

NQF

THE NATIONAL QUALITY FORUM

**National
Voluntary Consensus
Standards for Adult
Diabetes Care**

A
CONSENSUS
REPORT

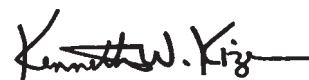
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Foreword

Diabetes mellitus is one of the most common and most costly medical conditions in the United States. It is the leading cause of kidney failure, blindness, and amputation. The condition currently affects approximately 17 million Americans—disproportionately affecting racial and ethnic minority patients—and its occurrence is rising rapidly.

For both medical and economic reasons, it is imperative that diabetic patients be carefully managed according to the best available evidence of what constitutes good care, since inadequately managed diabetes is much more likely to trigger life-threatening events and/or lead to serious complications like blindness and kidney failure. Toward this end, the NQF promulgates this first ever set of national voluntary consensus standards for the care of adults with diabetes. These measures are based on the pioneering work of the National Diabetes Quality Improvement Alliance and its predecessors. The measures are intended to promote both public accountability and quality improvement, and they were endorsed pursuant to the National Technology Transfer and Advancement Act of 1995, conferring upon them the special status of “voluntary consensus standards”.

We commend the National Diabetes Quality Improvement Alliance, and its predecessors, for their commitment to developing and continually refining measures for assessing the quality of care for adults with diabetes. We also thank the members of the NQF and the NQF Diabetes Measures Review Committee for their thoughtful participation in endorsing these standards.



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National Voluntary Consensus Standards for Adult Diabetes Care

Table of Contents

Introduction	1
Purpose	2
Identification of the Measure Set.....	2
Criteria for Measure Evaluation	3
Distinction Between Accountability and Quality Improvement Measures.....	3
Distinction Between Guidelines and Measures	3
Recommended Consensus Standards	4
Acknowledgements.....	4
Table 1 – National Voluntary Consensus Standards for Adult Diabetes Care.....	5
Appendix A – Review Committee, Alliance Members, and Project Staff.....	A-1
Appendix B – Review Committee and Alliance Commentary	B-1
Appendix C – Clinical Rationale for Measures.....	C-1
Appendix D – List of Abbreviations	D-1
Appendix E – Members and Board of Directors	E-1
Appendix F – Consensus Development Process: Summary	F-1

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National Voluntary Consensus Standards for Adult Diabetes Care

Introduction

Diabetes is one of the most common and costly medical conditions in the United States. An estimated 17 million Americans have diabetes, and the direct and indirect costs of the disease are approximately \$98 billion per year.¹ Diabetes is the sixth leading cause of death for Americans overall, and it exacts an even greater burden on racial and ethnic minority patients, who are more likely to die from diabetes and suffer serious complications such as amputation and end-stage renal disease.² Improved quality of care for diabetes could impact a large segment of the U.S. population.

In 1998, the Diabetes Quality Improvement Project (DQIP) established a single, standardized set of performance measures for diabetes care quality improvement and accountability. The DQIP measures were initially generated through the joint efforts and support of the Centers for Medicare and Medicaid Services, the American Diabetes Association, the National Committee for Quality Assurance (NCQA), and the Foundation for Accountability. Later, additional stakeholder organizations joined in support of the DQIP. The DQIP measures set a precedent for establishing an evidence-based performance measure set for a specific condition. A modification of the DQIP measures, based on additional discussions and agreement, resulted in the American Medical Association (AMA)/Joint Commission on Accreditation of Healthcare Organizations (JCAHO)/NCQA Core Measurement Set for the Management of Adult Diabetes, promulgated in April 2001. This measure set was similar but not identical to the DQIP measure set.

In early 2002, developers of both the AMA/JCAHO/NCQA and DQIP measure sets collaborated to form the National Diabetes Quality

¹American Diabetes Association, www.diabetes.org.

²Centers for Disease Control and Prevention, *1999 Diabetes Surveillance Report*, www.cdc.gov.

Improvement Alliance (“the Alliance”). In April 2002, the Alliance recommended a single performance measurement set for adult diabetes outpatient care that was intended to replace the previous two sets. The National Quality Forum (NQF) management convened the Diabetes Measures Review Committee (appendix A) to consider whether the measures were ready to be considered as voluntary consensus standards. The Review Committee subsequently recommended that the Alliance’s “Performance Measurement Set for Adult Diabetes” be endorsed by the NQF as national voluntary consensus standards for adult diabetes care.* Appendix B summarizes the Review Committee’s deliberations and the Alliance’s commentary on the measures.

Purpose

The consensus standards for adult diabetes care identified in this report are comprised of two groups of measures—one for the purpose of external accountability, including public reporting, and the other for the purpose of internal quality improvement. While the two groups of measures share common data elements, the measures are designed for use within their specified purposes only. That is, the quality improvement measures may not be appropriate for use in accountability or public reporting, and the accountability measures would be inadequate for effective quality improvement efforts. The comprehensive, core set of accountability and quality improvement measures is designed to assess the quality of care provided by health plans and healthcare providers for adult diabetics in the outpatient setting.

Identification of the Measure Set

The performance measures for adult diabetes care were developed and refined by the 11 public and private sector organizations that comprise the Alliance,** as well as those

* The NQF has completed or is currently conducting separate projects of direct or ancillary relevance to this report. *Improving Healthcare Quality for Minority Patients* reports on the recommendations of an NQF expert panel for ten actions that hold significant promise for improving the quality of care that is provided to minority patients. Also in progress is a report that identifies national voluntary consensus standards for acute care hospitals.

** As of July 2002

individual experts and stakeholder groups involved in the development of the earlier DQIP and AMA/JCAHO/NCQA measure sets. Detailed descriptions of the processes used by the DQIP and the AMA/JCAHO/NCQA groups for developing their measure sets are published elsewhere.^{3,4}

Criteria for Measure Evaluation

Thirteen criteria were used to evaluate potential measures for inclusion in the set.^{***} A detailed description of the criteria are in appendix B. The general criteria are as follows:

- Importance of topic area addressed by the measure
 - High priority for maximizing the health of persons or populations
 - Financially important
 - Demonstrated variation in care and/or potential for improvement
- Usefulness in improving patient outcomes
 - Based on established clinical recommendations
 - Potentially actionable by user
 - Meaningful and interpretable to user
- Appropriate measure design
 - Well-defined specifications
 - Documented reliability
 - Documented validity
 - Allowance for risk
 - Proven feasibility
 - Confidentiality
 - Public availability

Distinction Between Accountability and Quality Improvement Measures

The measures were selected for their intended purposes of either quality improvement or accountability based on several factors, including scientific strength and the ability to distinguish good from poor care. For example, accountability measures met a higher threshold for evidence linking measured processes to important clinical outcomes. They were determined to reliably distinguish between the quality of health plans and providers and were also designed to reduce the influence of patient characteristics on measure performance, thereby making risk adjustment unnecessary for fair comparisons. The quality improvement measures provide detailed information for gauging health plan and provider performance, but they do not categorically identify poor or high-quality care and may not be measured reliably enough to allow for accurate public comparisons between plans or providers.³

Distinction Between Guidelines and Measures

The specifications of the measures are directly related to well-known clinical practice guidelines for optimal care. The targeted levels of performance specified in the measures, however, are not always identical to those outlined in the guidelines

³Fleming BB, Greenfield S, Engelgau MM, et al. for the DQIP Group. The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic. *Diabetes Care*. 2001; 24(10):1815-1820.

⁴*Coordinated Performance Measurement for the Management of Adult Diabetes: A Consensus Statement from the American Medical Association, Joint Commission on Accreditation of Healthcare Organizations, and National Committee for Quality Assurance*; April 2001.

^{***} The Alliance's criteria closely mirror those recently endorsed by the NQF in its consensus report, *A National Framework for Healthcare Quality Measurement and Reporting*, 2002.

for several reasons, such as the following (additional discussion regarding the reasons for using guideline-based levels for performance in measures of accountability can be found in greater detail elsewhere^{3,5}):

- While performance measures for accountability must be applied consistently to all patients using fixed formulas in order to achieve reliable data, guidelines generally allow for individual differences and for greater flexibility in clinical practice than would be possible using standardized measures.
- Measures that do use the levels of care recommended in clinical practice guidelines often require risk adjustment to account for individual patient characteristics, such as comorbidities. To minimize burden and avoid methodological difficulties, the accountability measures tend to reflect levels of care that should be reached regardless of patient-specific factors that could otherwise bias results against providers who care for sicker patients.

Appendix C cites well-known guidelines for diabetes care that form the basis for these measures and also highlights the differences between levels of performance specified by the measures, particularly the accountability measures, and optimal levels recommended in the guidelines. The measure set is intended to fill a need for information that can be used for public reporting and for quality improvement

while retaining methodologically sound measures, not to set a low bar for quality of care or to prescribe standards for clinical practice. Providers and plans should aim for levels of care that are consistent with clinical practice recommendations, as appropriate.

Recommended Consensus Standards

Table 1 presents the NQF-endorsed national voluntary consensus standards for adult diabetes care. Specifically, the core set for accountability encompasses measures in six areas of outpatient care: hemoglobin A1c management, lipid management, urine protein testing, eye examination, foot examination, and blood pressure management. The measure set for quality improvement is composed of measures in these six areas and also includes measures in two additional areas— influenza immunization and office visits.

Acknowledgements

The NQF appreciates the input of members and staff of the National Diabetes Quality Improvement Alliance. It also greatly appreciates the support that was provided, in part, by the Robert Wood Johnson Foundation, California HealthCare Foundation, Horace W. Goldsmith Foundation, and Department of Veterans Affairs.

⁵Lee TH, Cleeman JJ, Grundy SM, et al. Clinical goals and performance measures for cholesterol management in secondary prevention of coronary heart disease. *JAMA*. 2000; 283(1):94-98.

Table 1 – National Voluntary Consensus Standards for Adult Diabetes Care

AREA	ACCOUNTABILITY MEASURES (PER YEAR)	QUALITY IMPROVEMENT MEASURES (PER YEAR)																						
<p>Hemoglobin A1c (HbA1c) management</p>	<ol style="list-style-type: none"> Percent of patients receiving one or more HbA1c test(s) Percent of patients with most recent HbA1c level >9.5% 	<p>Across All Patients</p> <ol style="list-style-type: none"> Percent of patients receiving one or more HbA1c test(s) Distribution of number of tests done (0, 1, 2, 3, or more) Distribution of most recent HbA1c value by range (6.0-6.9%, 7.0-7.9%, 8.0-8.9%, 9.0-9.9%, ≥10.0%, undocumented) <p>Per Patient</p> <ol style="list-style-type: none"> Number of HbA1c tests received* Trend of HbA1c values 																						
<p>Lipid management</p>	<ol style="list-style-type: none"> Percent of patients receiving at least one low-density lipoprotein cholesterol (LDL-C) test Percent of patients with most recent LDL-C level <130 mg/dL 	<p>Across All Patients</p> <ol style="list-style-type: none"> Percent of patients receiving at least one lipid profile (or all component tests) Distribution of number of profiles done (0, 1, 2, 3, or more) Distribution of most recent test values by range: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Total Cholesterol</td> <td style="width: 50%;">HDL Cholesterol</td> </tr> <tr> <td>≥240 mg/dL</td> <td><35 mg/dL</td> </tr> <tr> <td>200-239 mg/dL</td> <td>35-45 mg/dL</td> </tr> <tr> <td><200 mg/dL</td> <td>>45 mg/dL</td> </tr> <tr> <td>undocumented</td> <td>undocumented</td> </tr> <tr> <td>LDL Cholesterol</td> <td>Triglycerides</td> </tr> <tr> <td>≥160 mg/dL</td> <td>≥400 mg/dL</td> </tr> <tr> <td>130-159 mg/dL</td> <td>200-399 mg/dL</td> </tr> <tr> <td>100-129 mg/dL</td> <td><200 mg/dL</td> </tr> <tr> <td><100 mg/dL</td> <td>undocumented</td> </tr> <tr> <td>undocumented</td> <td></td> </tr> </table> <p>Per Patient</p> <ol style="list-style-type: none"> Number of lipid profiles received* Trend of values for each test 	Total Cholesterol	HDL Cholesterol	≥240 mg/dL	<35 mg/dL	200-239 mg/dL	35-45 mg/dL	<200 mg/dL	>45 mg/dL	undocumented	undocumented	LDL Cholesterol	Triglycerides	≥160 mg/dL	≥400 mg/dL	130-159 mg/dL	200-399 mg/dL	100-129 mg/dL	<200 mg/dL	<100 mg/dL	undocumented	undocumented	
Total Cholesterol	HDL Cholesterol																							
≥240 mg/dL	<35 mg/dL																							
200-239 mg/dL	35-45 mg/dL																							
<200 mg/dL	>45 mg/dL																							
undocumented	undocumented																							
LDL Cholesterol	Triglycerides																							
≥160 mg/dL	≥400 mg/dL																							
130-159 mg/dL	200-399 mg/dL																							
100-129 mg/dL	<200 mg/dL																							
<100 mg/dL	undocumented																							
undocumented																								
<p>Urine protein testing</p>	<ol style="list-style-type: none"> Percent of patients: <ul style="list-style-type: none"> receiving at least one test for microalbumin during the measurement year; or receiving at least one test for microalbumin within the past two years, if two of the three criteria for low risk are met: 1) not taking insulin; 2) HbA1c<8%; 3) no evidence of microalbuminuria in prior year; or who had evidence of medical attention for existing nephropathy or a positive test for macroalbuminuria 	<p>Across All Patients</p> <ol style="list-style-type: none"> Percent of patients who received any test for microalbuminuria Percent of patients with no urinalysis or with negative or trace urine protein who received a test for microalbumin <p>Per Patient</p> <ol style="list-style-type: none"> Any test for microalbuminuria received If no urinalysis, or with negative or trace urine protein, a microalbumin test received 																						

*Measure is intended for internal, informational assessment and does not imply an optimal number of tests or visits. Treatment must be based on individual patient needs and professional judgment.

Table 1 – National Voluntary Consensus Standards for Adult Diabetes Care (continued)

AREA	ACCOUNTABILITY MEASURES (PER YEAR)	QUALITY IMPROVEMENT MEASURES (PER YEAR)																		
Eye examination	6. Percent of patients who received a dilated eye exam or evaluation of retinal photographs by an optometrist or ophthalmologist within: <ul style="list-style-type: none"> ■ the reporting year; or ■ the past two years for patients at low risk of retinopathy (two out of three criteria met: 1) not taking insulin; 2) HbA1c<8%; 3) no evidence of retinopathy in prior year) 	Across All Patients 15. Percent of patients receiving a dilated retinal eye exam 16. Percent of patients receiving other eye exam (e.g., fundus-copic photo with interpretation or other) by type of exam Per Patient 17. Dilated retinal eye exam received 18. Other eye exam (e.g., fundus-copic photo with interpretation or other) by type of exam received																		
Foot examination	7. Percent of eligible patients (defined as those without bilateral amputations) receiving at least one foot exam, defined in any manner	Across All Patients 19. Percent of eligible patients (defined as those without bilateral amputations) receiving at least one complete foot exam (visual inspection, sensory exam with monofilament, and pulse exam) Per Patient 20. At least one complete foot exam received (visual inspection, sensory exam with monofilament, and pulse exam)																		
Blood pressure management	8. Percent of patients with most recent blood pressure <140/90 mm/Hg	Across All Patients 21. Percent of patients who received a blood pressure reading at each visit 22. Distribution of most recent blood pressure values by range: <table style="margin-left: 20px; border: none;"> <tr> <td style="padding-right: 20px;">Systolic (mm Hg):</td> <td>Diastolic (mm Hg):</td> </tr> <tr> <td><130</td> <td><80</td> </tr> <tr> <td>130-139</td> <td>80-89</td> </tr> <tr> <td>140-149</td> <td>90-99</td> </tr> <tr> <td>150-159</td> <td>100-109</td> </tr> <tr> <td>160-169</td> <td>≥110</td> </tr> <tr> <td>170-179</td> <td>undocumented</td> </tr> <tr> <td>≥180</td> <td></td> </tr> <tr> <td>undocumented</td> <td></td> </tr> </table> Per Patient 23. Percent of visits that included a blood pressure reading 24. Most recent systolic and diastolic blood pressure reading	Systolic (mm Hg):	Diastolic (mm Hg):	<130	<80	130-139	80-89	140-149	90-99	150-159	100-109	160-169	≥110	170-179	undocumented	≥180		undocumented	
Systolic (mm Hg):	Diastolic (mm Hg):																			
<130	<80																			
130-139	80-89																			
140-149	90-99																			
150-159	100-109																			
160-169	≥110																			
170-179	undocumented																			
≥180																				
undocumented																				
Influenza immunization		Across All Patients 25. Percent of patients who received an influenza immunization during the recommended calendar period 26. Percent of eligible patients who received an immunization or refused immunization during the calendar period Per Patient 27. Immunization status																		
Office visits		Across All Patients 28. Percent of patients with two or more visits Per Patient 29. Two or more visits*																		

*Measure is intended for internal, informational assessment and does not imply an optimal number of tests or visits. Treatment must be based on individual patient needs and professional judgment.

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Appendix A

Review Committee, Alliance Members, and Project Staff

NQF Diabetes Measures Review Committee

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* Joined the Alliance in September 2002 after the measures in this report had been approved by the Alliance.

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Appendix B

Review Committee and Alliance Commentary

This project, like all National Quality Forum (NQF) activities, involved the active participation of representatives from across the spectrum of healthcare stakeholders. This appendix summarizes the NQF Diabetes Measures Review Committee's deliberations supporting the recommendation to consider this set of measures and concerns about the measure set raised during the Member and public comment period that were addressed by the National Diabetes Quality Improvement Alliance ("the Alliance"). Information about the deliberations of the Alliance, its technical expert panels, or other groups involved in developing the relevant measures was not available.

Diabetes Measures Review Committee Deliberations

NQF management convened the Diabetes Measures Review Committee to recommend whether the ("American Medical Association [AMA]/Joint Commission on Accreditation of Healthcare Organizations [JCAHO]/National Committee on Quality Assurance [NCQA] Core Measurement Set for the Management of Adult Diabetes") should be advanced through the NQF Consensus Development Process (CDP). The Committee held three conference calls from February through April 2002 and completed its work on April 16, 2002, when it unanimously recommended that the Alliance's "Performance Measurement Set for Adult Diabetes" be endorsed by the NQF.

General Discussion

The Committee's early discussions focused on how to address discrepancies between the measure set recommended for consideration by the NQF Program Committee (the AMA/JCAHO/NCQA

set) and the set referred to as the “Diabetes Quality Improvement (DQIP)” measures. The AMA/ JCAHO/NCQA set was derived from the DQIP measures, but the two sets were not identical.

Both sets contained measures designated either for accountability or for quality improvement. Although the accountability measures were identical in the two sets, some differences existed between the quality improvement measures. In February 2002, the Committee initially recommended forwarding only the so-called accountability measures, identical in both sets, to the NQF CDP. However, because of ongoing work being conducted by a collaboration of the developers of both measure sets to resolve differences between them, the Committee later chose to defer its recommendation until April 2002. In early 2002, the AMA/JCAHO/NCQA and DQIP measure developers collaborated to form the National Diabetes Quality Improvement Alliance, and in April 2002, the Alliance reached agreement on a single set of measures for accountability and quality improvement.

Recommendation for Expedited Review

The Committee agreed that the Alliance’s “Performance Measurement Set for Adult Diabetes” was appropriate to recommend for expedited review under the CDP. Specifically, the Committee noted that the measure set:

- was consistent with the NQF Strategic Framework Board’s general criteria for measure evaluation: importance, scientific acceptability, usability, and feasibility;
- had extensive prior evaluation of measures and measure specifications by content area experts; and
- had a high level of prior consensus among major healthcare stakeholders, including some NQF members.

Updating

The Review Committee discussed the issue of how future updates to the measures for adult diabetes care (and other NQF-endorsed measures or standards) would be incorporated into existing NQF consensus standards, as the Alliance plans to periodically review updated clinical practice guidelines and new evidence to ensure that the measures remain appropriately designed. The Committee agreed that the issue of updating was much broader in scope than the diabetes project and that it was an appropriate topic for discussion and resolution in the context of NQF products and policies generally. The NQF is committed, however, to ensuring that the national voluntary consensus standards for adult diabetes care are updated in the future to consider issues raised during the comment period that could not be resolved in the near-term and to remain consistent with current knowledge and practice.

Implementation

The Committee did not specifically discuss how implementation should occur. However, it is expected that implementation of the consensus standards, including public reporting of the measures, will be conducted through the Alliance’s established channels and through NQF member organizations. Additional guidance issued by the Alliance, such as data abstraction instructions and parameters for public reporting, should be followed to assist in implementation of the core measure set among health plans, providers, and practices.

The implementation and reporting strategies for the core measure set should be consistent with those recommended for use with other NQF core measure sets in related areas. This includes the hospital care performance measures and nursing home care performance measures. Furthermore, the NQF report, *Improving Healthcare Quality for Minority Patients: Workshop Proceedings*, includes relevant recommendations, such as the standardized collection and use of race and ethnicity data with measures such as those in the national voluntary consensus standards for adult diabetes care.¹

Alliance Commentary

The NQF requested that the Alliance serve in a technical advisory role regarding any changes to specifications of the measures suggested in Member and public comments. Because the purpose of the NQF effort is to promote standardization of performance measures, any changes made to the NQF-endorsed set that were not consistent with the set in use by the Alliance would defeat the purpose of standardization. The Alliance was provided 30 days to respond to comments received from Members and the public, and it recommended NQF revisions to the proposed consensus standards based on those comments.

The Alliance did not agree that any substantive changes should be made to the measure specifications in the near-term, citing the need to refer any such changes to its technical expert panel for careful review

and evaluation according to the Alliance's Desirable Attributes of Performance Measures (table 1). The only substantive change that was made to the measure specifications from the review version was a clarification that those patients referred to as "eligible" in the foot examination measure were defined as diabetics without bilateral amputations. The urine testing accountability measure also was corrected to "no evidence of microalbuminuria". All other comments that suggested revisions to the measure specifications were recommended to the Alliance and its technical expert panel for future consideration in the measure updating process. These include the following:

- Integration of clinical practice guideline targets into accountability measures where feasible, particularly in levels of LDL-C, blood pressure, and HbA1c;
- Addition of new measures for lifestyle counseling (e.g., nutrition and exercise); pneumococcal vaccination; oral health; and use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers for diabetics;
- Use of comprehensive annual lipid profiles, in addition to annual LDL tests, to detect dyslipidemia that is characterized by elevated triglycerides and low HDL;
- Review of Adult National Cholesterol Education Program Adult Treatment Panel III guidelines for potential revision to classification schemes and treatment goals in lipid management measures;

¹The National Quality Forum. *Improving Healthcare Quality for Minority Patients: Workshop Proceedings*; 2002.

- Review of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines for potential revision of the blood pressure measure;
- Re-evaluation of the adequacy of criteria used to define “low-risk” patients with respect to eye examination measures;
- Consideration of specifying the level of quality of fundoscopic photograph evaluation that is acceptable in eye examination performance measurement;
- Further specificity in allowable exams for the foot examination accountability measure;
- Use of influenza immunization as an accountability measure, rather than only as a quality improvement measure;
- Use of the determination of glomerular filtration rate as the standardized measurement of kidney function in patients with macroalbuminuria;
- Modification of language in urine protein testing measurement area to refer to “urine protein testing” as “kidney function testing” and change of “macroalbuminuria” to “albuminuria”;
- Modification of language in eye examination measure to refer to “other eye exams” as “retinal eye exams”; and
- Consideration of other types of health-care encounters and episodes of care that reflect processes of care that are not accounted for in traditional office visits.

Table 1 – Attributes Used by the Alliance to Evaluate Diabetes Measures*

ATTRIBUTE	DEFINITION
1. Importance of topic area addressed by the measure	
a. High priority for maximizing the health of persons or populations	The measure addresses a process or outcome that is strategically important in maximizing the health of persons or populations. It addresses an important medical condition as defined by high prevalence, incidence, mortality, morbidity, or disability.
b. Financially important	The measure addresses a clinical condition or area of healthcare that requires high expenditures on inpatient or outpatient care. A condition may be financially important if it either has high per-person costs or if it affects a large number of people.
c. Demonstrated variation in care and/or potential for improvement	The measure addresses an aspect of healthcare for which there is a reasonable expectation of wide variation in care and/or potential for improvement. If the purposes of the measure are internal quality improvement and professional accountability, then wide variation in care across physicians or hospitals is not necessary.
2. Usefulness in improving patient outcomes	
a. Based on established clinical recommendations	For process measures, there is good evidence that the process improves health outcomes. For outcomes measures, there is good evidence that there are processes or actions that providers can take to improve the outcome.
b. Potentially actionable by user	The measure addresses an area of healthcare that potentially is under the control of the physician, healthcare organization, or healthcare system that it assesses.

*A consensus document of the National Diabetes Quality Improvement Alliance for desirable attributes of performance measures.

Table 1 – Attributes Used by the Alliance to Evaluate Diabetes Measures* (continued)

ATTRIBUTE	DEFINITION
c. Meaningful and interpretable to user	<p>The results of the measure are reportable in a manner that is interpretable and meaningful to the intended user.</p> <p>For example, physicians must be able to use the information generated by the measure to improve patient care. Healthcare organizations must find the information useful for decision-making purposes. When measures are used to compare healthcare systems, users should be able to understand the clinical and economic significance of differences in how well systems perform on the measure.</p>
3. Measure design	
a. Well-defined specifications	The following aspects of the measure are to be well defined: numerator, denominator, sampling methodology, data sources, allowable values, methods of measurement, and method of reporting.
b. Documented reliability	The measure will produce the same results when repeated in the same population and setting (low random error). Tests of reliability include (a) test-retest (reproducibility): test-retest reliability is evaluated by repeating administration of the measure in a short timeframe and calculating agreement among the repetitions; (b) inter-rater: agreement between raters is measured and reported using the kappa statistic; (c) data accuracy: data are audited for accuracy; and (d) internal consistency for multi-item measures: analyses are performed to ensure that items are internally consistent.
c. Documented validity	The measure has face validity—it should appear to a knowledgeable observer to measure what is intended. The measure also should correlate well with other measures or the same aspects of care (construct validity) and capture meaningful aspects of this care (content validity).
d. Allowance for risk	<p>The degree to which data collected on the measure are risk adjusted or risk stratified depends on the purpose of the measure.</p> <p>If the purpose of the measure is for internal continuous quality improvement and professional accountability, then requirements for risk adjustment or risk stratification are not stringent.</p> <p>If the purpose of the measure is comparison and accountability, then either the measure should not be appreciably affected by any variables that are beyond the user’s control (covariates), or to the extent possible, any extraneous factors should be known and measurable. If case-mix and/or risk adjustment is required, there should be well-described methods for either controlling through risk stratification or for using validated models for calculating an adjusted result that corrects for the effects of covariates. (In some cases, risk stratification may be preferable to risk adjustment because it will identify quality issues of importance to different subgroups.)</p>
e. Proven feasibility	<p>The data required for the measure can be obtained by physicians, healthcare organizations, or healthcare systems with reasonable effort and within the period allowed for data collection.</p> <p>The cost of data collection and reporting is justified by the potential improvements in care and outcomes that result from the act of measurement.</p> <p>The measure should not be susceptible to cultural or other barriers that might make data collection infeasible.</p>
f. Confidentiality	The collection of data for the measures should not violate any accepted standards of confidentiality.
g. Public availability	The measure specifications are publicly available.

*A consensus document of the National Diabetes Quality Improvement Alliance for desirable attributes of performance measures.

THE NATIONAL QUALITY FORUM

Appendix C

Clinical Rationale for Measures

This appendix contains brief summaries of the clinical practice guidelines issued by well-known sources that are related to the national voluntary consensus standards for adult diabetes care and that highlight key differences between measure design and optimal goals for patient management. Summaries of selected measures that contain target levels of performance are provided, and differences with those recommended in clinical practice guidelines should be noted. Levels of performance specified in the measures may be partly based on technical considerations in measurement; they are not intended to imply that those levels are optimal for clinical practice. Providers should refer to the full clinical practice guidelines and other appropriate sources for guidance on treatment goals in adult diabetes care management.

GENERAL ASPECTS OF CARE	CLINICAL RATIONALE AND ASSOCIATED GUIDELINES
<p>Hemoglobin A1c (HbA1c) management</p> <ul style="list-style-type: none"> ■ Annual HbA1c test ■ HbA1c >9.5% 	<p>The American Association of Clinical Endocrinologists (AACE) recommends a glycosylated hemoglobin test be performed during an initial assessment and during follow-up assessments every three months.¹</p> <p>The American Diabetes Association (ADA) recommends that glycated hemoglobin testing be performed routinely for all patients with diabetes, although for any individual patient the frequency of glycated hemoglobin testing depends on the treatment regimen used and on the judgment of the clinician. In the absence of well-controlled studies that suggest a definite testing protocol, expert opinion recommends glycated hemoglobin testing at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and more frequently (quarterly assessment) in patients whose therapy has changed or who are not meeting glycemic goals. HbA1c levels of <7% are recommended as the goal of therapy, and levels of >8% are considered high enough to warrant a significant change in treatment regimen.²</p>
<p>Lipid management</p> <ul style="list-style-type: none"> ■ Annual low-density lipoprotein cholesterol (LDL-C) test ■ Annual lipid profile ■ LDL-C control (<130 mg/dL) 	<p>The AACE recommends a fasting lipid profile be done at initial assessment and during follow-up visits as necessary.¹ In its cardiac-cerebrovascular-peripheral vascular module and for the prevention of coronary artery disease, the AACE recommends a complete fasting lipid profile at least yearly for all diabetic patients and sets the target LDL-C level at <100 mg/dL.^{1,3} Borderline and high-risk serum lipid concentrations for dyslipidemia (in diabetics and non-diabetics) are, respectively, 200-239 and ≥240 mg/dL for cholesterol, 35-45 and <35 for HDL-C, 130-159 and ≥160 for LDL-C, and 150-200 and >200 for triglycerides.³</p> <p>The ADA recommends that levels of low-density lipoprotein (LDL), high-density lipoprotein (HDL), total cholesterol, and triglyceride be measured every year in adult patients. If values fall in lower-risk levels, assessment may be repeated every two years. Optimal LDL-C levels for adults with diabetes are <100 mg/dL (100-129 is borderline, ≥130 is high), optimal HDL-C levels are >45 mg/dL (35-45 is borderline, <35 is high), and desirable triglyceride levels are <200 mg/dL (200-399 is borderline, ≥400 is high).⁴</p> <p>The National Cholesterol Education Program's Adult Treatment Panel III guidelines cite LDL-C levels of <100 mg/dL as optimal for diabetics, 100-129 as near optimal/above optimal, 130-159 as borderline high, 160-189 as high, and ≥190 as very high. It classifies total cholesterol as <200 desirable, 200-239 borderline high, and ≥240 high; for HDL-C, <40 is low and ≥60 is high.⁵</p>
<p>Urine protein testing</p> <ul style="list-style-type: none"> ■ Annual microalbumin test for nephropathy or biennial test for low-risk patients 	<p>The AACE recommends the initial assessment include a urinalysis, test for microalbuminuria, and creatinine clearance. The renal module, which should be performed annually, also calls for testing of microalbuminuria and creatinine clearance.¹</p> <p>The ADA recommends routine urinalysis at initial visit for type 2 diabetics and microalbumin analysis annually, if indicated, in continuing care. If the urinalysis is positive for protein, a quantitative measure is frequently helpful in development of a treatment plan. If the urinalysis is negative for protein, a test for the presence of microalbumin is necessary.^{6,7}</p>
<p>Eye examination</p> <ul style="list-style-type: none"> ■ Annual dilated eye exam, biennial eye exams in low-risk patients ■ Other eye exam annually (e.g., funduscopic photo) 	<p>The AACE recommends ophthalmology in follow-up assessments, and its retinal module, which should be performed annually, recommends ophthalmology, tests of visual acuity (Snellen chart), funduscopic examination and photographs (if indicated), and intraocular pressure tests.¹</p> <p>The American Academy of Ophthalmology recommends eye examination by ophthalmologists for patients with diabetes onset at age 29 years and younger, beginning five years after the diagnosis of type 1 diabetes, with routine minimum follow-up yearly. For patients with diabetes onset at age 30 years and older, ophthalmic examination at the time of diagnosis is recommended, with routine minimum follow-up yearly.⁸</p>

GENERAL ASPECTS OF CARE	CLINICAL RATIONALE AND ASSOCIATED GUIDELINES
<p><i>continued</i></p> <p>Eye examination</p> <ul style="list-style-type: none"> ■ Annual dilated eye exam, biennial eye exams in low-risk patients ■ Other eye exam annually (e.g., funduscopy photo) 	<p>The American Optometric Association recommends eye examinations to determine level of diabetic retinopathy as follows (individual situations and level of eye disease may suggest more frequent eye examinations): patients age 29 years or younger (generally type 1 diabetes)—within three to five years after diagnosis of diabetes once a person is age 10 years or older and annually thereafter; patients age 30 years or older (generally type 2 diabetes)—at the time of diagnosis and annually thereafter; pregnancy in pre-existing diabetes—prior to conception and during the first trimester, with follow-up evaluation during pregnancy based on findings of the first trimester examination and six to eight weeks <i>post partum</i>.⁹</p> <p>The ADA recommends annual dilated eye examinations by an ophthalmologist or optometrist who is knowledgeable and experienced in the management of diabetic retinopathy. These exams should be given to patients 10-29 years of age with type 1 diabetes within three to five years after diagnosis of diabetes; patients 30 years of age and older; and patients with visual symptoms and/or abnormalities.⁷</p>
<p>Foot examination</p> <ul style="list-style-type: none"> ■ Annual foot exam 	<p>The AACE recommends foot examination upon initial visit and follow-up visits. Annual module-specific follow-up assessment for neuropathy should include thorough foot examination; review of symptoms relevant to peripheral nerve and autonomic dysfunction; and testing of vibratory sensation, soft-touch, and pinprick.¹</p> <p>The ADA recommends foot examination upon initial visit and annually during continuing care.⁷ This examination should include assessment of protective sensation, foot structure and biomechanics, vascular status, and skin integrity. People with one or more high-risk foot conditions should be evaluated more frequently for the development of additional risk factors. People with neuropathy should have a visual inspection of their feet at every visit with a healthcare professional.¹⁰</p>
<p>Blood pressure management</p> <ul style="list-style-type: none"> ■ Blood pressure <140/90 mm/Hg ■ Blood pressure evaluation 	<p>The AACE recommends blood pressure evaluation (including orthostatic) at initial and follow-up visits.¹</p> <p>The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure gives <130/85 mm/Hg as the treatment goal for hypertensive diabetic patients. For diabetics, 130-139/85-89 mm/Hg is high-normal, 140-159/90-99 is stage 1 hypertension, and ≥160/≥100 are stages 2-3 hypertension; drug therapy is recommended for diabetics in all these ranges. To detect evidence of autonomic dysfunction and orthostatic hypertension, blood pressure should be measured in the supine, sitting, and standing positions in all patients with diabetes mellitus; automated ambulatory blood pressure monitoring may be especially helpful.¹¹</p> <p>The ADA recommends blood pressure measurement during the initial evaluation and in routine follow-up examinations. The ADA also recommends that blood pressure in adults should be decreased to <130/80 mm/Hg.⁷</p>
<p>Influenza immunization</p> <ul style="list-style-type: none"> ■ Annual influenza immunization 	<p>Influenza immunization for diabetic patients is recommended by both the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices¹² and the ADA.¹³</p>
<p>Office visits</p> <ul style="list-style-type: none"> ■ Number of office visits 	<p>The AACE recommends interim assessments every three months for all diabetic patients and annual assessments of specific complication modules.¹</p> <p>The ADA recommends quarterly follow-up visits for patients who are not meeting treatment goals and semiannual visits for others. The frequency of patient visits should depend on type of diabetes; blood glucose goals and the degree to which they are achieved; changes in the treatment regimen; and presence of complications of diabetes or other medical conditions.⁷</p>

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THE NATIONAL QUALITY FORUM

Appendix D

List of Abbreviations

AACE	American Association of Clinical Endocrinologists
ADA	American Diabetes Association
AMA	American Medical Association
CDP	Consensus Development Process (of the NQF)
DQIP	Diabetes Quality Improvement Program
HbA1c	Hemoglobin A1c
HDL	High-density lipoprotein (cholesterol)
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LDL	Low-density lipoprotein (cholesterol)
LDL-C	Low-density lipoprotein cholesterol
NCQA	National Committee for Quality Assurance
NQF	National Quality Forum

THE NATIONAL QUALITY FORUM

Appendix E

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*As of July 2002, when voting under the NQF Consensus Development Process was initiated for this report.

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THE NATIONAL QUALITY FORUM

Appendix F

Consensus Development Process: Summary

The National Quality Forum (NQF) is a voluntary consensus standards organization. The NQF brings together diverse healthcare stakeholders to develop consensus on core measures of healthcare quality. The primary participants in the NQF consensus process are NQF member organizations. These include:

- consumer and patient groups;
- healthcare purchasers;
- healthcare providers and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement can apply to be a member of the NQF. Membership information is available on the NQF web site (www.qualityforum.org).

Members of the public with particular expertise in a given topic may also be invited to participate in the early identification of draft standards as technical advisors or Steering Committee* members. In addition, the NQF consensus process explicitly recognizes a role for the general public to comment on draft standards and to appeal quality measurement standards adopted by the NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted on the NQF web site.

Each project the NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four critical stakeholder perspectives. With the assistance of NQF staff and technical advisory panels and the ongoing input of other NQF members, a Steering Committee conducts an overall assessment

*For this document, a Review Committee was used pursuant to the expedited process.

of the state of the field in the particular topic area and recommends a set of draft measures, indicators, or practices for review, along with the rationale for selecting them. The recommended measure set is distributed for review and comment, first to NQF members and then to the general public.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous within or across all Member Councils for consensus to be achieved. If a majority of members within each Council do not vote approval, staff attempt to reconcile differences among members to maximize agreement, and a second round of voting is conducted. Proposed products that have undergone this process and have

been approved by at least two Member Councils after the second round of voting are forwarded to the NQF Board of Directors for consideration. All products must be approved by a vote of the NQF Board.

Affected parties may appeal standards approved by the NQF Board of Directors. Once a measure set has been approved, the federal government may utilize the information for standardization purposes in accordance with the provisions of the National Technology Transfer Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Standards are updated as warranted.

For this report, the NQF Consensus Process, version 1.5, was in effect. The complete process can be found at www.qualityforum.org.

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