidence and resulting recommendations for these content areas with the 2004 American Diabetes Association Clinical Practice Recommendations.

RESULTS — The VA/DoD Guidelines and the ADA Clinical Practice Recommendations reported similar strength of evidence findings by content area, but clinical recommendations varied. The VA/DoD Guidelines and practice recommendations emphasize the use of data on absolute risk reduction from available published randomized clinical trials rather than relative risk reduction from observational analyses. The VA/DoD Guidelines employ an algorithm-based methodology to guide clinicians through a risk-stratified approach to managing individual patients rather than promoting a single standard for most or all patients without explicit consideration of competing comorbidities.

CONCLUSIONS — The VA/DoD Guidelines are intended to guide diabetes care by providing Internet-ready, evidence-based annotations in algorithmic form to help clinicians set and revise individual treatment goals for their patients.

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The Department of Veterans Affairs (VA) and Department of Defense (DoD) together comprise the largest nationwide system of integrated medical care in the U.S. In 2003, the VA and DoD provided health care to about 4.6 million veterans and over 2 million military health care beneficiaries, respectively (1). In order to reduce practice variation, to optimize the widespread use of best practices, and to provide common metrics for self-assessment, performance measurement, and benchmarking, the VA and DoD agreed upon a joint approach to the development of guidelines, including those for the care of patients with diabetes.

The major guiding principle for the joint venture was the development of evidence-based recommendations in a format intended to be helpful and flexible for clinicians. The Guideline Development Group sought to provide primary care clinicians with a summary of the best available evidence to guide recommended actions, including initiation of diet and drug therapy and referral of patients to specialists. The Diabetes Guideline Development Group intended that the guidelines would help clinicians improve their individual knowledge, clinical care, and efficiency in the delivery of high-quality care to the >1,000,000 persons affected by diabetes in the VA/DoD health care networks.

General process for the joint development of the diabetes guidelines

The first iteration of diabetes practice guidelines was developed by the VA and published in March 1997. The original guidelines emphasized management of type 2 diabetes because nearly 95% of this population of veterans, active and retired military personnel, and dependents have type 2 diabetes. Over 70 experts representing diverse VA health care professionals, federal agencies, and experts from

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Abbreviations: ADA, American Diabetes Association; DBP, diastolic blood pressure; DoD, Department of Defense; SBP, systolic blood pressure; UKPDS; U.K. Prospective Diabetes Study; VA, Veterans Affairs.

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Table 1 —*Strength of evidence*

Quality of evidence	
I	At least one properly done randomly controlled trial
II-1	Well-designed controlled trial without randomization
II-2	Well-designed cohort or case-control analytic study
II-3	Multiple time series, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, case reports, and expert committees
Overall quality	
Good	High-grade evidence (I or II-1) directly linked to health outcome
Fair	High-grade evidence (I or II-1) linked to intermediate outcome, or grade evidence (II-2 or -3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Source: U.S. Preventive Services Task Force (3).

clinical and academic settings participated in the initial guideline development process. After the joint VA/DoD agreement in 1999, the diabetes guidelines were updated by an expert panel representing the Development Group and reissued in 2000. New scientific findings from randomized controlled trials, analytic studies, and observational studies of glycemic control, hypertension, hyperlipidemia, renal disease, foot care, eye care, and diabetes education were included, and the guidelines were reissued again in 2002/2003. The guidelines and algorithms are available on the Internet to facilitate clinician access (2).

General structure of the guidelines

Using structured evidence reviews that were independently prepared, a module was developed for each of eight areas of diabetes care: screening, glycemic control, hypertension, lipids, nephropathy, retinopathy screening, foot risk screening, and diabetes education/self-monitoring. The group developing each module critically reviewed relevant literature for scientific merit, clinical relevance, and applicability to the federal health care system. Each module was organized for ease of use by clinicians, beginning with an algorithm that followed a consistent "yes/no" format and followed by appropriate annotations, descriptive tables, discussion, and references. Recommendations were embedded in each algorithm. The strength of the recommendations, as well as the level of evidence cited, was graded using recommendations from the U.S. Preventive Services Task Force as summarized in Tables 1 and 2 (3). Annotations for each module were provided to synthesize the evidence and identify references supporting recommendations.

Comparison with the American Diabetes Association Clinical Practice Recommendations

The VA/DOD Guidelines and American Diabetes Association (ADA) Clinical Practice Recommendations incorporated explicit grading criteria in 2000. However, VA/DoD and ADA guidelines differ in the evidence synthesis and formulation of clinical practice recommendations. VA/DoD evidence-based guidelines are explicit in promoting a risk stratification approach in clinical decision making. Algorithms accompany text and quickly guide clinicians to decision points where they assess the risks and benefits of therapeutic targets for individual patients. The VA/DoD Guidelines do not propose single "optimal" or "ideal" target values to be applied to most or all patients. We illustrate these points in the following sections by describing the following content areas: glycemic control, management of hypertension, and assessment of retinopathy.

Glycemic control

Overview of available evidence. Clear evidence from prospective randomized clinical trials in patients with both type 1 and type 2 diabetes indicates that outcomes related to microvascular damage are related to glycemic control (4–7). The Diabetes Control and Complications Trial is the largest trial of intensive insulin therapy in type 1 diabetes. Patients receiving intensive therapy over an average 6.5-year follow-up period reduced their risk of development and progression of reti-

Table 2 —*Strength of recommendation*

Net effect of the intervention	
Substantial	More than a small relative impact on a frequent condition, with a substantial burden of suffering, or a large impact on an infrequent condition, with a significant impact on the individual patient level
Moderate	A small relative impact on a frequent condition, with a substantial burden of suffering, or a moderate impact on an infrequent condition, with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition, with a substantial burden of suffering, or a small impact on an infrequent condition, with a significant impact on the individual patient level
Zero or negative	Negative impact on patients or no relative impact on either a frequent condition, with a substantial burden of suffering, or an infrequent condition, with a significant impact on the individual patient level
Grade the recommendation	
A	A strong recommendation that the intervention is always indicated and acceptable
B	A recommendation that the intervention may be useful/effective
C	A recommendation that the intervention may be considered
D	A recommendation that a procedure may be considered not useful/effective or may be harmful
I	Insufficient evidence to recommend for or against, the clinician will use clinical judgment

Source: U.S. Preventive Services Task Force (3).

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Table 3 —*Determination of target HbA_{1c}*

Major comorbidity or advanced physiologic age*	HbA_{1c} recommendation by microvascular complications		
	Absent or mild†	Moderate‡	Advanced§
Absent¶	7%(<1% above upper normal range)	<8% (<2% above upper normal range)	<9% (<3% above upper normal range)
Present‖	<8% (<2% above upper normal range)	<8% (<2% above upper normal range)	<9% (<3% above upper normal range)
Marked**	<9% (<3% above upper normal range)	<9% (<3% above upper normal range)	<9% (<3% above upper normal range)

*Major comorbidity includes, but is not limited to, any or several of the following conditions: cardiovascular disease, chronic obstructive pulmonary disease, chronic liver disease, stroke, malignancy, etc. †Mild microvascular disease is defined by early background retinopathy and/or microalbuminuria and/or mild neuropathy. ‡Moderate microvascular disease is defined by preproliferative (without severe hemorrhage, intraretinal microvascular abnormality, or venous bleeding) or retinopathy or persistent fixed proteinuria (macroalbuminuria) and/or demonstrable peripheral neuropathy (sensory loss). §Advanced microvascular disease is defined by severe nonproliferative (with severe hemorrhage, intraretinal microvascular abnormality, or venous bleeding) or proliferative retinopathy and/or renal insufficiency (serum creatinine >2.0 mg/dl) and/or insensate extremities or autonomic neuropathy (gastroparesis, impaired sweating, orthostatic hypotension, etc.). ¶Surrogate for >15 years of life expectancy. ‖Moderate degree of major comorbid condition (surrogate for 5–15 years of life expectancy). **Severe degree or end-stage major comorbid condition (surrogate for <5 years of life expectancy).

nopathy by 63%, their risk of severe retinopathy by 47%, their risk of early nephropathy (microalbuminuria) by 39%, their risk of fixed proteinuria by 54%, and their risk of detectable neuropathy by 60% compared with patients on conventional treatment (4). Few end-stage microvascular complications (end-stage renal disease, blindness, and amputations) occurred in either the control group or the intensive therapy group.

The benefit of glycemic control in type 2 diabetes was convincingly demonstrated in the U.K. Prospective Diabetes Study (UKPDS). In the UKPDS, 2,729 patients were randomized to receive intensive treatment with the goal of fasting plasma glucose <6 mmol/l with any necessary combination of diet, oral hypoglycemic agent, and/or insulin, whereas 1,138 patients were randomized to receive diet-only therapy with a goal of attaining fasting plasma glucose <15 mmol/l. Over 10 years of observation, the mean HbA_{1c} was significantly lower in the intensive treatment group compared with the diet-only group (7.0 vs. 7.9%, $P < 0.001$). The absolute risk reduction in diabetes-related clinical end points was about 5 per 1,000 patient-years (41 vs. 46 events/1,000 patient-years, $P = 0.03$). The lower incidence of microvascular complications ($P = 0.01$) among the intensive group over an average of 10 years was primarily due to a reduction in photocoagulation treatment for retinopathy (6). There was a nonstatistically significant reduction in coronary disease, stroke, diabetes-related deaths, and all-cause mortality between the intensive and diet groups. Amputation, end-stage renal disease, and blindness were uncommon outcomes in both study groups.

Establishment of glycemic target values. The VA/DoD Guidelines encourage health care providers and their patients to establish individually negotiated targets based on personal preferences and individually appraised risks and benefits. Clinicians' decision making compares the likelihood that a proposed treatment will produce benefit compared with the likelihood of known treatment risks. Thus, in developing targets for glycemic control, the VA/DoD Diabetes Guideline Development Group addressed three issues: *1*) which patients have the most, or the least, to gain by excellent glycemic control with regard to microvascular damage; *2*) which patients may be harmed by efforts at intensive control; and *3*) in which patients would severe comorbidity, and its attendant decreased life expectancy, attenuate the benefits of excellent glycemic control?

Who might benefit from near-normal glycemic control? Based on the accumulated evidence from well-designed clinical trials, a strong case can be made for intensive glycemic control among patients who are free, or nearly free, from diabetic microvascular disease and who are, at the same time, otherwise healthy and without psychosocial contradictions, such as substance abuse. This is not the case for patients with existing microvascular disease because the large trials of intensive therapy in both type 1 and type 2 diabetes excluded patients with significant microvascular damage (proliferative retinopathy, renal insufficiency and/or fixed proteinuria, and significant peripheral and/or autonomic neuropathy) (4–7). Thus, there is currently little evidence that intensive glycemic control improves or delays the rate of progression of moderate or advanced microvascular disease, as is defined in Table 3.

Who may be harmed by intensive glycemic control? Intensive glycemic control is known to increase the incidence and severity of hypoglycemia. Further, in type 1 diabetes, autonomic neuropathy enhances the risk of hypoglycemic unawareness, thus patients experience no adrenergic warning symptoms of hypoglycemia (e.g., nervousness, palpitations, increased sweating, or anxiety) before the onset of neurocognitive dysfunction (amnesia, behavioral disturbance, loss of consciousness, or seizure). Psychosocial problems, substance abuse, or impaired vision may result in impaired ability to self-adjust insulin doses; to accurately perform, interpret, and record blood glucose self-monitoring; or to recognize symptoms of hypoglycemia, thereby potentiating the risk of severe hypoglycemia. Patients with significant renal disease may have a prolonged biologic half-life of insulin and oral agents, thereby enhancing the risk of unintended episodic supply-and-demand mismatch and the likelihood of hypoglycemia. These factors need to be critically appraised by clinicians as they negotiate treatment goals and glycemic targets with their patients.

In whom does severe comorbidity attenuate the benefit of glycemic control? The impact of significant comorbid health conditions on diabetes-specific treatment outcomes is largely unstudied. It is difficult to extrapolate results from trials in otherwise healthy diabetic patients to populations of patients exhibiting severe comorbidities because these conditions (e.g., metastatic cancer, Childs' Class C cirrhosis, or chronic obstructive lung disease with cor pulmonale) reduce life ex-

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pectancy and thus the length of time that diabetes will persist. The reduced duration of diabetes can be expected to produce fewer microvascular complications. This is another consideration for practitioners negotiating glycemic control targets with their patients.

In the development of the VA/DoD Guidelines, life expectancy was considered to be a proxy for the effect of comorbid conditions on the benefit of glycemic control. To evaluate this factor, the VA/DoD Guidelines relied on previous estimates from Markov model computer simulations where absolute risk reduction of end-stage microvascular complications was using age of diabetes onset as a surrogate for life expectancy (8,9). A limitation of these studies was their failure to model the development and effect of intermediate complications (such as visual loss or neuropathy) on patients' quality of life. Studies (7,8) estimate that the incidence of end-stage microvascular complications is low when diabetes develops at age ≥65 years, primarily because life expectancy is <10 years.

In practice, life expectancy is difficult to assess. However, others have shown that physicians can accurately estimate severity of illness without the use of complex medical models. In one study (10) of 604 medical inpatients, physicians' assessment of patients as minimally, mildly, moderately, or severely ill or moribund correlated well with observed mortality rates. Until computerized life expectancy calculators are readily available, physicians must use their judgment in assessing a patient's severity of illness and life expectancy.

Recommendations for glycemic control. Based upon these considerations, the VA/DoD Guideline recommends a stringent glycemic control target (HbA_{1c} <7.0%) for patients with a life expectancy >15 years who have no, or only minimal, microvascular complications. A less stringent minimum target (HbA_{1c} <8.0%) is appropriate for patients with life expectancy of 5–15 years or for those who have preproliferative or severe proliferative retinopathy, fixed proteinuria, or severe sensorimotor or autonomic neuropathy. For patients with life expectancy <5 years because of advanced physiologic age or severe comorbidity, a less stringent minimum HbA_{1c} target (<9.0%) is recommended. The incidence of microvascular complications in such patients is estimated to be quite low, and attainment of this target goal should prevent symptoms of uncontrolled hyperglycemia. Thus, the target value for an individual patient considers the approximate risk-to-benefit ratio of the treatment necessary to achieve it. Table 3 is a tool to assist in negotiating an appropriate target for glycemic control.

The 2004 ADA Clinical Practice Recommendations recommend <7% as a target level for glycemic control in adults and encourage negotiation of target levels as low as 6%. However, the ADA notes that a major limitation is that the available data do not identify the optimum level of control for particular patients because there are individual differences in risks and adverse effects (11). The ADA Clinical Practice Recommendations state that there are no clinical trial data available for the effects of glycemic control in patients with advanced complications and in the elderly (≥65 years of age) and acknowledge that less stringent goals may be appropriate for individuals with limited life expectancy (11).

Hypertension in diabetes

The decision to treat. Hypertension is common in diabetes and is associated with the onset and progression of both microvascular and macrovascular complications. Multiple clinical trials in hypertensive patients document the efficacy of antihypertensive treatment in reducing the morbidity and mortality of cardiovascular disease. There is evidence for this benefit among hypertensive patients with diabetes in the subgroup analyses of the Systolic Hypertension in Europe (Syst-Eur) trial (12), the Hypertension Optimal Treatment (HOT) Trial (13), and the UKPDS Tight Blood Pressure Control study (14).

The systolic blood pressure (SBP) and diastolic blood pressure (DBP) treatment targets recommended by the VA/DoD Group were derived from the results of the HOT and UKPDS trials. In the HOT trial, a cohort of 1,500 patients with diabetes and an initial DBP of 100–115 mmHg were randomized to one of three treatment target diastolic pressures of <90, <85, and <80 mmHg. Fewer major cardiovascular events were observed in the groups targeted for a DBP <85 mmHg (mean DBP attained was 87 mmHg) or <80 mmHg (mean DBP attained was 82 mmHg) compared with the group targeted for a DBP <90 mmHg. By contrast, targeting an SBP <140 mmHg was not associated with fewer cardiovascular events (13).

In the UKPDS, 1,148 patients with diabetes and hypertension were randomly assigned to either a "tight" control target of <150/85 mmHg or a "conventional" target of <180/105 mmHg. Compared with the "conventional" group, which attained a mean blood pressure of 154/87 mmHg, the "tight" treatment group, which attained a mean blood pressure of 144/82 mmHg, had 24% fewer pooled microvascular and cardiovascular events (14). Since patients were not randomized to lower intensive treatment targets, the results of the UKPDS study did not establish an additional benefit of lowering blood pressure to <135 mmHg as compared with a target of <140 mmHg, at least in patients without renal insufficiency (14).

Therefore, the VA/DoD Guidelines recommend initiation of antihypertensive treatment in individuals with diabetes who have SBP ≥140 mmHg and/or DBP ≥80 mmHg. Although the definition of hypertension is SBP ≥140 and/or DBP ≥90, evidence supports treatment when DBP is >80 mmHg (12–14).

The 2004 ADA Position Statement (15) recommends a target blood pressure <130/80 mmHg for most patients with diabetes, based on epidemiological data, while acknowledging that randomized clinical trials have demonstrated the benefit of lowering blood pressure to <140 mmHg and <80 mmHg diastolic in individuals with diabetes. Actually, these studies (16) demonstrated the benefit of taking up to 3–4 antihypertensive medications, with a "goal" diastolic blood pressure of <80 mmHg. Ongoing clinical trials are designed to determine whether more intensive treatment to achieve lower target blood pressures, particularly for SBP, is associated with improved outcomes.

Retinopathy screening

Periodic screening for diabetic retinopathy is well established as a cost-effective strategy for preventing vision loss (17–19) when accomplished as fundoscopy through dilated pupils (20) or multifield fundus photography interpreted by an experienced reader (21). However, there is

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no experimental controlled research on the optimal screening intervals. If previous retinal exams have been normal, there is no evidence to suggest that patients receive substantial clinical benefit from a repeat eye examination for diabetic retinopathy at intervals more frequent than every other year. Data from the Early Treatment Diabetic Retinopathy Study suggest that individuals free of retinopathy at baseline are unlikely to progress to proliferative retinopathy within 2 years (22). These findings were subsequently confirmed by analyses conducted on the UKPDS cohort (23,24). The authors confirmed that early retinopathy on previous examinations was the main risk factor for requiring photocoagulation within the next 3–6 years. Of 2,316 patients with no retinopathy at baseline, only 0.2% required any photocoagulation within 3 years and only 1.1% needed treatment within 6 years, despite this cohort having many patients with poor glycemic and blood pressure control. There is no additional published epidemiological evidence to suggest that screening intervals more frequent than every other year provide clinical benefit for those whose previous examinations have been normal. Indeed, there is some evidence to suggest that progression to advanced disease within 2–3 years is also very rare for those with minimal retinopathy (23), reinforcing the conservative nature of the VA-DOD clinical recommendation to restrict biennial screening only to individuals with no prior retinopathy.

The VA-DOD Group recommended that clinicians exert caution in extending biennial (every other year) examinations to those patients at high risk for retinopathy and retinopathy progression. Although the UKPDS results suggest that 2-year screening intervals are adequate even when the patient population includes many with poor glycemic and blood pressure control (14), there may still be high-risk patients for whom every 12 to 18 months screening is preferable. Risk factors for rapid progression of retinopathy include poor glycemic or blood pressure control, pregnancy with preexisting diabetes, and recent initiation or intensification of insulin therapy (25–30). Risk factors for a high prevalence of retinopathy include the following: evidence of other glycemic-related complications (nephropathy and neuropathy), need for insulin treatment, and long duration of disease (25–30). There is some evidence to suggest that ethnicity may be an additional risk factor for some Native and Mexican Americans, independent of the control (31,32). The VA-DOD Working Group noted that this recommendation applies only to patients who have had no retinopathy on all previous retinal examinations (screening examinations). More frequent follow-up (i.e., surveillance examinations) is important for patients with known retinopathy. The use of algorithms to guide clinicians through the risk stratification process for retinopathy screening is presented in Fig. 1.

The ADA Clinical Practice Recommendations (33) acknowledge that the rationale for annual retinal screening examinations "for patients without retinopathy or with only few microaneurysms. . . is not as well defined." Nonetheless, ADA recommends that patients with diabetes should continue to have an annual eye exam (unless advised by an eye care professional), in part because of their concerns that patients will be lost to follow-up and in part because of the possibility of coexisting ocular conditions such as glaucoma.

CONCLUSIONS — In this work, we described the development of evidence-based guidelines for the care of patients with diabetes by primary care practitioners, using glycemic and blood pressure control and retinal screening as examples. The careful review and analysis of an independently prepared, evidence-based synthesis by a multispecialty panel of experts provided the best available evidence to the working group. Guidelines are meant to be applicable to large and complex health care systems and yet to empower the process of individual patient-practitioner counseling and goal setting based on individual risk stratification. The VA/DoD Clinical Guidelines for Treatment of Diabetes are intended to be a unifying standard of medical practice for the two largest agencies in the federal health care system that provide direct health care.

Some may criticize certain recommendations as being economically motivated with a design to minimize short-term costs. However, any target value endorsed by a guideline obligates system resources and their attendant costs in terms of medications prescribed, tests ordered, and examinations performed. Resources for health care in the U.S. are constrained whether one is operating in a globally budgeted or other environment. Nevertheless, most would agree that care should be based on best evidence, whether the evidence leads to a decrease or an increase in short-term costs. Policy considerations and available funds may dictate shifts in care at a local level, but evidence-based guidelines provide strategic direction. In contrast to seeking or even dictating "optimal care," often construed as anything that might help or might be desired regardless of the strength of the evidence, the VA/DoD Guideline Group considered the public health value of interventions to be the highest priority for a clinical recommendation. The clinicians' judgment in the application of these recommendations to individual patients remains intact and is explicitly encouraged.

Recommendations for particular actions, particularly treatment, were strongest when the benefit of treatment had been conclusively established by prospective scientific investigation and validated by rigorous peer review. When the strength of evidence indicated a less clearly established benefit of treatment, the guidelines were more cautious. In such situations, the VA/DoD Group chose to acknowledge the limitations of available data, to acknowledge controversy where it existed, and to encourage clinicians to share these limits of knowledge in dialogue with their patients. The Group adopted the concept that individual risk-benefit appraisal and stratification is of prime importance in a value-oriented health care system. It is likely that future refinement of evidence-based practice will include increasingly accurate computer modeling to enable clinicians to better predict morbidity and mortality outcomes in both individual patients and populations. Such an approach should lead to increasing sophistication in "trade-off" decisions when assessing the relative merits of short-term versus long-term treatment benefits, risks, and

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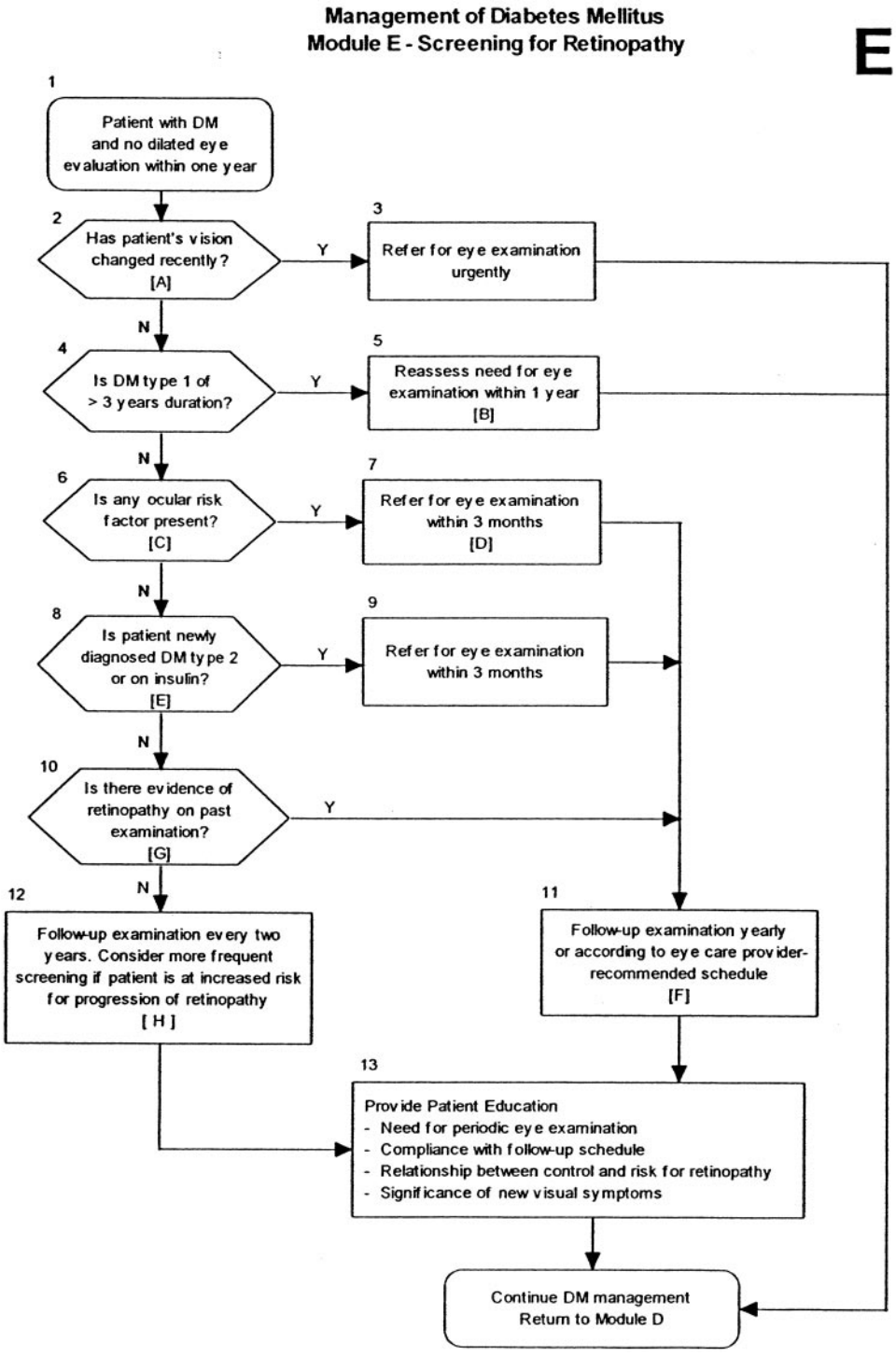

Figure 1—*VA-DoD algorithm for retinopathy screening in patients with diabetes (DM). Source: Diabetes mellitus: clinical practice guidelines (2).*

costs. Until such modeling is ready for everyday use, clinicians and their patients should continue to consider individual circumstances, events, and preferences within the context of the strength of available evidence. The tool included within these guidelines may assist conscientious patients and practitioners in the difficult and shifting process of decision making. The VA/DoD Guideline Development Group believes that the interaction between practitioners and their patients continues to be the essence of clinical practice.

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APPENDIX

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