Towards a Comprehensive Diabetes Measure Set: Value-Based Episodes of Care

Washington, DC: September 23, 2008
Workshop Summary

Introduction

Although significant gains have been made in the treatment of diabetes, many individuals do not receive the evidence-based interventions known to be effective in the management of their disease and avoidance of diabetes-related complications, such as blindness or kidney failure. Building on the work of public and private driven initiatives, NQF is working to identify a comprehensive diabetes measure set by applying the recently endorsed NQF framework for assessing "episode efficiency" for chronic conditions to the diabetes community. Given the longitudinal nature of diabetes, with its complexity and diversity of care providers and care settings, and the vital role of patient self-management, diabetes emerges as an excellent condition for exploring the potential of moving towards this episodic assessment of what constitutes optimal care and how this can be achieved in the most efficient manner.

Project Background

This project built upon prior work at the National Quality Forum (NQF) completed under the National Voluntary Consensus Standards for Adult Diabetes Care project, as well as work under the auspices of the patient-focused episodes of care project which has developed a measurement framework for evaluating efficiency across episodes of care.

The aim of this project was to provide the government with recommendations for a path forward for diabetes quality measurement. The project was guided by a Planning Committee, chaired by Richard Kahn, PhD (American Diabetes Association), and comprised of experts from the diabetes community and others with expertise in performance measurement (Appendix A). Primary support for this project was provided by the Department of Veterans Affairs.

Specifically for this project, NQF worked with the full range of stakeholders to:

- Commission a white paper outlining the current state of performance measurement in diabetes care and key issues around the development of a comprehensive measurement strategy;
- Plan and support a workshop to create an action plan for developing the next generation of diabetes quality of care measures; and
- Map out an action plan for development of the next generation of diabetes measures, including a gap analysis of needed measures and possible application of the NQF framework for evaluating efficiency across episodes of care to diabetes.

The following workshop summary is organized by the content prepared for and discussed at the workshop, *Towards a Comprehensive Diabetes Measure Set: Value-Based Episodes of Care*, convened September 23, 2008, in Washington, DC (see Appendix B for agenda). The summary will: (1) briefly address the current state of diabetes quality measurement; (2) present one approach for measuring quality care through the episode of care approach and describe the Planning Committee's conceptualization of episodes of care for diabetes; (3) highlight recognized gaps in measures of diabetes care quality; and (4) summarize a path forward as well as challenges in diabetes care and management offered by the experts at the workshop to view these gaps and challenges as opportunities for improvement.

Where We Are Today: The Current State of Diabetes Quality Measurement

Diabetes quality measures were among the first developed by researchers in the late 1970s, and among the first addressed by HEDIS in the mid-1990s on a national basis.[1] Thus in many ways, diabetes provides an ideal template for the development of chronic disease quality measures. There are clear diagnostic criteria for diabetes, and achievement of recommended clinical goals in several key clinical domains (e.g., glucose, blood pressure, lipids) can be tracked using measures that providers routinely obtain to guide clinical care of diabetes patients. Moreover, diabetes is a common disease associated with high complication rates and high expenses, and the gap between recommended and actual levels of care that has persisted for over 40 years. In addition, there is evidence that better control of glucose reduces risk of microvascular complications, and that blood pressure and lipid control reduce the risk of macrovascular and microvascular complications. These data are reflected in clinical recommendations embodied in a number of widely available evidence-based diabetes clinical guidelines from groups such as the Institute for Clinical Systems Improvement (ICSI) and the American Diabetes Association (ADA).

Still, the diabetes care community is lacking the evidence-based clinical guidelines that are needed to integrate research results into a set of clear recommendations to guide the actions taken by primary care providers, subspecialty providers, other providers, and patients. Increasingly, providers and care systems have devoted the limited resources available for care improvement to improve performance on publicly reported quality measures promulgated by organizations such as NQF, the National Committee for Quality Assurance (NCQA), and the Centers for Medicare & Medicaid Services (CMS).

These same quality measures are increasingly used to financially reward or penalize medical groups and individual providers based on performance, and are a strong motivator of clinical behavior. Financial benefits offered by the NHS in the U.K. for improved care led to substantial improvements in diabetes care and care of many other conditions in a short period of time. Likewise, state-wide public reporting of a broad set of quality measures by the Minnesota Community Measures, a state-wide collaboration

[1] HEDIS, *National Committee for Quality Assurance. Health plan employer data and information set.* 1995, Washington, DC: NCQA.

of health plans and provider groups, has attracted and held the attention of medical groups and health plans and has also served to document substantial state-wide improvements in diabetes care since 2003.[2]

For the purpose of this project, a white paper was commissioned to provide a detailed overview of the current state of diabetes care quality measurement. Dr. Patrick J. O'Connor, MD, MPH (HealthPartners Research Foundation), authored the paper (see Appendix C), which offered not only a retrospective and current look at quality measurement in this area, but also offered context to the complexities involved in closing the existing measure gaps and in getting to a desired state of diabetes care quality measurement. The author specifically addressed what makes assessing the quality of diabetes care particularly challenging and what critical aspects in research, policy, and implementation must be considered in order to move forward.

> Even as these core measures are refined and fielded as a single comprehensive outpatient diabetes quality measure, it is clear that important gaps in diabetes care measures remain unaddressed….It is very likely that developing quality measures for these domains would direct attention and resources to these important current challenges in diabetes care (O'Connor, 2008).

Since its founding in 1999, NQF has devoted a great deal of attention to the review and endorsement of diabetes quality measures, and updated these endorsements in 2005. Through various related projects since then, NQF continues to address diabetes care quality, and hopes to drive toward measure sets that speak to the best care for the patient. This approach will be addressed through cross-cutting projects on care coordination; efforts underway through the National Priorities Partnership (NPP);[3] and continued collaboration with individuals and organizations that are driving toward a high-value healthcare system.

> Developing these measures, testing them, modifying them, and implementing them would expand quality measures across a broader scope of diabetes care. Moreover, development of measures of resource use will shift quality measurement from a "quality at any cost" mindset to a "quality as a value proposition" orientation. This seismic shift would address a major unintended consequence of current diabetes quality measures—that they may actually be driving up costs of care more rapidly than they are driving up quality of care (O'Connor, 2008).

A table summarizing the most recent NQF-endorsed measures related to diabetes care can be found in Appendix D. Furthermore, while much work with respect to measurement has been accomplished for this condition, much more remains to be done to assess quality, efficiency, and patient-driven outcomes. NCQA, ADA, ICSI, and numerous others have been heavily engaged in measure development for diabetes care. A review of past efforts as well as efforts currently underway is outlined in the white paper.

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[2] *MN Community Measurement.* Available at www.mnhealthcare.org/~main.cfm.
[3] National Priorities Partnership web site: www.nationalprioritiespartnership.org.

One Approach to Quality Measurement and Performance Improvement: The Patient-Focused Episode of Care Framework

NQF's Measurement Framework for Evaluating Efficiency across Patient-Focused Episodes of Care

Considering the complexity of diabetes, as well as its numerous care settings and care providers, conceptualizing valuable and efficient care for patients and their families can prove challenging. NQF has endorsed a patient-focused measurement framework through which such complex conditions can be diagnosed, treated, and followed-up. The *Framework for Measuring Efficiency across Patient-Focused Episodes of Care* offers an approach to evaluating efficiency across episodes of care while taking into careful consideration not only the various settings and providers of care (and transitions between them), but also specifically the treatment and outcome preferences of the patient. Furthermore, in presenting the opportunity to assess efficiency (as a function of cost and quality of care) from the patient's perspective as well as the provider's, the framework also specifically allows for the assessment of gaps in measurement, care provision, and patient-provider and provider-provider communication, driving toward a comprehensive set of measures of efficiency in the system and value to the patient.

The episode of care approach offers strengths and limitations with respect to feasibility and measurement among others, especially as they apply to a range of conditions from acute to chronic. But it is by looking at the episode of care approach through the lens of these various conditions, including diabetes, which allows for these strengths to be bolstered and limitations addressed moving forward.

Strengths:

1. *Patient-centered* way of evaluating health system performance.
2. Clinical guidelines offer *clear pathways*: The diabetes community has developed and put into practice detailed and evidence-based guidelines that provide for clearer mapping to the episode approach and offer measurable points by which diagnoses, processes, and outcomes can be assessed.
3. A way to shift performance measurement towards assessments that allow judgments to be made about *value*—by providing measures of quality, cost of care, and outcomes that can only be interpreted in the light of patients' well-informed preferences.
4. Potential to foster and enable *new strategies for financing* healthcare that could eliminate current incentives to overuse certain services (i.e., imaging for low back pain) and underuse others (i.e., preventive care such as mammograms), and could facilitate the development of alternate payment models.
5. Allows for *comparisons for conditions over time*, not simply between clinical encounters: This timing construct provides for linkages with payment and

performance reporting systems, and may also provide the opportunity for a patient's progress to be tracked from year to year, thereby extending the larger episode beyond the single year timeframe.

Limitations:

Despite its advantages, limitations are associated with attempting to evaluate efficiency across episodes. These stem mainly from the inability of existing commercial episode grouper methodologies to:

1. Address *appropriateness* of care.
2. Adequately *risk-adjust* for different populations.
3. Manage measurement of patients with *multiple chronic conditions and complex comorbidities* (especially relevant in diabetes care).
4. Facilitate *comparisons among organizations*.

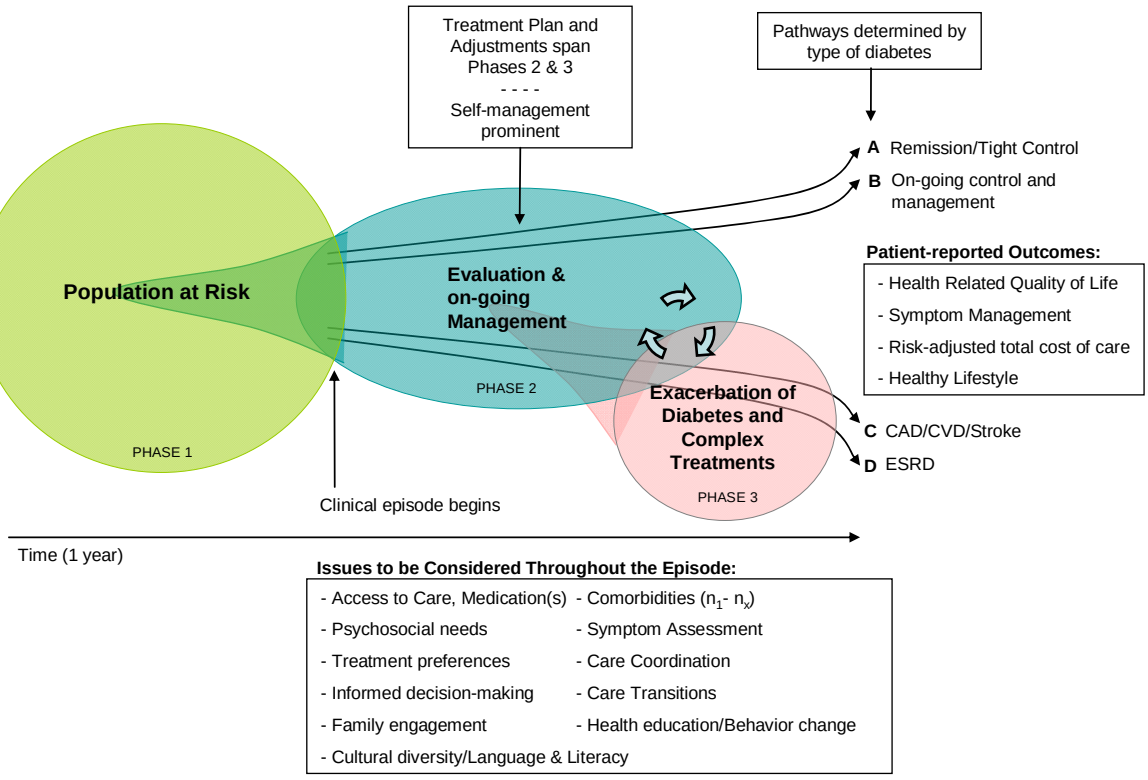
The Framework offers further discussion of additional considerations with regards to both the strengths and limitations of the episode of care approach, including: access; limits of 1-year timeframe; difficulty of payment structure; and data needs.

Conceptual Episode of Care Model for Diabetes

It is important to note that while *diabetes* encompasses a range of specific conditions (i.e. type 1 or insulin-dependent diabetes mellitus, type 2 or adult on-set diabetes, gestational diabetes), the planning committee and workshop attendees focused their attention on addressing type 2 diabetes, which is the most common form of diabetes and thereby impacts the greatest number of individuals and health care systems.

In preparation for the workshop, experts in diabetes care delivery and measurement worked with NQF staff to conceptualize diabetes within the episode of care framework. Using diabetes treatment guidelines and endorsed measures for support, a diabetes episode model was created to visually represent this conceptualization and understand the various pathways that a patient may enter a diabetes episode of care. This model is elaborated on in Figure 1.

Figure 1: Context for Considering a Diabetes Episode of Care



Covering the full range of severity of diabetes, the model demonstrates the complexity of issues (access to care, psychosocial needs, treatment preferences, informed decision making, and health literacy among others) to consider both within and beyond the health care system as a patient moves through the episode. The model further presents several pathways by which a patient at risk of developing diabetes might negotiate his or her subsequent diagnosis, treatment, and follow-up with multiple care providers and settings, as well as consideration for several patient-reported and desired outcomes. A brief overview of the various phases of the diabetes episode is provided below.

Episode phases

Phase 1: Population at Risk

Ideally, in evaluating how well the health care system performs in providing high quality diabetes care, it would be important to consider the population at risk and to capture the period preceding diagnosis, when it is conceivable that the diabetes—and its diagnosis and subsequent treatment—could have been detected at an earlier stage or optimally could have been postponed.

In this phase, the focus is on prevention, particularly behavioral and lifestyle modification interventions that fall outside of the clinical setting. Additionally,

interventions to offset the complications of diabetes may focus on glycemic control, lipid management, and blood pressure control. This phase may extend to up to a two- to three-year window for measurement.

Phase 2: Evaluation and On-Going Management
This phase begins with presentation of a patient with diabetes-like symptoms or through screening, and includes the diagnosis of diabetes by type of diabetes. Pathways A through D are built upon evidence-based guidelines and offer the various ways (and corresponding timeframes) by which a patient diagnosed with diabetes navigates the diagnosis, evaluation and management, and treatment and follow-up care specific to the diabetes type and related outcomes/comorbidities.

In this phase, accountability tends to rest with the primary care provider (PCP), with exceptions. The focus is on prevention of complications through: 1) glycemic control; 2) hypertension and lipid management; and 3) screening for complications and early treatment. The team approach to treatment becomes critical in this phase. The performance measurement interval tends to be one year, with possible exception of early eye screening.

Phase 3: Exacerbation of Diabetes and Complex Treatments
The third phase of the diabetes episode, which allows the patient to return to the maintenance pf diabetes in Phase 2, accounts for the undesired but common exacerbations of the condition and the various complex treatments necessary for the patient.

Although shared accountability of numerous health care providers plays a critical role throughout a diabetic's care, it is particularly important that the following providers work closely together in this advanced phase: PCP, Endocrinologist, Ophthalmologist, Nephrologist, Cardiologist, Podiatrist, Neurologist, Diabetes Educator, Dietitian, Mental Health Professional, Pharmacist, and others. For these complex patients the focus will shift to surveillance and treatment of complications and comorbidities in order to return to achieving glycemic control. Performance measurement targets may change in relation to coexistent hazards, risk/benefit of intervention, and relative value of long-term gains.

Appendix E serves as a preliminary outline for further operationalizing diabetes to the episode model. This model and accompanying outline could prove helpful in guiding future work to build a comprehensive measure set for diabetes care.

Addressing Measurement Gaps: Driving Toward the Desired State of Diabetes Quality Measurement

The episode of care approach provides a useful framework for mapping existing diabetes measures as well as for highlighting measure gaps, and thus can inform us about areas in

need of measure refinement or development. The Workshop built upon gaps offered in the White Paper and provided an open forum through which experts in diabetes and quality measurement could expand on these identified gaps and dive deeper. A summary is offered below.

Mapping measurement needs to the proposed episode model for diabetes above highlights specific measurement gaps:

A. ***Patient-focused Measurement:*** Patient outcomes, patient self-management, treatment goals, shared decision-making, patient/family engagement, and other factors intrinsic to the episode framework are not fully captured by current measures.
B. ***Care Coordination:*** Current measures do not take into consideration the multidisciplinary and interdisciplinary provider teams working across multiple and varied care settings involved in diabetes care. These factors must be taken into account in order to report on measures for the full episode of diabetes care and to be able to make comparisons between providers and settings. Included in this effort is a focus on the value and efficiency associated with coordinated, patient-focused care.
C. ***Prevention and Population Health:*** Current measures are focused on the clinical setting and do not consider measurement prior to the onset of symptoms. Current measures also do not assess the quality of prevention efforts or other related efforts in the broader community or public health setting.
D. ***Chronic Care in the Acute Care Setting:*** Although some measures exist for diabetes care in the acute care setting, more work is needed to develop and implement measures that will ensure an integrated approach to care regardless of primary reason for admission so that the patient is discharged in good glycemic control.

Additional Challenges Moving Forward

In additional to these recognized measurement gaps, there are several barriers/challenges that Workshop experts suggest must be considered. The challenges are not limited to the list provided below, but offer additional discussion on other significant hurdles that remain with respect to diabetes care:

The patient plays a strong role in determining the success of diabetes care interventions and subsequent outcomes of care. Therefore, any efforts at quality measurement will need to consider the level of patient engagement in care.

The economic impact of diabetes in considerable by conservative estimates, both in terms of health care costs and productivity lost in the workplace. This only bolsters the argument for the need for greater attention on prevention efforts in the community.

Diabetes can cause a wide range of complications and can also be one of multiple chronic diseases that a patient deals with. Capturing an accurate representation of this through the episode framework proves particularly challenging.

Advances in health information data and its sharing, as well as in disease management, will need to be employed in a broad and thoughtful manner to provide and assess the various tools offered to and used by patients with and at risk for diabetes.

The Path Forward: Expert Recommendations of Needs and Next Steps

In an effort to fully capture the expertise assembled at the Workshop, a concluding exercise was conducted whereby each attendee offered concrete recommendations for closing the diabetes quality measurement gaps highlighted above.

While the recommendations detailed within this workshop summary do not comprehensively capture all that must be achieved to continue to measure and improve the quality of diabetes care in the United States, they offer concrete and critical suggestions for a path forward, using the gaps and challenges discussed as opportunities for improvement, and taking into consideration all aspects of care, complex as they may be.

A. Patient-Focused Measurement

One of the most apparent themes across the suggested recommendations for closing the diabetes quality measurement gap was a call for patient-centered measurement. Workshop participants spent significant time discussing that a focus on outcomes and cross-cutting issues must come first, but also that shared decision-making and clear communication were critical as well. In essence, measures must reflect not only patient preference but also the agreement between the patient and provider on the goals of the treatment plan.

Much discussion ensued at the workshop on the appropriate hemoglobin A1c target to work towards for all patients. While the scope of the workshop did not include the discussion of the optimum target level to promulgate, it was agreed amongst the participants that any measure used for accountability and/or public reporting ought to allow for the individualization of treatment goals, particularly with respect to the A1c target.

Finally, described as one of the most critical aspects of a treatment plan, many workshop participants called for measures that would speak to a patient's successful self-management. With this element of care integral for any diabetic's success, not having

measures that account for this aspect of care would mean that an incomplete picture of quality care from the patient's perspective would be presented.

B. Care Coordination; Value and Efficiency of Care

As discussed in the earlier sections, diabetes care involves a wide range of expertise to successfully manage the condition and handle the complexities and comorbidities that may arise. These experts operate within and across multiple care settings. Therefore, measures should make sure to capture this wide range of providers and settings, including the community. Next steps clearly point to the need for shared accountability across health professionals and provider organizations. As such, multidisciplinary care coordination emerged as a strong recommendation from the workshop participants.

The continued development of cost and quality measures should also be encouraged. Such measures can speak to the value a diabetic patient places on the care received. They can also address the multidimensional nature of efficiency, bringing in not only resource utilization, but also congruence of treatment plans with patient preferences and desired outcomes mentioned earlier.

C. Prevention and Population Health

This particular condition, with documented economic and social impacts beyond the clinical arena, represents great impetus for measurement to be pushed earlier and into the broader public health and community setting. Specifically, developing and using community indices of health to compare those communities, track improvement, and better target at-risk populations will help to focus efforts at preventing the development of diabetes rather than only treating the disease post-diagnosis.

Such an approach would also help bolster efforts of employers and purchasers of health care to develop wellness and other support programs to help reduce the economic impacts of the disease while increasing productivity and well-being.

D. Chronic Care in the Acute Care Setting

Although NQF-endorsed measures for diabetes care exist for the hospital, workshop participants strongly suggested that much more work can and should be done to better measure the quality of diabetes care provided in the acute care setting. Understanding the complexities of treating a chronic condition such as diabetes in this setting will provide greater opportunity for improved diabetes management and coordination of care from treatment to discharge, with the goal of reducing and preventing readmissions related to complications from diabetes.

Conclusions and Next Steps

It is clear that barriers exist today that do not allow for providers and communities to offer the best possible care to all diabetes patients. Current measures are limited in scope and significant data and research needs exist. Furthermore, as various stakeholders in the continuum of diabetes care begin to work to close the measurement gap and achieve more efficient and more valuable care for the patient, the role the patients and their families play will prove critical to any future success, as will the level of coordination between the multiple care providers and settings. Measurement's reach will also need to consider broadening beyond the clinical setting and into communities, where the much-needed preventive efforts and psychosocial supports can be provided and the cultural and social factors associated with diabetes development and treatment (including disparities) addressed.

NQF has been active in taking steps to help close these gaps. As the convener and a Partner of NPP, NQF has worked with 27 other key stakeholders in health and health care to establish national priorities and goals for performance measurement and public reporting. The Partnership has identified an initial set of six national priorities (patient and family engagement; population health; safety; care coordination; palliative care; overuse), with corresponding goals and actions. Several of these priorities directly relate to the gaps and path forward described in this summary, particularly patient and family engagement, population health, and care coordination. Furthermore, in an effort to continue many years of work on the episode of care approach to measurement, NQF will continue to convene experts in this approach and related cost and resource utilization aspects of care to work toward encouraging the development and construction of usable, cross-cutting measure sets to assess care for chronic and acute conditions alike.

Taken together, the recognized gaps in diabetes quality measurement and the expert recommendations provided through this NQF workshop provide a better understanding of key measurement gaps and a conceptual framework—patient-focused episodes of care—for moving forward.

Appendix A:

Towards a Comprehensive Diabetes Measure Set – Value-Based Episodes of Care: Workshop Planning Committee

Richard Kahn, PhD, *Chair*
American Diabetes Association, Alexandria, VA

David Ballard, MD, MSPH, PhD, FACP
Baylor Health Care System, Institute for Health Care Research and Improvement, Dallas, TX

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Christine Whipple
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NQF Staff

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Vice President, National Priorities

Anisha S. Dharshi, MPH
Program Director

Nadine C. Allen
Administrative Assistant

Appendix B:

TOWARDS A COMPREHENSIVE DIABETES MEASURE SET:
VALUE-BASED EPISODES OF CARE – WORKSHOP

Tuesday, September 23, 2008

Hotel Monaco
700 F Street, NW
Washington, DC 20004

WORKSHOP AGENDA

8:00 am Continental Breakfast

8:30 am Welcome & Opening Comments
Janet Corrigan, NQF, President and CEO
Richard Kahn, American Diabetes Association, Planning Committee Chair

Message from the Sponsor
Stephan Fihn, U.S. Department of Veterans Affairs

8:45 am **Current State of Diabetes Quality Measurement Field: A Retrospective and Prospective Approach**

Panel IA: White Paper Presentation: Overview of Current State of Diabetes Quality Measurement (Retrospective)

Patrick O'Connor, HealthPartners

9:30 am Discussion Period with Invited Participants
Moderator: *Richard Kahn*

10:15 am Break

10:30 am **Panel IB: Addressing Gaps: Areas of Quality Measurement that Need to be Addressed** (Prospective)

David Ballard (health system perspective)
Helen Dumski (patient/consumer perspective)

11:00 am Planning Committee or Diabetes Community Reactants

Leonard Pogach (integrated system perspective)
Tommy Johnson (pharmacy/CDE perspective)
Sally Lundeen (nursing/cross-setting, disparities perspective)
Jaime Davidson (primary care/endocrinologist perspective)

11:45 am Discussion Period with Invited Participants
Moderator: *Richard Kahn*

12:15 pm Working Lunch

1:15 pm **Panel II**
NQF's Measurement Framework: Application of the Episode of Care Framework to Diabetes Care

Brief review of Episode of Care Framework: Presentation of Measurement Framework

Robert Bonow

1:30 pm Application of Episode of Care Framework to Diabetes Care: Necessity and Modified Model(s)

James Rosenzweig
François de Brantes

2:00 pm Discussion Period with Invited Participants
Moderator: *Richard Kahn*

2:45 pm Break

3:00 pm **Next Steps Discussion: Final Diabetes Care Recommendations for NQF and the Broader Health/Public Health Community**

Review of Suggested Measurement and Prioritization Areas
Future of Performance Measurement
Key Delineation of Next Steps

Moderator: Richard Kahn

4:15 pm Closing Comments
Janet Corrigan
Richard Kahn

4:30 pm Adjourn

Appendix C: White Paper

NQF
Revised 11-5-08

DRAFT: Not for citation or reproduction; figures in this draft are preliminary and some may be incomplete or require further specification.

Towards a Comprehensive Diabetes Quality Measure Set: New Measurement Opportunities and Methodological Challenges

A white paper to serve as a background discussion document for an NQF workshop designed to adapt and improve diabetes quality measures in a changing information and practice environment.

Patrick J. O'Connor MD MPH
Senior Clinical Investigator
HealthPartners Research Foundation

Communication to:
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1 Executive Summary

Type 2 diabetes (T2DM) affects approximately 20 million Americans and in 2007 cost the nation in excess of $150 billion in direct and indirect costs. Clinical care for T2DM is complex, and major deficits in diabetes quality of care have been widely recognized since the 1960s. Substantial improvements in diabetes care in the U.S. have been documented in the past 8 years. By 2004 the mean glycated hemoglobin (A1c) had improved to 7.18% (based on NHANES data), and sustained improvements in blood pressure (BP) and LDL-Cholesterol (LDL) control, decreased tobacco use, and increased aspirin use were also documented. As of 2005, the risk of diabetes complications had decreased over 50% compared to levels of risk in 1995. However, only about 20% of adults with T2DM simultaneously achieve recommended goals for A1c, BP, LDL, aspirin use and tobacco non use. This indicates there remains a need for further improvements in care.

It is likely that diabetes quality measures have made a substantial contribution to the recent improvements in diabetes care. In this paper, we focus on three urgent issues related to maintenance and ongoing development of relevant and effective diabetes quality measures:

(a) Modify Current Measures. Recent major shifts in the evidence upon which diabetes care recommendations rest indicate the need to review and modify some current diabetes quality measures.

(b) Fill Measurement Gaps. Lack of quality measures related to key dimensions of diabetes care including

(i) primary prevention of T2DM,

(ii) measures of quality of care provided to hospitalized adults with T2DM,

(iii) conjoint measures of quality and cost of care that will replace the unintended message of “quality at any cost” with the message that “quality is a value proposition.”

(c.) Address Methodologic Challenges Related to Quality Measures. Key challenges include development of episode-based diabetes quality measures, validating quality measures for medical groups and individual providers, exploring methods to prioritize measures based on relative cost-effectiveness, and others.

Table of Contents

1 Introduction

Quality measures for care of patients with type 2 diabetes have evolved remarkably in the past decade. Yet, ongoing evolution in the evidence base that guides diabetes care, and in models for providing diabetes care present new challenges and new opportunities related to diabetes quality measurement. These three opportunities are:

(a) Modify the glucose quality measure. Due to new data from large and well-designed randomized clinical trials (ACCORD[1] and ADVANCE[2, 3]), there is a need to adjust the current glucose control measure. The current measures for blood pressure (BP) and lipid control may need to be reconsidered when additional ACCORD trial data are reported in late 2009 or early 2010.
(b) Identify new measurement strategies that address major gaps in currently deployed measures. The three gaps that most urgently need attention are:
    a. Develop measures that encourage judicious resource use in diabetes care,
    b. Develop measures that focus on primary prevention of diabetes, and
    c. Develop measures of quality of care provided to hospitalized diabetes patients regardless of the reason for hospitalization.
(c) Strengthen the credibility and advance the science of quality measurement by systematically and publicly addressing a set of methodological challenges that are articulated in this report. Among the challenges here is to incorporate an episode framework for diabetes quality measures wherever possible.

1. The History and Goal of Publicly Reported Diabetes Quality Measures

1.1 1.1 Epidemiology and Natural History of Type 2 Diabetes

The prevalence of type 2 diabetes mellitus (T2DM) is rapidly increasing, and now affects an estimated 20 million Americans. By 2020, T2DM will affect about 30 million Americans and an estimated 300 million people worldwide. [4] [5] Figure 1 shows common comorbidities and complications associated with T2DM. Among adults with T2DM, about 70% have concurrent hypertension (HT), over 90% have concurrent lipid disorders, 15% have concurrent congestive heart failure (CHF), 20-30% have concurrent coronary heart disease (CHD), and about 15% have concurrent symptoms of depression. The lifetime prevalence of these comorbidities in those with T2DM is even higher. T2DM is associated with several microvascular complications, including nephropathy, retinopathy, and neuropathy. However, despite the profound disability and suffering caused by *microvascular complications*, the *macrovascular complications* of T2DM, including myocardial infarction and stroke as well as peripheral vascular disease, are by far the leading cause of excess mortality and excess costs of care in adults with T2DM. For example, an estimated 65-70% of adults with T2DM die of heart attacks, strokes, or other macrovascular complications, while less than 5% of T2DM patients die of all microvascular complications combined.

1.2 1.2 Early Diabetes Quality Measures

Diabetes quality measures were among the first developed by researchers in the late 1970s, and among the first addressed by HEDIS in the mid-1990s on a national basis, [6] thus in many ways, diabetes provides an ideal template for the development of

chronic disease quality measures. There are clear diagnostic criteria for diabetes, and achievement of recommended clinical goals in several key clinical domains (glucose, BP, lipids) can be tracked using inexpensive measures that physicians routinely obtain to guide clinical care of diabetes patients. Moreover, diabetes is a common disease associated with high complications rates and high expenses, and the gap between recommended and actual levels of care that has persisted for over 40 years. In addition, there is evidence that better control of glucose reduces risk of microvascular complications, and that BP and lipid control reduce the risk of macrovascular and microvascular complications. These data are reflected in clinical recommendations embodied in a number of widely available evidence-based diabetes clinical guidelines from groups such as the Institute for Clinical Systems Improvement (ICSI) and the American Diabetes Association (ADA).

However, it is instructive to note that in 1995, the HEDIS diabetes quality of care measure was limited to reporting the proportion of diabetes patents that had an annual eye exam to detect retinopathy.[6] While this quality measure was justified based on the primitive state of quality measurement technology, the choice of this quality measure had an important unintended consequence. In the 1990s most health plans responded to the publicly reported eye exam measure by seeking to improve eye exam rates—and ignored the more challenging and arguably more important goal of improving glucose and BP control, long known to be the major drivers of retinopathy. The public reporting of eye exam rates likely contributed to the failure of glucose control levels to improve substantially from 1995 to 2001, when HEDIS added the critically important domains of glucose control and LDL-cholesterol control to the diabetes quality measurement set. [7]

1.3 1.3 Have diabetes quality measures improved quality or reduced costs of care?

Evidence-based clinical guidelines are needed to integrate research results into a set of clear recommendations to guide the actions taken by primary care providers, subspecialty providers, other providers, and patients. Increasingly, providers and care systems have devoted the limited resources available for care improvement to improve performance on publicly reported quality measures promulgated by organizations such as NQF, NCQA, and CMS.

These same quality measures are increasingly used to financially reward or penalize medical groups and individual providers based on performance, and are a strong motivator of clinical behavior. Financial benefits offered by the NHS in the U.K. for improved care led to substantial improvements in diabetes care and care of many other conditions in a short period of time. Likewise, state-wide public reporting of a broad set of quality measures by the Minnesota Community Measures, a state-wide collaboration of health plans and provider groups, has attracted and held the attention of medical groups and health plans and has also served to document substantial state-wide improvements in diabetes care since 2003. [8]

Although it is impossible to prove causality, most policy makers and quality improvement experts believe that quality measures have been a powerful force contributing to improved diabetes care, and improved care in other clinical domains as well.

1.4 1.4 Maintaining the ethical credibility of diabetes quality measurement.

1.4.1 Conflicts of Interest. Quality measures must necessarily evolve as evidence-based guidelines evolve to accommodate new data from clinical trials and other sources.

In making these inevitable and necessary changes, it is important to develop a process that assures input from a wide range of stakeholders. To assure the integrity of this process, it is incumbent upon stakeholders (both organizations and individuals) to disclose any potential conflicts of interest, such as financial connections to pharmaceutical or device manufacturers.

1.4.2 Interventions with Benefits may also have Substantial Risks. It is apparent that publicly reported quality measures should not hold providers accountable to deliver care that is more aggressive than what is recommended in evidence-based clinical guidelines. Likewise, publicly reported quality measures should generally not endorse treatment strategies whose benefits do not consistently and substantially outweigh their risks. For example, estrogen use slows osteopenia, reduces fractures, and ameliorates menopausal symptoms in many women. Yet, it is not desirable to encourage estrogen use through quality measures because estrogen use also increases risk of heart attacks, blood clots, and breast cancer. Each woman considering this therapy must decide whether the benefits outweigh the risks, and providing incentives to physicians with high rates of estrogen use would rightly be viewed as unethical.

Likewise, a treatment strategy (aggressive glucose control) that benefits some patients by reducing proteinuria, but creates major risks for other patients by increasing mortality, is not a good choice for a quality measure, because treatment decisions must be individualized with major input from individual patients, who will weigh these risks and benefits differently. Provider incentives that encourage broad use of a treatment strategy that may be harmful to a substantial subset of patients may rightly be regarded as unethical, and have unintended consequences related to health outcomes, costs of care, and legal liability. Such use of quality measures oversteps the intent of these measures, which is not to replace clinical judgment in situations that demand individualized care.

2 2. Review of Current Diabetes Quality Measures and Need for Changes

There are dozens of diabetes care recommendations that are evidence based, but only a small subset of the most clinically powerful and safe interventions is suitable for selection as a publicly reported quality measure.

2.1 2.1 Current Diabetes Care Quality Measures

2.1.1 2.1.1 Clinical Interventions with Major Benefits for Patients with T2DM

The Evidence Tables in Appendix 2 provide detailed data from major research studies that justify the selection of BP control, lipid control, tobacco non-use, glucose control, and aspirin use as components of a comprehensive diabetes quality of care measure. These clinical domains are currently considered to have a stronger beneficial impact on morbidity and mortality related to T2DM, although the evidence base continues to change. Figure 2 and 3 lay out a method to rank the benefits of each of these components of diabetes care, based on reduction in macrovascular complications (Appendix 2), reduction in microvascular complications (Appendix 2), and cost.

Blood Pressure Control. Not all diabetes patients have hypertension, but about 70% do. BP control to < 130/80 mm Hg is recommended in most guidelines, although there is no randomized controlled trial (RCT) evidence to support a systolic target <135 mm Hg. ACCORD will compare 135 mm Hg to 120 mm Hg, with results expected in late 2009.

BP control appears to be cost saving in adults with diabetes across the entire adult age spectrum to approximately 80 years old.

LDL Cholesterol Control. The most common U.S. LDL treatment goal is < 100 mg/dl, with an optional goal of < 70 mg/dl for those with CHD. Evidence also supports treatment with simvastatin 40 mg a day even for those with untreated LDL < 100 mg/dl. Using generic statins appears to be cost saving in adults with diabetes. However, the long-term safety of other LDL-lowering agents such as ezetimibe is unsure.[9, 10]

Glucose Control. Current ADA and ICSI guidelines recommend individualized A1c targets based on age, comorbidity, life expectancy, ability to recognize hypoglycemic symptoms, cognitive status, and other factors. A common clinical goal is A1c <7%, but certain sizeable groups of diabetes patients are more safely and appropriately treated to higher A1c targets such as A1c < 8% (AGS,[11] ADA,[12] ICSI[13]). The evidence base, clinical merits, safety, ethics, and cost implications of recommending an A1c < 7% target for publicly reported quality measures is a matter of active current debate. The precedent of establishing a public accountability measure that rewards more aggressive care than that recommended in evidence-based clinical guidelines is an issue that needs to be addressed. This debate will need to include parties beyond the medical care community. There is a real danger that quality measures that go beyond a conservative approach to therapy and infringe on personalization of care and physician clinical judgment could lead to the loss of credibility of quality measures overall, and expose sponsoring organizations to legal and well as ethical risk. This is especially true, in the case of aggressive glucose control in T2DM, because of uncertain long-term safety of agents needed to achieve aggressive glucose control in many patients, and the documentation of harm to some groups of patients who achieve A1c < 7%.[1, 14, 15]

Aspirin Use. There are mixed RCTs on this topic,[16] with meta-analyses suggesting a modest benefit. Cost-effectiveness appears robust.

Tobacco Non-Use. This is a major risk factor for microvascular and especially macrovascular adverse outcomes, and is a high treatment priority with proven benefit and cost-effectiveness. About 13-20% of adults with diabetes are current smokers.

2.1.2 Use of a Comprehensive Diabetes Quality Measure

The quality of diabetes care in each of these five domains can be reported separately, or these five measures can be combined into a “comprehensive” diabetes quality measure. In most settings, a patient is classified as “at goal” if they meet in one year the clinical goals for all five of these domains (currently A1c < 8%, BP < 130/80 mm Hg, LDL < 100 mg/dl, documented non-tobacco user, and use aspirin). If a patient is not at goal on any one of these five measures, they are classified as “not at goal.” Providers, medical groups, and health plans are then compared on the proportion of their diabetes patients who are simultaneously “at goal” for all five clinical domains.

Although the concept of a comprehensive measure is attractive, it is possible for medical groups to increase their performance on the comprehensive measure by ordering more frequent A1c and LDL tests, without any improvement in mean or median A1c, BP, or LDL control, as shown in a recent report by Peterson et al.[17]

2.1.3 Current Performance on Diabetes Quality Measures

Despite the major advances in all five of these major clinical domains (A1c, BP, LDL, ASA, Tobacco non-use) in recent years, less than 20% of adults with type 2 diabetes reach the comprehensive quality goal. For example, in one high performing multispecialty medical group in Minnesota the best individual primary care physicians now have 40% of their patients at the comprehensive diabetes goal. The overall proportion of diabetes patients at goal is 20% in primary care clinics, and 13% in endocrinology clinics.

By definition, the comprehensive measure is the product of multiplying five decimals. Thus, even if 80% of all diabetes patients were at goal on each of the individual measures, the comprehensive "at goal" metric could be as low as 33%, or theoretically range as high as 80%. This point is not appreciated by the general public or by many policy makers, who would likely view a physician or medical group or health plan with only 40% of patients "at goal" as providing very poor care.

This point is illustrated in Minnesota, where a state-wide coalition of payers supported by the state health department has set a state-wide goal that 80% of diabetes patients should be able to reach the comprehensive goal of A1c < 7%, BP < 130/80 mm Hg, LDL < 100 mg/dl, aspirin use, and non-tobacco use. Based on recent RCT findings, if providers intensified care to achieve A1c < 7% for at least 80% of all adults with diabetes, not only would costs rise precipitously;[1, 2] but treatment side effects would include increased obesity[1, 2], severe hypoglycemia[1, 2], congestive heart failure, and increased hospitalizations;[2] and mortality in T2DM patients with CHD would increase significantly (per results of ACCORD, in which there was one excess death for every 90 T2DM patients treated to a mean A1c of 6.4% over a 3.5 year period[2]). It is unlikely that encouraging health systems and physicians to pursue (via public reporting and/or incentives) this aggressive treatment strategy would benefit either patients or payers.

2.2 Modifications Needed to Current Diabetes Measures

2.2 2.2.1 Need to Reconsider and Modify the Glucose Control Quality Measure

Clinical reports from ACCORD, ADVANCE, UKPDS[18] and Steno-2 suggest that it is not possible to categorically recommend a single A1c goal for all T2DM patients. In the light of recently reported evidence, NCQA has recently (September 2008), modified its A1c goal categories. All major clinical guidelines (ADA,[12] ICSI[13], AGS[11]) now recommend personalizing A1c goal (usually between 6.5% and 8%) based on each specific patient's clinical circumstances. Factors that need to be considered in this individualized glucose control goals include age, life expectancy, pregnancy status, occurrence of severe hypoglycemia, hypoglycemia unawareness, cognitive status, autonomic neuropathy/gastroparesis, coronary heart disease (CHD) status, numerous other comorbidities that limit life expectancy, access to care, insurance status and affordability of care/pharmacy coverage, and patient preference.

It is an ongoing challenge to maintain a set of A1c quality measures that accommodate the need for clinicians to individualize A1c treatment goals, while at the same time maintaining some emphasis on the importance of good glucose control, which has well-documented clinical benefits and is especially appropriate in younger or more recently diagnosed patients.[18] One reason why ACCORD, ADVANCE, and VADT (the only RCTs that have ever achieved and maintained A1c =< 7% in T2DM) showed no benefit of aggressive A1c control on CV events and mortality may be that better background BP and LDL control reduces the incremental benefit of tight glucose control. Another reason why ACCORD, ADVANCE, and VADT showed no benefit of aggressive A1c control on

CV events or mortality may be that the long-term safety (especially the long-term CV safety) of many agents used to lower glucose, is uncertain (this includes sulfonylureas, TZDs, incretin mimetics, sitaglipitn, analog insulins, and others). If future studies confirm that BP and LDL reduction are the most beneficial components of T2DM therapy, and/or that long-term safety of glucose-lowering drugs is questionable, then less emphasis on aggressive A1c control may be warranted in future T2DM quality measures.

Meanwhile, a quality measure set at A1c < 8%, for example, would avoid potential harm to patients (ACCORD)[1] and encourage levels of glucose control proven to confer a 50% reduction in complications noted in Steno-2, and major benefits in the UKPDS follow-up study as well. Note that the achieved A1c in UKPDS was below 7% initially, then rose steadily to 8%, for a mean harmonic A1c of around 7.3%. This degree of glucose control was far superior to a level of 8% and overachieved by the control group in the UKPDS.

The possibility of having a quality measure that accommodates different A1c goals for different groups of patients might be considered. However, this approach presents daunting challengers in

(a) complexity of measurement,
(b) cost of data collection,
(c) unable to capture patient preferences, and
(d) could be confusing to those who need to understand and interpret the quality measures results (physicians, patients, employers).

2.2.2 Other Clinical Threshold Changes May Soon Be Needed

Studies that will conclude in 2009 and be reported in late 2009 or early 2010 may provide data that will affect the BP goal for T2DM patents, or affect recommendations for lipid therapy of T2DM patients. The present BP quality measures threshold is BP < 130/80 mm Hg. There is substantial data to support the DBP measure, but the lowest achieved SBP in a major clinical trial of diabetes patients is < 135 mm Hg in ADVANCE, reported in late 2007.[3, 19, 20] The pending ACCORD BP Study will compare results at SBP of 120 mm Hg to SBP of 135 mm Hg when it is reported in 2009 or 2010. Some recent reports have also raised questions about the degree of benefit obtained from aspirin therapy in diabetes patients, although no studies to date have suggested harm from this therapy.

2.2.3 Should Diabetes Quality Measures be Equally or Unequally Weighted?

All evidence-based diabetes care recommendations are not of equal clinical value, nor are they equal in cost-effectiveness (Evidence Tables, and Figures 2 and 3). Moreover, the cost-effectiveness of intensive glucose control decreases with increasing age, and some studies suggest that for substantial subgroups of adults with T2DM, the risks of intensive glucose control may be substantial and sometimes outweigh the benefits. Equal weighting of unequal clinical domains in a comprehensive quality measure may lead to unintended negative consequences for patient outcomes, costs of care, or both.

Perusal of the Evidence Tables (Appendix 2) clearly demonstrates that these five clinical domains (glucose control, BP control, lipid control, aspirin use, and non-use of tobacco) do not have equal benefits on patient outcomes including macrovascular complication, microvascular complications, and mortality. Some clinical domains provide greater benefits to patients than others, and therefore may deserve greater emphasis in quality measures. However, the current comprehensive diabetes quality measure incorporates glucose control, BP control, lipid control, use of aspirin, and non-use of tobacco as equal components. Many experts have suggested that these quality measures be weighted,

with more weight assigned to measures that are most effective and less weight assigned to those that are less effective[21], or less cost-effective.[22] Figures 2 and 3 illustrate the use of a well-established approach to rank the five clinical domains in the comprehensive measure based on their relative impact on macrovascular complications, microvascular complications, and costs.[23, 24] Additional discussion of weighted quality measures is found in section 4.1.

2.3 2.3 Cost and Complexity Limit the Number of Diabetes Quality Measures

In selecting the optimal set of diabetes quality measures, it is critically important to recall that dozens of important quality measures for conditions unrelated to diabetes have been and continue to be developed, and that there is a practical and financial limit on how many diabetes and total quality measures may realistically be put into the field. For this reason, it is unlikely that developing a diabetes quality measurement set of more than five measures is realistic based on cost, complexity, and competing measurement demands beyond diabetes.

Based on the above discussion and the data available from research studies, quality reporting organizations are well-justified in not publicly reporting performance on many evidence-based diabetes care elements beyond those now reported. Note that in some instances, internal collection of additional measures may provide useful insights to those attempting to improve diabetes measurement or quality of care at specific sites.

Process of Care Measures. Some diabetes process of care measures (such as frequency of A1c tests, LDL tests, BP measures) are not tightly linked to intermediate outcomes of care (A1c levels, BP levels, LDL levels). However, other diabetes process of care measures (eye exam rates, foot exam rates) are correlated with important measures of clinical outcome (vision, amputation rates). Nevertheless, both amputation and retinopathy rates are affected profoundly by glucose and/or BP control. Thus, when limited resources are available for both care and for quality measurement, measures of the degree of glucose or BP control is arguably more important than focusing on rates of screening for the sequellae of poor glucose or BP control, and keeps provider attention and QI resources focused on the most important clinical activities—those that prevent complications, as opposed to those that seek to detect preventable complications. This logic supports the need to limit the set of diabetes quality measures, and keeps the focus on preventing diabetes complications.

It is important to note that current recommendations for periodicity of diabetes visits, A1c tests, LDL tests, MAU tests, eye exams, and foot exams are largely based on expert opinion rather than strong randomized trial evidence. On the other hand, multifactorial intervention trials such as Steno-2, ACCORD, and ADVANCE show that certain multi-faceted clinical protocols powerfully improve intermediate outcomes of care and mortality.

Preventive Care Measures. Preventive care is as important for adults with T2DM as for any other group, and influenza or pneumococcal immunizations may be more important in diabetes patients than many other groups. However, because most evidence-based preventive interventions are broadly recommended for groups that include diabetes patients, the corresponding quality measures, although very important, are not specific to diabetes care and are judged beyond the scope of this discussion.

Specific Treatments with Minor Benefits. Beyond treatments with major benefits to patients with T2DM listed in Appendix 2, there are dozens of clinical interventions for

patients with type 2 diabetes that demonstrate some degree of benefit in at least one clinical trial. Many of these interventions have not been thoroughly vetted for long term impact on complications, adverse events, or mortality. Some "evidence-based" interventions have benefits that are quite small (relative to glucose, BP, or lipid control), or only apply to a small subset of adults with diabetes. At present few of these other treatment strategies deserve consideration as a quality measure. Examples include fish oil, chromium, antioxidants, certain vitamins, garlic/alcohol/fiber consumption, mind-body stress reduction, etc.

Diabetes Disease Management, Patient Education, and Home Glucose Monitoring. Additional important elements of diabetes care have often been suggested for quality measures. Home glucose monitoring is an important element of care for some patients with diabetes, and is broadly reimbursed by insurers, but randomized trials show inconsistent benefits. Diabetes patient education is an essential element of care, but meta-analyses indicate the measurable benefits are modest.[25] Similarly, the impact of disease management on costs and outcomes for diabetes patients has been mixed, and less beneficial than initially hoped.[26] Thus, current data strongly suggests that new models of diabetes patient education and disease management, especially models which sharpen their focus on behavior change, and incorporate more content on BP control, lipid control, and smoking cessation, be developed before being widely applied as a quality measure. In this regard, the recently popular concept of a "medical home" which has the potential to integrate diabetes education and disease management services with primary care services, should be rigorously evaluated, along with other new delivery system innovations.

Use of Outpatient Electronic Medical Records (EMR) or other Care System Innovations. The literature on EMR impact on quality of diabetes care is mixed at best. Major studies from Mayo Clinic, Boston, Minnesota, and New Jersey have demonstrated that offices that use EMRs do more frequent A1c and LDL testing, but achieve no better levels of glucose, BP, or lipid control than practices without EMRs.[27-30] Thus, it seems premature to advocate quality measures endorse the use of these new and still immature technologies at this time.

2.4 2.4 Summary: What Changes are Needed in Current Diabetes Quality Measures?

The current diabetes comprehensive set includes measures of glucose control, BP control, lipid control, aspirin use, and tobacco non-use. This approach to diabetes quality measures seems reasonable and should be maintained. However, the glucose threshold in the diabetes quality measure requires review and modification, and questions about prioritizing or weighting the components of the comprehensive measure remain important.

Many evidence-based clinical interventions do not meet the standards for selection of quality measures that have been previously articulated by NQF, NCQA, and other authorities and are not suitable for quality measures. Note that diabetes quality measures that are widely applied will remain a small subset of all evidence-based interventions for most clinical conditions at least until EMR systems are very widely implemented.

3 3. Addressing Important Gaps in Diabetes Quality Measures: Top Priority Diabetes Care Measures to Consider for Development and Implementation

Even as these core measures are refined and fielded as a single comprehensive outpatient diabetes quality measure, it is clear that important gaps in diabetes care measures remain unaddressed. Here we will focus on three major gaps in diabetes quality measures:

(a) Primary prevention of T2DM,
(b) Diabetes care quality for hospitalized patients with type 2 diabetes, and
(c) Integration of cost and quality in diabetes care measures,

It is very likely that developing quality measures for these domains would direct attention and resources to these important current challenges in diabetes care.

3.1 3.1 Quality Measures that Target Primary Prevention of Diabetes

Although most diabetes quality measures are focused on those already diagnosed and treated. Additional quality measures are needed to address primary prevention of type 2 diabetes.

Lifetime risk of developing T2DM in the U.S. is currently 35% for women and 30% for men; the risk is even higher for African Americans, Latinos, and Asian Americans, and is trending upward. Among those with prediabetes (defined as a fasting glucose of 100 mg/dl to 125 mg/dl), about 10% per year go on to develop diabetes. Currently, the mean age at diabetes diagnosis is about 55-56 years, but this is dropping, and there is clear evidence that younger adults and adolescents are developing diabetes at rates that are rapidly increasing over time.[4, 31] The major driver of increased diabetes risk is overweight (BMI 25 to 29.9) and obesity (BMI >=30). The prognosis for those who develop T2DM at younger ages is ominous, since they will be exposed to the ravages of the disease for more years of their lives. However, effective lifestyle and pharmacologic interventions are available for those with pre-diabetes (or impaired glucose tolerance) that slow the progression to overt diabetes. Ultimately, the ONLY way to "reduce" costs of care for diabetes is through primary prevention of obesity and T2DM.

Measures of primary prevention of T2DM could appropriately be directed to a broad range of stakeholders. There are evidence-based activities that health plans, employers, worksites, payers, schools, local and state governments, and public health policy makers, as well as clinicians and medical groups may engage in to slow progression to obesity and diabetes. Inclusion of a broad range of stakeholders in Figure 5 is meant to be suggestive, not proscriptive, and recognizes that the diabetes epidemic is a society-wide problem whose solution cannot be limited to the narrow confines of the traditional health care system. To successfully blunt the pressing epidemic of obesity and concurrent diabetes, preventive measures will need to be implemented broadly across a range of settings, as recent reports have emphasized.[31]

Thus, in developing quality measures related to primary prevention of T2DM, a broad range of stakeholders including health plans, worksites, payers, public health policy makers, and clinicians will have important contributions to make. A recently developed evidence-based guideline for prevention of chronic diseases (including but not limited to diabetes) is available on the website of the Institute for Clinical Systems Improvement (www.icsi.org) in Minnesota and provides suggestions on developing quality measures that are reflected in Figure 5 of this report.

3.2 3.2 Quality Measures that Target Quality of Care for Hospitalized Diabetes Patients

There is a current dearth of quality measures for inpatient diabetes care.

The most urgent need may be for a measures of glucose control in diabetes patients hospitalized on medical and surgical wards for a wide variety of conditions, such as elective surgery, non-elective non-cardiac surgery, pneumonia, urosepsis, asthma, depression, and myriad other conditions. Although evidence for extremely rigorous glucose control even in intensive care units remains controversial,[32]many patients suffer prolonged and extreme hyperglycemia that increases risk of infections, slows healing, and likely contributes to longer hospitalizations.

Inpatient care units (hospitals, or wards within hospitals) would be the most likely reporting unit and accountable party for such measures. Quality measures for inpatient settings may be based on clinical guidelines for inpatient diabetes care, such as those now published by the ADA (www.diabetes.com) or those being developed at the Institute for Clinical Systems Improvement in Minnesota for inclusion in the 2009 Treatment of Type 2 Diabetes Clinical Guideline (www.icsi.org). Representative candidate measures for providers and hospitals could include these:

--Number of patient-days with a sugar > 300 mg/dl, divided by number of diabetes patient days.
--Number of diabetes patents-days with administration of basal insulin (or insulin pump) divided by number of diabetes patient-days.
--Rate of use of insulin pumps in diabetes patients in intensive care units,
--Rate of use of standard standing orders for glucose control at time of admission,
--Evidence of well-planned and coordinated transitions in care both at (and before) admission and at (and after) discharge.

3.3 3.3 Measures that Assess Resource Use in Diabetes Care

Diabetes care is very expensive on a per-patient basis, and the rapid increase in number of adults and adolescents with diabetes multiplies these high costs by millions of more people each decade. The cost of care for adults with diabetes is 250% to 300% higher than comparably aged non-diabetes patients. In Minnesota in 2004, mean direct health care costs for those with diabetes were $13,042 compared to $2,905 per year for those without diabetes[33]. However, measures of diabetes quality have rarely incorporated assessment of resource use related to diabetes care.

When considering outpatient care, there is no conclusive evidence that higher quality is related to higher outpatient costs of care. A number of recent studies strongly suggest that diabetes quality of care is only weakly related to outpatient resources used for diabetes management. For example, Figure 6 shows that medical groups with similar levels of diabetes quality of care have outpatient costs of diabetes care (including outpatient visits and pharmacy charges) that differ three-fold.

Current publicly reported diabetes quality measures are limited to reporting quality of care, and pay no attention at all to resource use (cost) of diabetes care. A set of diabetes measures that conjointly consider both quality and costs might encourage medical groups to adopt simple strategies to control diabetes care costs. The data shown in Figure 6 strongly suggest that substantial reductions in cost of care could be

achieved in many (but not all) medical groups without reducing quality of care. Here we present some ideas to catalyze the development of measures that consider resource use in diabetes care:

3.3.1. Develop Measures that Encourage Use of Generic Drugs for BP, Glucose, and Lipid Control A simple first step towards improving the value equation in diabetes care would be to develop measures that focus primarily on cost-related issues, such as use of generic medications. One could measure at the health plan, medical group, or provider level the percent use of generic agents in drug classes with generic availability.

Most recommended first and second line agents in BP, lipid, and glucose control are available as effective and inexpensive generic medications.[34-36] Many medical groups closely affiliated with health plans (and the VA) have formularies and monitor individual physicians' rate of generic drugs. Some provide feedback to physicians that monitors and encourages use of effective and inexpensive generic drugs. These medical groups (many of which, including HealthPartners, are national leaders in diabetes quality of care) have documented savings of millions of dollars a year in each of multiple drug classes.

Increased use of effective and less expensive generic medications would likely be welcomed by patients who pay an increasing share of pharmacy costs out-of-pocket. Reduced out-of-pocket costs per prescription would enable some patients to afford additional medications needed to achieve important clinical goals. An example of the huge differences in cost of generic and branded BP and lipid medications is found in a recent report [37] that estimated the annual costs of branded BP and lipid drugs at $1,238 and $1,543 respectively. Generic equivalents of many such drugs can be had for a total cost as little as $40 per year at Target or Wal-Mart.

3.3.2 Assign Greater Measurement Weight to Diabetes Care Quality Measures that have Maximal Cost-Effectiveness. Quality measures could be weighted to focus provider attention on interventions that have superior cost-effectiveness. As an example of this, intensive A1c control was estimated by CDC in 2003 to cost about $40,000 per QALY gained in middle age patients, and over $100,000 per QALY gained in older patients. The widespread use of more expensive glucose-lowering drugs since 2002 would raise the cost per QALY saved by intensive glucose control considerably. On the other hand, intensive BP control, which has been shown to reduce CV events, CV mortality, and totals mortality in multiple RCTs [3, 38-40], is cost saving from age 35 to 80 years. [41] From the point of view of cost and effectiveness, it may be useful to weight BP control more that glucose control.[2, 3, 42-44]

A cost analyses by leaders of the ADA, AHA and ACS using the Archimedes model to assess cost effectiveness has recently been published.[37] This paper concludes that insufficient resources are available to provide all recommended evidence-based care that will reduce the cardiovascular disease burden in America. If we cannot afford to pay the cost of all evidence-based elements of diabetes care for the rapidly increasing number of adults with T2DM, then it seems logical to prioritize care domains and emphasize those with superior cost-effectiveness at the policy (not the individual patient) level. This process could be implemented and reinforced if quality measures assigned greater weight to diabetes care domains with maximal cost-effectiveness. This may also re-frame pharmaceutical manufacturers approach to pricing branded products. New products would do best if they were priced so as to be competitive in terms of cost-

effectiveness with inexpensive generic products. To merit a higher price, the product would have to deliver a greater clinical benefit.

A recent report indicates that in Steno-2, a multifactorial intervention was able to reduce CV events and mortality over 50%, and also substantially reduce microvascular complication rates. Relative to control group, intervention group patients gained 1.66 QALY at an incremental cost of Euros 2,538 per QALY added. The intensive group achieved the following clinical goals: A1c 7.7%, LDL 70 mg/dl, SBP 136 mm Hg, frequent use of aspirin, and frequent use of ACE. These clinical goals may be quite reasonable targets for value-based diabetes care. Steno-2 could serve as a template for modifications to current U.S. diabetes quality measures, which currently overemphasize A1c control relative to BP and LDL control based RCT evidence reviewed in Appendix 2.

3.3.3 Measures that assess the ratio of diabetes care quality to costs of care at the patient level.

Another measurement option related to resource use in diabetes care is to develop a measure that considers the ratio of costs to the quality of care at the health plan or medical group level. This notion introduces the concept of efficiency of care, although the use of the word "efficiency" tends to provoke disagreements among economists and others experts over the technical use of the term. An analysis of the ration of costs to quality of diabetes care at the medical group level is presented in Figure 6.

Costs of care may be measured in many ways. In Figure 6, costs were limited to total outpatient and diabetes-related pharmacy costs and averaged for diabetes patients in each medical group. Costs could, however, be defined to include total costs, inpatient costs, outpatient costs, drug costs, and costs for durable medical equipment. Costs may be aggregated at the patient level, or attempts may be made to partition costs attributable to diabetes (versus conditions other than diabetes) using diagnostic groupers or other strategies. These strategies are complex and yield less than perfect results, and tend to underestimate the impact of diabetes, which affects costs of care for many other clinical categories through longer hospitalizations and other mechanisms. Comparison of costs of care across geographic regions and across time presents additional challenges. Total costs may need to be expressed in utilization units, rather than dollars, to permit valid comparisons across time and geographic region.

It is unlikely that individual providers will be responsible for enough diabetes patients to accurately estimate diabetes care costs at the provider level. Moreover, most diabetes patients see many different physicians, so that accurate allocation of costs at the physician level or at the medical group level may be very challenging, incomplete, or inaccurate. Sophisticated methods to link patients to providers and partition costs across providers are under development. Meanwhile, development of ratio measures that incorporate both cost and quality of care is well underway, and many of the problems that have been identified thus far are amenable to solution.

3.4 3.4 Summary of Top Priority Diabetes Care Measures to Consider for Development and Implementation

This section has made the case for prioritizing the development of new diabetes measures that:

(a) Target primary prevention of diabetes,
(b) Assess quality of diabetes care on hospital medical and surgical wards, and

(c) Conjointly consider both quality and cost of diabetes care.

Developing these measures, testing them, modifying them, and implementing them would expand quality measures across a broader scope of diabetes care. Moreover, development of measures of resource use will shift quality measurement from a "quality at any cost" mindset to a "quality as a value proposition" orientation. This seismic shift would address a major unintended consequence of current diabetes quality measures—that they may actually be driving up costs of care more rapidly than they are driving up quality of care.[33, 45]

Next we will turn our attention to a set of methodological challenges whose resolution may inform development of future diabetes quality measures.

4 4. Technical Issues and Challenges in Diabetes Quality Measurement

The conceptualization, design, pilot testing, and implementation of diabetes quality measures is a complex and necessarily adaptive enterprise. Many organizations, researchers, and agencies have devoted substantial resources and talent to investigate fundamental issues related to diabetes quality measures and their impact. In the last ten years, we have learned a lot about quality measurement, but several pressing methodological issues remain unresolved. Additional investments to address methodological challenges is needed to assure the long-term viability and relevance of quality measures related to diabetes and other conditions.

This short list of technical issues is necessarily incomplete, and the author welcomes feedback and suggestions related to these topics, or suggestions of other topics that might be added to this list.

4.1 4.1 Methods to Prioritize Diabetes Quality Measures Based on Relative Clinical Benefit and Relative Cost-Effectiveness

It is apparent that all evidence-based care recommendations do not have equal benefit from the perspective of populations. Therefore, proposing that all evidence-based care components be assigned equal priority in quality measures defeats the goal of maximizing clinical benefit per unit of resources devoted to care. One way to quantify the relative clinical benefit of diverse components of care is to assess the *number needed to treat* (NNT) to prevent a specific adverse event, such as an amputation or a heart attack. The Evidence Tables included in Appendix 2 use the NNT approach to compare the relative clinical effectiveness of various diabetes care strategies (BP control, glucose control) on microvascular or macrovascular complication rates. Use of this method to compare benefits of treatment strategies has increased in recent years, but NNT methods have some important limitations and drawbacks.

A more sophisticated approach to comparative assessment of diverse care components is to employ cost-effectiveness analysis (CEA). In pioneering work, Maciosek and colleagues have prioritized preventive health care services based on conjoint ranking of both clinical effectiveness and cost, using data derived from clinical trials and from formal cost-effectiveness analyses. This approach, which is logical and can be understood by non-economists, could be adapted to weight or prioritize components of diabetes care for quality measures (See Figures 2 and 3). There are several useful examples of CEA in the diabetes literature,[37, 40, 41, 46, 47] which provide comparative cost-effectiveness data for various components of diabetes care.

As an important disclaimer, please note that methods designed to rank or prioritize quality measures are NOT designed or intended to guide clinical practice or replace clinical judgment. Prioritization strategies are only meant to guide the selection and weighting of quality measures for diabetes care—not to guide care of individual patients.

4.2 4.2 Should Diabetes Quality Measures Be Adjusted for Patient Characteristics like Insurance Status, Race, Age, and SES?

Patient response to recommended intensification of therapy is uneven, and is influenced by insurance status, educational level, race, and other factors. When uninsured or publicly-insured patients are concentrated in certain practice settings (such as Community Health Centers), it is difficult to compare clinicians in these settings to their suburban peers in an even-handed way.

In response to this concern, some argue that all Americans should receive the same high standard of care. However, an unintended consequence of unadjusted quality reporting (when linked to public reporting or economic incentives) is to drive very capable primary care and subspecialist clinicians out of inner city clinics and care settings to the suburbs, where patients have generally higher socioeconomic status and providers may much more easily obtain payments related to superior clinical performance. This ultimately will weaken, rather than improve, the care infrastructure for many patients struggling to deal with diabetes.

Some reports of diabetes care quality are stratified by insurance type (Commercial, Medicare, Medicaid) because of the persistent lag in diabetes care quality among Medicaid and uninsured patients. Some argue that additional adjustment is justified; others contend that adjustment for additional factors would be too cumbersome and expensive, and may make interpretation of results more difficult. More work on this topic is needed; the inclusion of a separate category for uninsured would be desirable for several reasons.[48]

4.3 4.3 Lack of Evidence on How Best to Treat Patients with Multiple Chronic Diseases

Patients with T2DM commonly have multiple chronic conditions, each of which has its own set of evidence-based care recommendations (Figure 1). Some evidence-based recommendations for other chronic diseases that commonly co-occur with diabetes, such as hypertension (thiazide diuretics), arthritis (NSAIDs, steroids), and COPD (steroids), may worsen glucose or BP control. The American Geriatrics Society and others recognize that patients with multiple chronic conditions require personalization of care, which complicates quality measurement.

There is a great deal of attention now being devoted to this knowledge gap.[49, 50] The availability of large clinical databases, especially those that include comprehensive data derived form Electronic Medical Records (EMRs) will accelerate knowledge generation and provide needed evidence to guide development of more appropriate and useful clinical guidelines and quality measures that accommodate the complex care needs of these challenging patients.

4.4 4.4 Should Diabetes-Related Measures Focus on Structure, Process, and/or Outcome?

Structural measures: Certain structural measures may be useful in some situations. Examples, include availability in clinics of point of care A1c testing; use of accurate electronic equipment to measure BP; and payer (employer, insurer) provision

of adequate insurance coverage for those with diabetes. Use of EMRs is addressed in Section 5.2.

Process measures: Many diabetes process measures are not linked strongly to intermediate outcome measures. For example, A1c and LDL test frequency are not strongly related to better A1c or LDL levels. On the other hand, regular foot exams reduce amputation rates—but foot exam rates are notoriously hard to document. Eye exam rates may be related to less progression of retinopathy when laser treatment is available. However, both foot exams and eye exams have drawbacks as quality measures because they only detect complications, they do not actually prevent the occurrence of a complications, as control of A1c, BP, and LDL do. Thus, the later are nearly always preferred as quality measures.

Intermediate clinical outcome measures such as A1c, BP, and LDL levels are linked in clinical trials to hard outcomes like stroke, heart attacks, mortality, blindness, and nephropathy. Use of intermediate outcome measures has many advantages, and there is considerable experience with these measures, which have overall performed quite well. Remaining refinements may include ongoing adjustment of target levels as evidence changes, prioritizing these measures based on their unequal clinical value or cost effectiveness, and adjustment for patient characteristics when publicly reporting quality measures to avoid discrimination against providers serving patient populations that are uninsured, use Medicaid, or have low health literacy.

Specific adverse events, such as emergency department visits or hospitalizations, are viewed by some purchasers as failures of clinical care. However, this point of view overlooks the fact that human life expectancy is in fact limited, death is not ultimately preventable, and the hospital is an excellent place to be under certain conditions. Quality measures that reward physicians for not hospitalizing patients, or which penalize health care providers when their patients visit the ED, could have many unintended consequences that might harm some patients. Any arrangement that connected these measures to financial incentives for providers, medical groups, or health plans, could be widely perceived as being ethically questionable.

Definitive clinical outcomes: CV events, CV mortality, overall mortality, blindness, amputation, and ESRD (dialysis/renal transplantation) appear to be logical quality measures. However, all require large sample size for stable measures, and this rules out application at the level of individual physicians, clinics, and all but very large medical groups. Fair comparison of event and mortality rates across medical groups or health plans would require sophisticated adjustment for many patient factors and comorbidities that inevitably are unevenly distributed. Mortality reporting entails substantial expense as well as a time delay of up to two years related to use of National Death Index data.

4.5 4.5 Advantages and Limitations of Comprehensive Measures

Comprehensive diabetes quality measures have several advantages. They are simple, easy to explain to both physicians and to patients/public/employers, emphasize a limited subset of very important clinical domains, and guarantee due to math (multiplying multiple decimals) that there will always be a lot more room for improvement.

Comprehensive measures also have some disadvantages. Current versions assume all recommendations are equal clinical benefit—a demonstrably false assumption. It is difficult to get many patients, especially those who deny that they have diabetes, or those with low health literacy—to achieve multiple clinical goals. In addition, current

comprehensive measures usually do not give "partial credit", do not weight measures by what is most important; take no account of resource use and may encourage providers to focus on patients near goals instead of those way out of range who may often benefit the most from additional attention. Moreover, comprehensive measure performance can be improved by doing more A1c and LDL tests—without improving levels of A1c, BP, or LDL control.[17] This scenario increases costs with no clinical benefit to patients.

4.6 4.6 Resolving the Debate Between "Threshold Measures" versus "Incremental Improvement from Baseline" Measures

There is debate in the academic and business community about whether performance measures should best be designed to reward performance based on achieving a pre-set static performance benchmark, or whether it is better to tailor performance goals to current levels of performance. Static goals have a variety of advantages. They are simpler to understand, and to administer. Static goals are likely to engage delivery units who are close to goal, but not quite there. Static goals also reward delivery units that have a long track record of effort in quality improvement, and who are closer to goal or above goal. On the other hand, static goals may fail to engage those furthest from the goal--those delivery units with the most urgent need to improve.

4.7 4.7 Using an Episodes of Care Approach for Diabetes Quality Measures

An "episode of care" approach to diabetes quality measurement offers a unique set of advantages, but has some specific limitations that must be acknowledged. Perhaps the principal challenge to this approach is the difficulty of "staging" a person's diabetes career into specific segments with associated variation in care recommendations based on clinical trial data.

Conditions that are amenable to an episodes of care approach due to clearly delineated time intervals associated with procedures or conditions include episodes of:

(a) Cancer,
(b) Care related to surgical or other major procedures (such as cholecystectomy, cataract surgery, coronary artery bypass surgery or hip replacement),
(c) Care related to acute illnesses (such as cystitis, pneumonia, or myocardial infarction), and
(d) Relapse in chronic diseases (status asthmaticus, status epilepticus, depression relapse, hospitalization related to bipolar condition, etc.).

However, there are a number of instances with respect to type 2 diabetes that may be suitable for an episode of care approach to quality measurement. These instances might include:

(a) The one-year interval form the date of a new diabetes diagnosis. There is considerable data to show that most patients with newly diagnosed type 2 diabetes have major deficits cardiovascular risk factor control at the time of diabetes diagnosis, but that many achieve substantial improvements in risk status within the first year of diabetes including better A1c control, better BP control, better LDL control, increased rates of aspirin use, and reduction in obesity.[51]

(b) Hospitalizations of those with diabetes could be used to define the beginning of an episode of care. The start date of the episode might be defined as several weeks antecedent to the date of hospitalization, and the end date of the episode could be at a defined time (such as one month) after hospital discharge. Quality measures most appropriate for such episodes might include assessment of glucose control

(avoiding extremes of glucose values) during the hospital stay, and assessment for error-free transitions in care at hospital admission and discharge, among others.

(c) Newer data from ACCORD and other trials suggest that those with type 2 diabetes may benefit form different degrees of glycemic control at different stages of their diabetes careers. For example, those with diabetes for less than 5 years, who are younger, and who are free of clinical coronary artery disease (CHD) may benefit from more stringent glycemic control (A1c < 7%), whereas those that are older, with longer duration diabetes, or with CHD, may benefit more from less stringent glycemic control (A1c 7.0-7.9%)[1]. These two patient states (older with complications, versus younger without complications) could be viewed as stages of progression in a patient's career with type 2 diabetes, and care recommendations may differ in these two "episodes."

(d) Episodes may be defined from the onset of a new diabetes-related complication, be it CHD, elevated CHD risk beyond a defined threshold value (such as a CHD risk in excess of 10% in the next 10 years), onset of blindness, stage 3 or worse Chronic Kidney Disease (CKD), or others. These "episodes" could have specific measures for quality of care related to the managing the complication(s) or conditions of interest.

(e) A default "episode of care" for any patient with type 2 diabetes could be a one year period. In this case, most of the quality measures discussed elsewhere in this paper could be applied quite easily over this defined time segment.

Episodes of care have been proposed as a framework for care reimbursement and payment across a team of providers responsible for the care of specific patients. This concept, which is under development as part of the Bridges to Excellence and other programs, depends to some degree not only on clinical definition of widely accepted "episodes of care" but also on the creation of a payment or reimbursement structure that would correspond to the clinically defined episode of care.

4.8 4.8 Measurement of Use of Optimal Treatment Strategies (such as use of metformin, ACE/ARB, or statins) rather than reaching specific Treatment Goals (A1c < 7%, BP < 130/80 mm Hg, LDL < 100 mg/dl)

The present diabetes comprehensive measure is goal-based. It assesses the proportion of patients who reach "evidence-based" clinical goals for A1c, BP, and LDL. An alternative approach, advocated by some, is to assess whether patients with diabetes are receiving specific treatments related to A1c, BP, or LDL control. Advantages of this treatment-based approach include the following:

(a) Many clinical trials have tested specific treatment strategies, rather than specific clinical goals.

(b) Some older treatment strategies (metformin, statins) have proven long-term safety. Goal-based quality measures implicitly encourage widespread use of newer drugs (TZDs, ezetimibe) with unproven long-term safety.

Treatment-based approach to quality measures is most promising for lipid control. Instead of assessing the proportion of patients who reach the goal LDL < 100 mg/dl, a treatment-based measure would report the proportion of diabetes patients who are on a

statin dose equivalent to 40 mg or more of simvastatin (the dose indicated as beneficial in the most relevant RCTs).

A treatment-based measure for glucose control might assess the proportion of T2DM patients using metformin. Metformin is widely regarded as the preferred first-line drug for T2DM treatment in those with adequate renal and hepatic function and no congestive heart failure or emphysema.[18, 52] However, metformin monotherapy is often inadequate, and sophisticated clinical data systems would be needed to determine patient eligibility for and tolerance of metformin therapy.

A treatment-based approach to hypertension treatment in diabetes patients is even more problematic. About 30% of patients with diabetes do not have hypertension, so the use of a BP medication in these patients, even one as widely endorsed as ACE or ARB therapy, may not be indicated for many subjects. The antidote to this limitation is to identify the subset (about 70%) of diabetes patients with hypertension, and assess the proportion of those on an ACE/ARB. However, this is strategy may be unwieldy to implement in the field in the absence of sophisticated data systems or EMRs that capture BP measures.

4.9 4.9 Measure Treatment Intensification or Therapeutic Inertia

Therapeutic inertia is an important factor that contributes to failure to reach evidence-based clinical goals in both primary care and subspecialty care.[53-57] Therapeutic inertia may be measured at either the visit level, or at the patient level over a defined period of time, such as one year (a measure that is quite congruent with an episode of care approach).

To assess therapeutic inertia one must be able to (a) identify patients who are not at goal, and (b) ascertain from pharmacy data whether or not therapy has been intensified. These steps are conceptually simple, but are operationally complex and would be expensive to operationalize on a widespread basis, even if EMR systems were in place. Moreover, the link between therapeutic inertia and improved intermediate care outcomes is not as robust as one might wish.

4.10 4.10 Patient Reported Measures of Quality of Life (QOL), Satisfaction with Care/Patient Experience of Care.

QOL. There are many measures of QOL available, both for global QOL and diabetes-specific QOL, but all involve the administration of sets of questions that are scored as scales for psychometric validity. Commonly used measures include the HUI-2, HUI-3, Euroqol, and SF-12. QOL is only tenuously related to quality of diabetes care. Some recent work indicates that insulin use is associated with lower QOL—yet is necessary of the treatment of diabetes in many patients with T2DM.

Satisfaction with Care. Studies have shown that satisfaction with care is not related to achieved levels of A1c, BP, or LDL. For this reason, it must be considered an independent measure in its own right, and not a substitute for measuring biological measures that predict clinical outcomes and costs of care. Relying on satisfaction measures independent of biological measures of quality could have many negative unintended consequences, because the things that providers need to do to achieve evidence-based targets for A1c, BP, and LDL may be different than the things providers would choose to do if their principal goal was to maximize patient satisfaction with care.

A promising measure of **Patient Experience of Care** is the one developed by Safran et al. This measure covers multiple domains of care including access, communication, and overall satisfaction with both the provider and the facility. Because "patient experience of care" is related to health plan disenrollment and probably to likelihood of changing clinical or medical groups, it is highly valued by care delivery organizations. However, this scale is not tailored to diabetes patients, and there is low correlation between these scores and measures of diabetes intermediate outcome (A1c, BP, LDL) measures.

4.11 4.11 Quality Measures that hold Patients Accountable for Meeting Evidence-Based Diabetes Care Goals

Some have advocated providing positive (or negative) financial incentives to patients with diabetes who achieve (or fail to achieve) recommended clinical goals. This approach could be extended to patients without diabetes who successfully manage risk factors for diabetes such as obesity, physical inactivity, BP, lipids, and tobacco use. However, there is insufficient data available now to recommend or not recommends such strategies. Moreover, the financial cost of such strategies is likely to be high, especially if the target group is large. These measures need more development before they are ready for implementation.[58, 59]

4.12 4.12 Summary of Technical Issues and Challenges in Diabetes Quality Measurement

There are many technical challenges related to diabetes quality measures. There is also considerable ongoing research work to clarify the issues involved, identify and explore feasible strategies to address identified problems, and use newly acquired knowledge to advance the science of quality measurement in diabetes care. It is important that such "development" work continue, and strategies that both assure adequate resources for this work and also pool expertise into larger working groups, would likely accelerate progress.

5 5. Implementation of Diabetes Quality Measures: Start with the End in Mind

Quality measure development is a complex process, but implementing an effective set of quality measures may be even more challenging. HEDIS was designed to assess quality of care for insured patients, and designed for use at the health plan level. Over the last 15 years, quality measures have been extended to all diabetes patients, not only those employed or insured, and to medical groups and providers as well as health plans. As measures evolve over time and are designed to measure new dimensions of care, including resource use, continued attention to implementation of measures will remain an essential activity.

5.1 5.1 Should Diabetes Quality Measures Be Reported for Health Plans Only, or also for Medical Groups and/or Individual Providers of Care?

Health Plan Level. Current NCQA diabetes quality measures were introduced for use at the health plan level. However, in highly penetrated markets, most health plans contract with essentially the same set of medical groups. There is data from Minnesota (a highly penetrated managed care market with only about six remaining health plans) that show very little variation in quality measures across health plans, and much greater variation across medical groups and across individual providers.

Medical Group Level. There is growing interest in implementing diabetes quality measures at the medical group level. A large experiment with public reporting of diabetes (and other) quality measures at the medical group level has been underway in Minnesota since around 2003. This project, Minnesota Community Measurement, has collected, processed, and publicly reported detailed quality measures on a variety of

clinical quality measures, including a comprehensive diabetes care measure. The cost of data collection, data consistency across years and across medical groups, and data interpretation are challenging issues in an enterprise of this sort. Moreover, reports are typically issued only annually. Once data issues are resolved, quality reporting at the medial group level could be a powerful way to drive further improvement in diabetes care. One important question in search of an answer is what features of medical groups are linked to better diabetes care quality after controlling for patient mix.

Provider Level. Developing quality measures at the provider level presents a number of challenges that have been well described. Measurement of diabetes care quality at the provider level is somewhat constrained by the fact that the median number of diabetes patients per primary care provider (PCP) is about 50, with wide variation. Moreover, many patients have multiple providers, making assignment of responsibility for a given patient's care to one PCP challenging. For example, Medicare reports that its average beneficiary sees a mean of over 8 providers a year. Both older and recent studies raise concerns that providers might exclude difficult patients from their care to improve their performance measures, creating burdens for vulnerable patients and possibly rewarding providers for an ethically questionable practice.

Other obstacles to quality measurement at the provider level include the cost of data collection on a large number of diabetes subjects, and the resources needed to provide large enough financial incentives on an ongoing basis to a large pool of providers to attract and hold their attention on diabetes care improvement. Over-emphasis on diabetes measures risks the unintended consequences of directing provider attention away from other common and serious clinical conditions (such as CHF and depression) that urgently need improvement—although this is an issue at the health plan and medical group level as well. Finally, there is insufficient power at the provider level to compare resource use related to diabetes care.

Hospital Measures. Measures aimed at inpatient diabetes care would logically be implemented at the hospital level (or ward level if the hospital wished). There is broad recognition that glucose control is a particularly challenging aspect of care when diabetes patients enter the hospital for other conditions. There is limited evidence from intensive care unit (ICU) settings on the benefits of very tight glucose control in some clinical scenarios, such as acute heart attacks. However, these data are inconsistent across studies, and few studies have established the safety of intensive glucose control (which often involves insulin pumps) in non-ICU wards and units. Nonetheless, avoiding pronounced hyperglycemia is a practice that is widely recognized as beneficial. Inpatient measures might be incubated now for use later, depending on the results of future studies.

Patient / Member Level. Several thought leaders have recently proposed that financial incentives for better diabetes care (or healthier lifestyles to prevent diabetes and other problems) be directed to patients or health plan members. Many health plans provide certain types of positive financial incentives by, for example, subsidizing health club monthly dues if members exercise frequently. This approach has so far shown mixed results (those who get the health club discounts tend to be those who already exercise regularly). Active issues that remain unresolved include which patients to target, how much and what type of an incentive to provide, how to deliver the incentive, and whether this approach can incite and sustain desired improvements in care or lifestyle. It may be

worth considering what measures would be applied to assess qualification for such incentives if they were to be offered to more patients in the future.

A unified and coordinated set of diabetes quality measures that are specifically designed for applications at the health plan, medical group, and provider level could be desirable if it led to a synergistic effect on diabetes care quality improvement. On the other hand, the resources needed to sustain such an effort may be inefficient compared to targeting the level with the most potential to drive improvement—likely the medical group or provider level.[60-63]

5.2 5.2 Will widespread EMR implementation facilitate diabetes quality measurement or diabetes care improvement?

5.2.1 EMR Impact on Quality Measurement. At present EMRs are used by only 18% of the nation's medical physicians, despite many years of policy support from the federal government, threats from CMS, and encouragement from other payers to use EMR technology.[64, 65] The future rate of EMR implementation remains uncertain, although some states (like Minnesota) have mandated that all practitioners use EMRs by a certain date (2012).

Theoretically, EMRs would reduce the cost and increase the speed with which quality measures for diabetes and other conditions could be assessed at the medical group or physician level. However, dozens of different EMR systems are now in use within the U.S., and it is difficult and expensive to extract and combine data from different systems into a cohesive analytic data file. Moreover, the completeness, accuracy, and comparability of data elicited from various systems is uncertain.

5.2.2 EMR Impact on Quality of Diabetes Care. If EMRs came into wide use, they would permit detailed profiling of provider practice patterns, and ongoing assessment of individual physician adherence to recommended treatment strategies. For example, after mapping the "clinical decision space" for T2DM care, we profiled 122 primary care physicians across 20 distinct care domains related to glucose, BP, and lipid control in adults with T2DM. We then used the profile results to construct physician-specific learning interventions (completing simulated cases with feedback) that successfully improved subsequent diabetes care.[66]

Beyond monitoring and profiling diabetes care at the physician level, EMRs can be used to deliver clinical decision support at the point of care. For example, we programmed outpatient EMRs at HealthPartners to deliver drug-specific clinical decision support at visits by diabetes patients who were above evidence-based glucose, BP, or lipid goals. We showed that patients of physicians randomized to use this tool had significantly greater improvement in A1c and SBP levels than patients of physicians randomized to not have this clinical decision support tool.[66] Thus the detailed data available through EMR databases has the potential not only to expand the scope and reduce the cost of quality measurement, but also affords a potent introspective platform from which physician-customized (and patient-customized) care improvement interventions could be launched.

5.3 5.3 Linking Quality Measures to Positive or Negative Financial Incentives

One of the factors that drives provider and medical group interest in diabetes quality measures is the fact that in many communities, these measures are used as a basis to provide additional income to providers who meet or exceed defined quality of care

standards. The largest natural experiment yet, in Britain's NHS, led to considerable improvement in quality (or documentation) of diabetes care and in quality (or documentation) of care for many other conditions in a relatively short space of time. However, the cash incentives offered were several billion pounds, and increased physician income 15-25% in many cases. In the U.S, few programs have offered comparably sized financial incentives for care improvement. If CMS implements P4P for diabetes care in the next couple of years as planned, it is likely that other insurers and payers will follow suit. These incentives could drive broad use of diabetes quality measures at the medical group and provider levels.

5.4 5.4 Formatting of Publicly Reported Quality Measures for Maximal Public Impact.

Low levels of health literacy and high levels of innumeracy have been well documented in the U.S. adult population, and these problems extend to those with diabetes. There is extensive literature that suggests the majority of Americans are not yet strongly influenced in their health care choices by publicly reported quality measures.[67] The impact of diabetes quality measures on the public might be enhanced by more research and by consultation with marketing experts on how to format and disseminate the information for maximal impact on health care consumers.

At this time, it appears that cost of care may override considerations of quality of care when patients select medical groups or health insurance packages. Thus, incorporating some measures of cost of diabetes care or of efficiency of diabetes care may broaden interest in publicly reported diabetes care measures, and enhance their impact on care seeking behavior.

5.5 *5.5 Can New Diabetes Quality Measures Blunt Accelerating Costs of Care?*

Even carefully planned diabetes quality measures may have unintended consequences. In the mid-1990s emphasis on diabetes eye exam rates delayed health plan efforts to improve glucose and BP control by about five years. This likely increased the number of patients with retinopathy, some of which might have been prevented by better glucose and BP control.

Current diabetes quality measures are much improved from the initial set in 1995, but current diabetes quality measures loudly and clearly transmit to medical groups and providers this message: "quality at any cost." Is this the message that payers want to transmit? "Quality at any cost" may not be sustainable in the face of rising costs per patient, and rapidly rising prevalence of diabetes. Careful selection of diabetes measures that conjointly consider both quality and cost of care has the potential to replace the "**quality at any cost**" message with a "**quality as a value proposition**" message.

The best opportunities to reign in escalating diabetes care costs include the following:

--Primary prevention of diabetes. This is the only way to actually "save" money on diabetes care. Effective strategies are available, but are not widely implemented due to lack of resource sand lack of political will.[68, 69]

--Encourage and reward the use of generic drugs for glucose, BP, and lipid control.

--Emphasize elements of diabetes care that have maximal cost effectiveness: BP control, lipid control, aspirin use, and tobacco non-use. Each of these is cost saving to

payers, and each is a powerful clinical strategy to reduce microvascular and macrovascular complications.

--Steno-2 achieved A1c of 7.7%, LDL of 78 mg/dl, SBP of approximately 132/76 mm Hg and encouraged aspirin use. Relative to a randomized usual care group, patients who achieved these levels of care had more than a 50% reduction in major CV events and about a 45% reduction in mortality. They gained an average of 1.6 quality-adjusted life years at a cost of Euros 2,538 per QALY gained—a remarkable efficient use of diabetes care resources.[47]

This is far less expensive than current or past estimates of the cost-effectiveness of intensive glucose control alone (to a goal of < 7%). The Steno-2 CEA authors note that when this care model is delivered in primary care settings with increased use of generic drugs, this clinical strategy is estimated to be cost-saving. The Steno-2 clinical and CEA data, in conjunction with ADVANCE and ACCORD, provides a clear and simple template for change in the comprehensive diabetes measure that would both maximize levels of clinical benefit while substantially blunting accelerating costs of care.

6 6. Summary and Recommendations

Type 2 diabetes (T2DM) is a disease that affects close to 20 million Americans and costs the nation in excess of $150 billion a year in 2007 in direct and indirect costs. Clinical care for T2DM is complex, and major deficits in diabetes quality of care have been widely recognized since the 1960s. In recent years, there have been dramatic improvements in diabetes care, including a national median glycated hemoglobin (A1c) of 7.18% based on NHANES data, better blood pressure (BP) and lipid control, decreased tobacco use, and increased aspirin use.

However, review and revision of current quality measures for type 2 diabetes is needed (a) to accommodate shifts in the evidence upon which diabetes care recommendations rest, (b) to assure that the diabetes quality measures remain safe, ethical, and credible, and (c) to consider pilot development of conjoint measures of quality and cost of care so that the unintended message of “quality at any cost” is replaced by the message that “quality is a value proposition.”

Here is a short list of key considerations for discussion by NQF and others at the upcoming workshop for the purpose of closing the gap in diabetes quality measurement:

1. Retain the concept of a comprehensive diabetes quality measure.
2. Expand publicly reported diabetes quality measures to individual providers and medical groups, along with health plans.
3. Substantially revise the glucose control component of the comprehensive measure to avoid the unethical scenario of influencing providers to adopt treatment policies that increase mortality, severe hypoglycemia, weight gain, and costs (and encourage widespread use of expensive new drugs with unknown long-term safety) in exchange for a very small microvascular benefit.
4. Anticipate the need to revise the systolic blood pressure (SBP) control component of the diabetes guideline in late 2009.
5. Consider weighting or prioritizing diabetes quality measures based on relative clinical effectiveness or relative cost-effectiveness.
6. Expand diabetes quality measures to include inpatient quality of care measures.

7. Expand diabetes quality measures to include measures of primary prevention of type 2 diabetes. Consider expanding public reporting for such as measure to include not only health plans and medical groups, but also employers, worksites, schools, public health authorities, and state and local governments.
8. Develop and pilot test measures that conjointly consider both quality and costs of diabetes care, to maximize the clinical return on resources devoted to diabetes care.

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TABLES AND FIGURES

Figure 1. Common Comorbidities and Complications associated with Type 2 Diabetes Mellitus.

Condition	Cross-Sectional Prevalence	Lifetime Risk in those with Type 2 diabetes
Common Comorbidities		
Hypertension	70%	>90%
Lipid Disorders	>80%	>90%
Smoking	12-20%	>50%
Congestive Heart Failure	10-15%	~30%
Depressive Symptoms	20-25%	40-50%
Microvascular Complications		
Retinopathy	20%	50%
Blindness In One or Both Eyes	3-5%	~8%
Nephropathy	30%	50%
End Stage Renal Disease	3%	~8%
Neuropathy	30%	50%
Death from Microvascular Complications	***N/A***	***5%***
Macrovascular Complications		
Coronial Artery Disease	20-30%	>80%
Cerebrovascular Disease	15-25%	~30%
Peripheral Vascular Disease	5-10%	~20%
Death from Microvascular Complications	***N/A***	***65-70%***

Figure 2. System to Rank Evidence-Based Diabetes Care Recommended Actions.

Points	Micro*	Macro	Costs	Risks
5	Strong Benefit	Strong Benefit	Low Costs / QALY Gained	Minimal Risks
4				
3				
2				
1	No Benefit	No Benefit	High Costs / QALY Gained	Substantial Risks
0				

*Based on NNT to prevent end-stage complications (blindness, ESRD, Amputation).

Figure 3. Comparative Effectiveness of Various Evidence-Based Elements of Diabetes Care Based on Clinical Impact and Cost.

Points are assigned based on (a) prevention or delay of Microvascular Complications, (b) prevention or delay of Macrovascular Complications, and (c) Cost of treatments as described in Figure 6. Total Points may range from 0 to 15, with higher scores indicating most valuable treatment priorities from the population point of view. Gaps between recommended and actual levels of care in a population (see Figure 8) must also be considered. For more details on this methodology for ranking clinical interventions see Maciosek et al[23][refs].

Clinical Domain	Score on Each of 3 Domains			Total Points for Each Clinical Domain
	Micro	Macro	Cost	
Glucose Control HbA1c<7%	5	0	1	6
Glucose Control HbA1c<8%	4	3	3	10
BP Control BP<135/80	5	5	5	15
Lipid Control	0	5	5	10
Aspirin Use	0	2	5	7
Non-Use of Tobacco	2	5	5	12

Figure 4A
Slides from NQF talk, on relative merits of various glucose goals, and glucose compared to other clinical domains.

Impact of Glucose Control on Macrovascular Complications

Study	**A1c < 7%**	**A1c 7-8%**
UKPDS F/U	Not Tested	Benefit
Steno-2	Not Tested	Benefit
VADT	No Benefit	-----
ADVANCE	No Benefit	Equal to A1c < 7%
ACCORD	Harm	Better than A1c < 7%

Figure 4B

Impact of Glucose Control on Microvascular Complications

Study	Eye	Neuropathy	Nephropathy
ADVANCE (A1c 6.5%)	None	Pending	Rx 100 prevent 1 proteinuria
ACCORD (A1c 6.4%)	TBA	TBA	TBA
Steno-2 (A1c 7.7%)	Rx 30 prevent 1 blind	Rx 4 prevent 1 autonomic neuropathy	Rx 30 prevent 1 dialysis

Figure 4C

Summary: Other Impacts of Intensive Glucose Control

Study	BMI	Severe Hypo	Hospitalizations	Costs
ADVANCE	Worse	Worse	Worse	Worse
ACCORD	Worse	Worse	Worse	Worse
VADT	Worse	Worse	--	Worse

Figure 5. Proposed Quality Measures Related to Primary Prevention of Type 2 Diabetes.

See ICSI "Primary Prevention Chronic Disease Risk Factors" Clinical Guideline (http://www.icsi.org/guidelines_and_more/gl_os_prot/preventive_health_maintenance/chronic_disease_risk_factors__primary_prevention_of__guideline__23506/chronic_disease_risk_factors__primary_prevention_of__guideline_.html) for a set of proposed interventions and measures. This group was led by Tom Kottke MD MPH.

Note: Many potential measures to promote primary prevention of T2DM will deal with weight management, physical activity, nutrition, and tobacco use. Future measures could focus on Polypills or other pharmacologic approaches to prevention of T2DM (i.e., metformin).

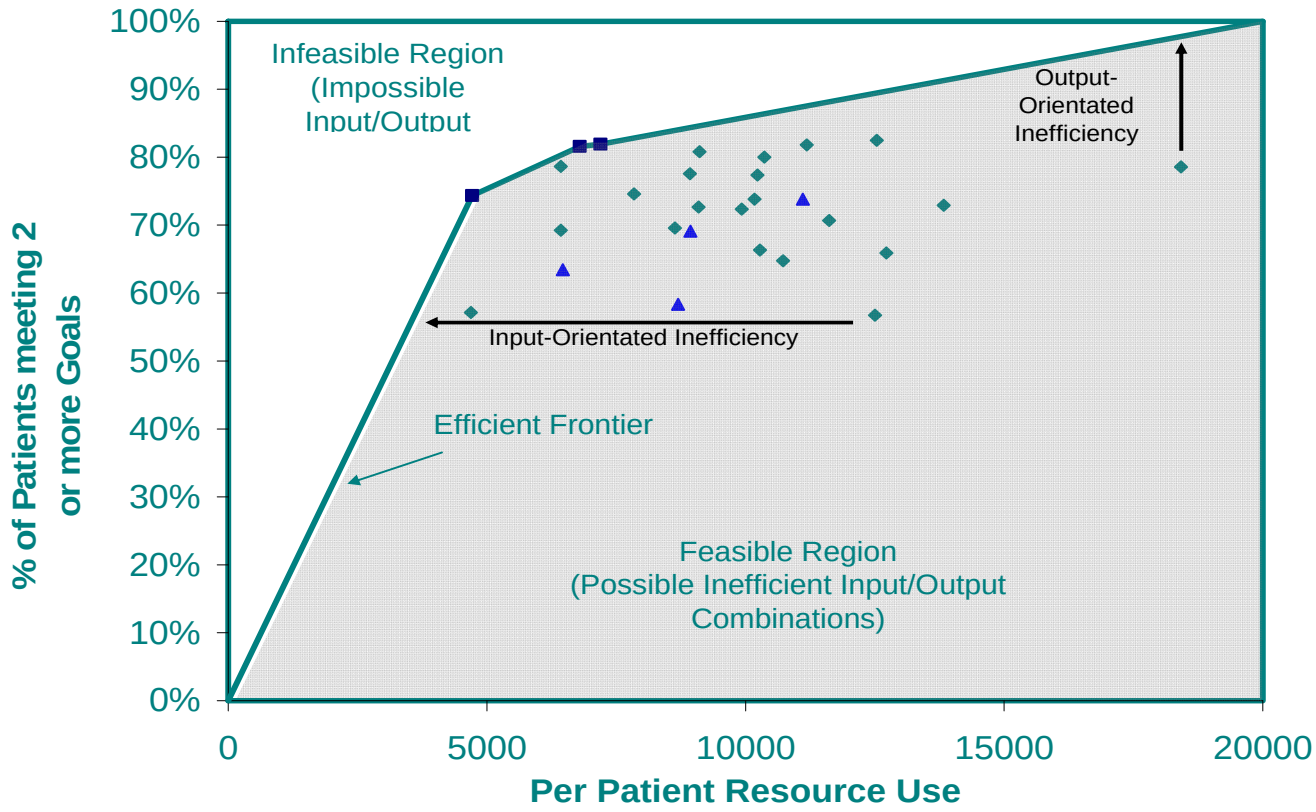
It is likely that with respect to lifestyle issues, what is good for prevention of diabetes is also appropriate for prevention of numerous other chronic diseases. This type of overlap is what led ICSI to write a guideline on "Primary Prevention of Chronic Disease Risk Factors" rather than targeting this guideline to only one disease such as diabetes or heart disease.

Distribution of Measures Across Stakeholders

Stakeholder	**Clinical Domains Related to Prevention of Type 2 Diabetes**			
	Physical Activity	**Nutrition**	**Weight Management**	**Tobacco Use**
Providers				
Medical Groups				
Health Plans				
Payers (CMS etc.)				
Employers/Worksite				
Schools				
State Public Health Departments				
Others (Patients/Members)				

Figure 6: Relation of outpatient care and pharmacy Resource Use (X-axis) to a measure of outpatient quality of diabetes care (Y-axis) among 23 medical groups.

Each medical group is plotted by their input (average resource use) and output (percentage of patients at 2 or more goals) combination. The three most technically efficiency groups appear on the efficiency frontier. The shaded area below the frontier represents feasible, but inefficient input/output combinations. All of the relatively inefficient medical groups appear in this area. For these inefficient groups, their potential resource savings appears as their horizontal distance to the efficient frontier, and their potential output gains as their vertical distance to the efficient frontier. Outlying medical groups, which cannot be compared to the other groups for technical reasons, are represented by a triangle.



Appendix 1.

Abbreviations Used in White Paper and Data Worksheets:

RCT	Randomized Clinical Trial
Cohort	Prospective Cohort Study
Quality +	Rigorously Designed and Well Conducted Study
Quality -	Poorly Designed or Poorly Conducted Study
Quality Fee	Conclusions Rest on Subgroup Analysis, or Flawed Design
CI	Confidence Interval (95% CI unless otherwise specified)
CAD	Coronary Artery Disease
CKD	Chronic Kidney Disease
eGFR	Estimated Glomerular Filtration Rate (Measures kidney function)
MI	Myocardial Infarction
CV	Cardiovascular
CVE	Cardiovascular Event
LDL	Low Density Lipoprotein Cholesterol
HDL	High Density Lipoprotein Cholesterol
A1c	Glycated Hemoglobin A1c
NNT	Number Needed to Treat [Calculated as the reciprocal of the absolute difference in risk ratios across treatment arms in RCTs, and specified as a function of the length of follow-up in the study.]
HR	Hazard Ratio
RRR	Relative Risk Ratio
ACE	Angiotensin Converting Enzyme Inhibitor (BP lowering drug class)
ARB	Angiotensin Receptor Blockade (BP lowering drug class)
ASA	Aspirin
BB	Beta blockers (BP lowering drug class)
BID	Twice a day
BP	Blood Pressure
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
PO	Per Oral (By mouth)
PRN	As needed
QID	Four times a day
QD	Once a day
SBP	Systolic Blood Pressure
SC	Subcutaneously (by injection using a short needle)
SU	Sulfonylureas (glucose lowering drug class)
T2DM	Type 2 Diabetes Mellitus
TID	Three times a day
TZD	Thiazolidinediones (glucose lowering drug class)
MET	Metformin (glucose lowering drug)

Appendix 2.

Evidence Worksheets* that Summarize Study Design, Size, Power, Outcome Measures, Results, and Limitations of Key Clinical Trials and Cohort Studies That Comprise the Evidence Foundation for Current Diabetes Care Recommendations.

*Worksheets are © by ICSI and included in the forthcoming 2009 Treatment of Type 2 Diabetes Clinical Guidelines, of which Dr. O'Connor is a co-author. These materials are updated periodically at www.icsi.org

Work Group's Conclusion: Observational studies and randomized controlled trials support a strong relationship between tight glycemic control (HbA1c levels) and a reduced risk of microvascular and macrovascular complications of diabetes. Studies thus far do not support a clear threshold goal HbA1c level, and aggressiveness of glycemic control should be individualized to the patient, balancing the potential reduction in complications from tight glycemic control with the risk of hypoglycemia, drug interactions and side effects, possible exacerbation of certain comorbidities, and the ability of the patient to adhere to complex treatment regimens. For many patients with diabetes, the evidence supports that an HbA1c goal of 6.5% to 7.5% achieves a reasonable balance between safety and reduction in long-term diabetic complications. For a certain subgroup of patients with co-morbidities such as coronary heart disease, hypoglycemic episodes, hypoglycemic unawareness, advanced age, cognitive impairment, limited life expectancy, or other relevant conditions, an HbA1c goal of less than 8.0% may be more appropriate. (Conclusion Grade II).

Author/Year	Design Type	Class	Quality (**+**,**–**,**ø**)	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Gaede et al., 2008	Randomized controlled trial (RCT)	A	+	-- Follow-up study after completion of interventional study (Steno-2 Study) -- 160 patients (mean age 55.1 years at baseline) with type 2 diabetes and microalbuminuria randomly assigned to intensive therapy group ([IG], target HbA1c < 6.5%, fasting	-- Used intention-to-treat principle -- Both groups similar at baseline -- Measured results were as follows: BP (mean systolic/diastolic mm Hg): IG: end of intervention: 131/73 end of follow-up: 140/74 CG: end of intervention: 146/78 end of follow-up: 146/73 HbA1c (mean	- - During entire follow-up period, death rate in CG was 50%; authors state this underscores poor prognosis without intensive treatment -- Study not designed to show which elements of intensive treatment contributed most to the CV risk reduction -- Significant

				cholesterol < 175 mg/dl, fasting triglycerides < 150 mg/dl, blood pressure < 130/80 mm Hg, and focused behavior modification) and a conventional (CG) multifactorial treatment group -- All patients received renin-angiotensin system blockers and low dose aspirin -- 3 patients withdrew, 27 died during interventional study, leaving 130 pts for start of follow-up study -- 37 died during follow-up period, leaving 93 subjects completing follow-up study -- Primary end point in follow-up trial was time to death (any cause), with secondary end points being death from cardiovascular (CV) causes, and composite of CV disease events -- Total mean follow-up time 13.3 years (7.8 years in interventional study and 5.5 years for observational follow-up)	%): IG: end of intervention: 7.9 end of follow-up: 7.7 CG: end of intervention: 9.0 end of follow-up: 8.0 Fasting total cholesterol (mean mg/dl): IG: end of intervention: 159 end of follow-up: 147 CG: end of intervention: 216 end of follow-up: 155 Fasting triglycerides (median mg/dl): IG: end of intervention: 115 end of follow-up: 99 CG: end of intervention: 159 end of follow-up: 148 -- During entire 13.3 years of follow-up, 24 IG pts died and 40 CG pts died (hazard ratio [HR] 0.54; p=0.02) -- 9 IG pts died of CV causes and 19 CG pts died of CV causes (HR 0.43; p=0.04) -- Total CV events: 51 in IG, 158 in CG (HR 0.41; p<0.001); no evidence of change in HR occurred between end of intervention and final observational follow-up -- Diabetic nephropathy developed in 20 IG pts and 37 CG pts (Relative risk [RR] 0.44; p=0.004) -- Progression of diabetic retinopathy occurred in 41 IG	differences in risk factors between the two groups between the intervention phase and final follow-up tended to converge (all pts were offered intensive treatment after intervention study ended), but time to first CV events continued to diverge; authors stated that this provided evidence that early intervention (intensive treatment) continues to show benefit long-term [*Note that although original HbA1c goal for intensive treatment was < 6.5% yet avg. at end of follow-up was 7.7%, underscoring the difficulty in attaining aggressive HbA1c goals]*

					pts and 54 CG pts (RR 0.57; p=0.01) -- Autonomic neuropathy progressed in 39 IG pts and in 52 CG pts (RR 0.53; p=0.004); peripheral neuropathy progression was not significantly different between the two groups -- Differences in hypoglycemic episodes were not significant between the two group (p=0.15 trend for more episodes in IG)	
Selvin et al., 2004	Meta-analysis	M	ø	-- Meta-analysis of prospective observational (cohort) studies on the association between HbA1c levels and incident cardiovascular disease, including fatal and nonfatal myocardial infarction, angina, and ischemic heart disease, cerebrovascular disease (fatal and nonfatal stroke), peripheral arterial disease, and a combined outcome that includes coronary disease and stroke -- Type 2 diabetes analyzed separately from type 1 -- Random effects model used to pool the results	-- Pooled relative risk for total cardiovascular disease (10 independent datasets of coronary disease alone, stroke alone, and combined stroke and coronary disease in type 2 diabetics) was 1.18 (95% CI, 1.10 to 1.26) for each 1% increase in HbA1c -- For the 5 independent studies of fatal and nonfatal coronary disease risk, the pooled relative risk was 1.15 (95% CI, 1.06 to 1.20), with the relative risk for fatal coronary disease being 1.16 (95% CI, 1.07 to 1.26) for each 1% increase in HbA1c -- For the 3 independent studies that included stroke risk assessment, the pooled relative risk was 1.17 (95% CI, 1.09 to 1.25) for each 1% increase in HbA1c	-- Data analysis supports moderate increase in cardiovascular risk with increasing HbA1c levels in type 1 and type 2 diabetics -- In some studies association of cardiovascular disease with increasing HbA1c levels was independent of other known cardiovascular risk factors -- Linear relationship of cardiovascular risk to HbA1c levels assumed in studies, but not clear if this is actually the case -- Future RCTs needed that specifically answer the question of the relationship of glycemic control

				-- Total of 17 study reports included, representing 13 unique samples (10 groups of type 2 diabetics – included UKPDS studies; total n=7435 for 10 studies) -- Adjustment for possible confounding factors varied considerably – about 50% of studies used automatic stepwise methods for determining multivariate models; only 3 studies simultaneously adjusted for known cardiovascular risk factors such as age, gender, lipid levels, blood pressure, and smoking	-- For the 3 independent studies that included peripheral arterial disease risk assessment, the pooled relative risk was 1.28 (95% CI, 1.18 to 1.39) -- Small number of studies limited the ability to ascertain important sources of heterogeneity among the studies	(specifically HbA1c levels) to cardiovascular disease and disease risk
Abraira et al., 1997	RCT	A	–	-- Feasibility study comparing standard vs. intensive insulin therapy -- 153 men with non-insulin dependent diabetes (NIDDM) were enrolled, average age 60 years, having diabetes for an average of 7.8 years, with poor glycemic control (mean baseline HbA1c > 9%) -- Above pts randomized to a standard insulin treatment group (SG, n=78, 1 morning insulin injection per day) and an intensive treatment group	-- IG had mean HbA1c of 7.1%, 2.1% lower than SG pts and maintained this difference for the 27 months of follow-up ($p<0.001$) -- Mild and moderate hypoglycemic events occurred more frequently in the IG (16.5 events per patient per year vs. 1.5 events per patient per year, $p<0.001$); severe hypoglycemic events were rare and not significantly different between the groups -- Groups not significantly different in baseline BMI, serum TG levels, total cholesterol/LDL/HD	-- Authors state that intensive insulin treatment designed to lower HbA1c levels can sustain a clinically significant separation in HbA1c levels without increasing BP, dyslipidemia, severe hypoglycemia, excessive weight gain or high insulin requirement -- Small sample size, short duration study noted mortality rates nearly identical between groups -- CV history

				(IG, n=75, stepped plan) -- Assessed cardiovascular events (new myocardial infarctions, congestive heart failure, stroke, amputations, cardiovascular mortality, angina/coronary disease, angioplasty/CABG, TIAs, peripheral vascular disease -- 38% of pts had known pre-existing CV disease -- Sample size and duration of feasibility trial not powered to demonstrate a treatment effect on CV disease, but objective was to assess frequency and types of CV end points in preparation for a longer-term trial	L levels, blood pressure, and cigarette smoking (but all 4 pipe smokers were randomized into the IG arm) -- 61 CV events occurred during the study; 33 occurred in 24 pts in the IG; 26 events occurred in 16 pts in the SG (p=0.10); 10 pts died during the study (5 in each group, with 3 in each group being CV-related) -- Multivariate analysis on times to CV event showed that the only significant predictor variable was a previous history of CV disease (p=0.04); lower HbA1c level was a borderline correlate when substituted for the treatment assignment variable -- When silent baseline CV abnormalities were combined with known previous CV events as the dependent variable, only the HbA1c level (lower level) rose to significance as a predictor of new CV events (p=0.05)	had a significant effect on risk of new events -- Borderline trend toward more CV events in patients with lower HbA1c levels, but finding needs cautious interpretation due to the short length of the study; insulin dose itself did not appear to be a significant predictor of events -- Need further prospective study before recommendations for NIDDM treatment can be made -- Authors state that benefit of HbA1c levels below 8% may be relatively small
Gerstein et al, 2008 (The ACCORD Workgroup)	RCT	A	+	-10,251 patients with a median baseline A1c of 8.1%, who had heart disease or evidence of atherosclerosis, albuminuria, hypertension, left ventricle hypertrophy, or two cardiovascular disease risk factors	- Primary outcomes measured were a composite of nonfatal myocardial infarction, nonfatal stroke, and death from cardiovascular disease. - Over 3.5 years of follow-up, the primary outcome occurred in 352 in the intensive therapy group and 371 in the standard	- compared to standard therapy, intensive therapy led to increased mortality and did not significantly reduce cardiovascular events. - differences in mortality emerged 1- 2 years after

				- Participants were randomized to receive either intensive therapy targeting reduction of A1c to below 6 or standard therapy targeting A1c between 7.0-7.9. - inclusion/exclusion criteria clearly defined -used intention to treat analysis	therapy group (RR 0.90, 95% CI 0.74-1.04, p=0.16). - There were 257 deaths in the intensive therapy group compared to 203 deaths in the standard therapy group (RR = 1.22, 95% CI 1.01-1.46, p=0.04). - in addition, hypoglycemia requiring attention and weight gain in excess of 10 kg occurred more frequently in the intensive therapy group.	randomization, which may indicate that the potential benefits of intensive therapy do not emerge for several years, during which time there is increased risk of mortality. -the standard therapy group had fewer visits and used fewer drugs in fewer combinations, thus the higher rate of mortality in the intensive therapy group may be related to the various strategies of intensive treatment.
Patel et al, 2008 (ADVANCE trial)	RCT	A	+	-11,400 patients with type 2 diabetes who were diagnosed after age 30 or were over 55 and had a history microvascular or macrovascular disease or at least one cardiovascular risk factor - randomized to standard glucose control or intensive therapy targeting <6.5% A1c.	- Primary outcomes were a composite of microvascular events (new or worsening nephropathy, need for renal replacement therapy, or death to renal disease) and a composite of macrovascular events (non-fatal myocardial infarction, non-fatal stroke, and cardiovascular disease death). - Over 5 years of follow-up, A1c was lower in the intensive therapy group (6.5%) compared to the standard glucose control group (7.3%). - Intensive control reduced the incidence of combined micro- and macrovascular events (18.1% v	- The observed 10% relative reduction in combined complications was primarily due to a reduction in worsening nephropathy. - In the ADVANCE trial, no subgroup of participants was identified to have evidence of an adverse effect of intensive glucose lowering on major vascular outcomes, including a subgroup with an initial median A1c comparable to the ACCORD study population - Intensive therapy significantly reduced the

					20.0% with standard control, hazard ratio 0.90 (0.82-0.98)). - A reduction in microvascular events was observed in the intensive treatment group (9.4%) compared to the standard control group (10.9%) with a hazard ration of 0.86 (0.77-0.97). - No reduction in macrovascular events was observed (hazard ratio 0.94, (0.84-1.06)).	primary composite outcome of major macrovascular or microvascular events. There was no separate significant reduction major macrovascular events, although this benefit could not be ruled out.
Holman et al, 2008	RCT [*This is a long-term follow-up of participants in the UKPDS intervention, during which time participants were not intervened upon nor were they encouraged to maintain their treatment assignment*]	A	+	- out of a trial of 4209 newly diagnosed diabetic patients randomly assigned to conventional therapy or intensive therapy, 3277 were available for post-trial observation - At the start of post-trial follow-up the median A1c was 7.9 in the sulfonylurea treatment group, 8.5 in the comparison group and 8.4 in the metformin treatment group, 8.9 in the comparison group -differences in A1c due to treatment group were lost by the end of 1 year post-trial with similar A1c levels thereafter in all groups, -A1C was 8% in the final year of post trial monitoring	-outcomes of interest were any diabetes related end point, diabetes related death, death from any cause, MI, stroke, peripheral vascular disease, microvascular disease -in the sulfonylurea arm, compared to the conventional therapy group the RR (95% CI) of diabetes related endpoint 0.91 (0.83-0.99), diabetes related death 0.83 (0.73-0.96), death from any cause 0.87 (0.79-0.96), MI 0.85 (0.74-0.97), Stroke 0.91 (0.73-1.13), PVD 0.82 (0.56-1.19), microvascular disease 0.76 (0.64-0.89) - in the metformin arm, compared to the conventional therapy group the RR (95% CI) of diabetes related endpoint was 0.79 (0.66-0.95), diabetes-related death 0.70 (0.53-0.92), death from any cause 0.73	-benefits of intensive therapy to control glucose were maintained for up to 10 years after the cessation of the randomized trial. - in the sulfonylurea group the reduction in microvascular disease risk and diabetes-related endpoint risk observed in the intensive therapy group was sustained throughout the post-trial period, despite rapid convergence of A1c values and similar use of glucose-lowering therapies In the metformin group, made up of overweight patients, risk reductions for MI and all-cause mortality were sustained throughout the post-trial period despite similar

					(0.59-0.89), MI 0.67 (0.51-0.89), stroke 0.80 (0.50-1.27), PVD 0.63 (0.32-1.27), microvascular disease 0.84 (0.60-1.17)	A1c levels between treatment and control group. [*Note: this report does not indicate what the target A1c levels were for the intervention study, nor what A1cs were achieved with intensive therapy during the trial. In the final year of post-trial follow-up, the median A1cs were around 8.*] [*Note: participants were excluded from the study if they had MI within one year, current angina or heart failure, more than one major vascular event, malignant hypertension, uncorrected endocrine disorder, retinopathy require laser treatment, elevated serum creatinine level, ketonuria. So, these patients did not have existing vascular disease or risk factors, unlike ACCORD and ADVANCE.*]

References:
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Selvin E, et al. Meta-analysis: glycosylated hemoglobin and cardiovascular disease in diabetes mellitus. Ann Intern Med 2004; 141:421-31.
Abraira C, et al. Cardiovascular events and correlates in the Veterans Affairs Diabetes Feasibility Trial. Veterans Affairs Cooperative Study on Glycemic Control and Complications in Type II Diabetes. Arch Intern Med 1997; 157:181-8

APPENDIX D:
SPECIFICATIONS OF THE NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR QUALITY OF DIABETES CARE (AS OF 5/15/09)

NQF Measure#	Title	Description	Measure Developers
5	CAHPS Clinician/Group Surveys - (Adult Primary Care, Pediatric Care, and Specialist Care Surveys)	•Adult Primary Care Survey: 37 core and 64 supplemental question survey of adult outpatient primary care patients. •Pediatric Care Survey: 36 core and 16 supplemental question survey of outpatient pediatric care patients. •Specialist Care Survey: 37 core and 20 supplemental question survey of adult outpatients specialist care patients. Level of analysis for each of the 3 surveys: group practices, sites of care, and/or individual clinicians.	Agency for Healthcare Research and Quality
6	CAHPS Health Plan Survey v 4.0 - Adult questionnaire	30-question core survey of adult health plan members that assesses the quality of care and services they receive. Level of analysis: health plan – HMO, PPO, Medicare, Medicaid, commercial.	Agency for Healthcare Research and Quality
7	NCQA Supplemental items for CAHPS® 4.0 Adult Questionnaire (CAHPS 4.0H)	20-questions supplement to the CAHPS Health Plan Survey v 4.0 adult questionnaire that assesses the health plan's role in offering information and care management to members. Level of analysis: health plan – HMO, PPO, Medicare, Medicaid, Commercial.	National Committee for Quality Assurance

NQF Measure#	Title	Description	Measure Developers
9	CAHPS Health Plan Survey v 3.0 children with chronic conditions supplement	31- questions that supplement the CAHPS Child Survey v 3.0 Medicaid and Commercial Core Surveys, that enables health plans to identify children who have chronic conditions and assess their experience with the health care system. Level of analysis: health plan – HMO, PPO, Medicare, Medicaid, commercial.	Agency for Healthcare Research and Quality
17	Hypertension Plan of Care	Percentage of patient visits during which either systolic blood pressure >= 140 mm Hg or diastolic blood pressure >= 90 mm Hg, with documented plan of care for hypertension.	American Medical Association
18	Controlling High Blood Pressure	Percentage of patients with last BP < 140/80 mm Hg.	National Committee for Quality Assurance; Centers for Medicare & Medicaid Services
19	Documentation of medication list in the outpatient record	Percentage of patients having a medication list in the medical record.	Centers for Medicare & Medicaid Services
23	Body Mass Index (BMI) in adults > 18 years of age	Percentage of adults with BMI documentation in the past 24 month.	City of New York Department of Health and Mental Hygiene
28	Measure pair: a. Tobacco Use Assessment, b. Tobacco Cessation Intervention	Percentage of patients who were queried about tobacco use one or more times during the two-year measurement period. Percentage of patients identified as tobacco users who received cessation intervention during the two-year measurement period.	American Medical Association

NQF Measure#	Title	Description	Measure Developers
55	Diabetes: Eye exam	Percentage of adult patients with diabetes aged 18-75 years who received a dilated eye exam or seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist or imaging validated to match diagnosis from these photos during the reporting year, or during the prior year, if patient is at low risk** for retinopathy. **Patient is considered low risk if the following criterion is met: has no evidence of retinopathy in the prior year.	National Committee for Quality Assurance
56	Diabetes: Foot exam	Percentage of adult patients with diabetes aged 18-75 years who received a foot exam (visual inspection, sensory exam with monofilament, or pulse exam).	National Committee for Quality Assurance
57	Hemoglobin A1c testing	Percentage of adult patients with diabetes aged 18-75 years receiving one or more A1c test(s) per year.	National Committee for Quality Assurance
59	Hemoglobin A1c management	Percentage of adult patients with diabetes aged 18-75 years with most recent A1c level greater than 9.0% (poor control).	National Committee for Quality Assurance
60	Hemoglobin A1c test for pediatric patients	Percentage of pediatric patients with diabetes with a HBA1c test in a 12-month measurement period.	National Committee for Quality Assurance
61	Diabetes: Blood Pressure Management	Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged > 18 years with diagnosed hypertension.	National Committee for Quality Assurance

NQF Measure#	Title	Description	Measure Developers
62	Diabetes: Urine protein screening	Percentage of adult diabetes patients aged 18-75 years with at least one test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy (diagnosis of nephropathy or documentation of microalbuminuria or albuminuria).	National Committee for Quality Assurance
63	Diabetes: Lipid profile	Percentage of adult patients with diabetes aged 18-75 years receiving at least one lipid profile (or ALL component tests).	National Committee for Quality Assurance
64	Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B Lipid management: LDL-C <100	Percentage of adult patients with diabetes aged 18-75 years with most recent (LDL-C) <130 mg/dL. B: Percentage of patients 18-75 years of age with diabetes whose most recent LDL-C test result during the measurement year was <100 mg/dL.	National Committee for Quality Assurance
88	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy AND the presence or absence of macular edema during one or more office visits within 12 months.	National Committee for Quality Assurance; American Academy of Ophthalmology; American Medical Association
89	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes regarding the findings of the macular or fundus exam at least once within 12 months.	National Committee for Quality Assurance; American Academy of Ophthalmology; American Medical Association

NQF Measure#	Title	Description	Measure Developers
166	HCAHPS	27-items survey instrument with 7 domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information.	Agency for Healthcare Research and Quality
272	Diabetes, short-term complications (PQI 1)	This measure is used to assess the number of admissions for diabetes short-term complications per 100,000 population.	Agency for Healthcare Research and Quality
274	Diabetes, long-term complications (PQI 3)	This measure is used to assess the number of admissions for long-term diabetes complications per 100,000 population.	Agency for Healthcare Research and Quality
285	Lower extremity amputations among patients with diabetes (PQI 16)	This measure is used to assess the number of admissions for lower-extremity amputation among patients with diabetes per 100,000 population.	Agency for Healthcare Research and Quality
300	Cardiac patients with controlled 6AM postoperative serum glucose	Percentage of cardiac surgery patients with controlled 6a.m. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.	The Joint Commission
416	Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing during one or more office visits within 12 month.	American Podiatric Medical Association

NQF Measure#	Title	Description	Measure Developers
417	Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	Percentage of patients, 18 years or older, with diabetes aged 18 years and older with who had a lower extremity neurological exam with risk cauterization performed and a treat plan established at least once within 12 months a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities during one or more office visits within 12 months.	American Podiatric Medical Association
486	Adoption of Medication e-Prescribing	Documents whether provider has adopted a qualified e-Prescribing system and the extent of use in the ambulatory setting.	Centers for Medicare & Medicaid Services
492	Participation in a Practice-based or individual Quality Database Registry with a standard measure set.	This Registry should be capable of: a. generating population based reports relating to published guideline goals or benchmarking data b. providing comparisons to the practitioner c. providing feedback that is related to guideline goals d. capturing data for one or more chronic disease conditions (i.e. diabetes) or preventive care measures (i.e. USPTF recommendations) for all patients eligible for the measures.	Centers for Medicare & Medicaid Services
519	Diabetic Foot Care and Patient Education Implemented	Percent of diabetic patients for whom physician-ordered monitoring for the presence of skin lesions on the lower extremities and patient education on proper foot care were implemented during their episode of care.	Centers for Medicare & Medicaid Services

NQF Measure#	Title	Description	Measure Developers
526	Timely Initiation of Care	Percent of patients with timely start or resumption of home health care.	Centers for Medicare & Medicaid Services
66	CAD: ACE inhibitor/angiotensin receptor blocker (ARB) Therapy	Percentage of patients with CAD who also have diabetes and/or LSVD who were prescribed ACE inhibitor or ARB therapy.	American Medical Association
451	Intravenous insulin glycemic control protocol implemented for cardiac surgery patients with diabetes or hyperglycemia admitted into an ICU	Intravenous insulin glycemic control protocol implemented for cardiac surgery patients with diabetes or hyperglycemia admitted into an intensive care unit.	STS
490	The Ability to use Health Information Technology to Perform Care Management at the Point of Care	Documents the extent to which a provider uses a certified/ qualified electronic health record (EHR) system capable of enhancing care management at the point of care. To qualify, the facility must have implemented processes within their EHR for disease management that incorporate the principles of care management at the point of care which include: - The ability to identify specific patients by disease, diagnosis, or medication use - The capacity to present alerts for disease management, preventive services and wellness - The ability to provide support for standard care plans, guidelines, protocols.	CMS-QIP
3	Bipolar Disorder: Assessment for diabetes	Percentage of patients treated for bipolar disorder who are assessed for diabetes within 16 weeks after initiating treatment with an atypical antipsychotic agent.	Center for Quality Assessment and Improvement in Mental Health

Appendix E:

CONTEXT FOR CONSIDERING A DIABETES EPISODE OF CARE

I. Introduction
   a. Brief background on efficiency framework as basis for work
   b. Context-setting for diabetes within the health care system
      i. Include cost data ($6 of every $10 in commercially insured population currently spent on avoidable complications)
   c. Context-setting for diabetic patient
      i. Extent of population at risk
         1. Prevalence by type of diabetes
         2. Increase in incidence in last decade
         3. "Obesity belt"
      ii. Prevention/monitoring of high-risk groups (?)
      iii. Disparities
      iv. Physical and psychological aspects of care
   d. Episode approach and measurement for diabetes
      i. Strengths
      ii. Limitations
      iii. Explanation of Pathways (A/B/C/D, etc.)
   e. Overall principles to guide techniques and treatment of diabetic patients
      i. Emphasis on self-management
      ii. Understanding of cultural diversity
      iii. Understanding of complexities, complications, and comorbidities
II. Phase 1 Discussion: Population at risk
   a. Presentation into potential episode
      i. Prediabetes
      ii. Type 2
      iii. Type 1
      iv. Metabolic syndrome
      v. Gestational
      vi. Others
   b. Opportunities for detection/screening → guidelines?
III. Phase 2 Discussion: Evaluation & On-going Management
   a. Clinical episode commences
   b. Presentation of a diabetes episode
   c. "Pathways" discussion
      i. Pathway A
      ii. Pathway B
      iii. Pathway C
      iv. Pathway D
   d. Treatment options
      i. Lifestyle change(s)
      ii. Oral medication(s)
      iii. Insulin
      iv. Combination treatments

        v. Ranking of interventions from an effectiveness/cost perspective
    e. Various providers and settings of care
    f. Treatment plan and adjustments spanning Phases 2 & 3

IV. Phase 3 Discussion: Exacerbation of Diabetes and Complex Treatments
    a. Development and management of complications
    b. Growing complexity of treatment
    c. Consideration of comorbidities (n_1 – n_x)

V. Issues for Consideration across the Episode
    a. Access to Care, Medication(s)
    b. Comorbidities
    c. Psychosocial needs
    d. Symptom Assessment
    e. Treatment preferences
    f. Care Coordination
    g. Informed decision-making
    h. Care Transitions
    i. Family engagement
    j. Health education/Behavior change
    k. Cultural diversity/Language & Literacy

VI. Patient-reported Outcomes
    a. Health Related Quality of Life
    b. Symptom Management
    c. Risk-adjusted total cost of care
    d. Healthy lifestyle