NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** OT1-009-09 **NQF Project:** Patient Outcomes Measures: Phases I and II
MEASURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Optimal Diabetes Care
De.2 Brief description of measure: The percentage of adult diabetes patients who have optimally managed modifiable risk factors (A1c, LDL, blood pressure, tobacco non-use and daily aspirin usage) with the intent of preventing or reducing future complications associated with poorly managed diabetes. Patients ages 18 - 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: A1c < 8.0, LDL < 100, Blood Pressure < 140/90, Tobacco non-user and for patients with cardiovascular disease daily aspirin use unless contraindicated.
1.1-2 Type of Measure: Outcome **De.3 If included in a composite or paired with another measure, please identify composite or paired measure** This is a composite "all or none" measure calculated at the patient level, each individual patient needs to meet all five component targets to be considered in the numerator. All components are contained within this measure and the measure is not paired with another measure.
De.4 National Priority Partners Priority Area: Patient and family engagement **De.5 IOM Quality Domain:** Effectiveness **De.6 Consumer Care Need:** Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* **A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes	**A** Y☐ N☐

A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** NQF data steward agreement_signed 2009.pdf	
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Severity of illness, Leading cause of morbidity/mortality 1a.2 1a.3 **Summary of Evidence of High Impact:** According to the MN Department of Health, diabetes is a high impact clinical condition in Minnesota. More than 1 in 3 adults and 1 in 6 youth in Minnesota have diabetes or are at high risk of developing it. Each year more than 20,000 Minnesotans are newly diagnosed with diabetes. Diabetes is the sixth leading cause of death in Minnesota and is a significant risk factor in developing cardiovascular disease and stroke, non-traumatic lower extremity amputations, blindness, and end-stage renal disease. Diabetes costs Minnesota almost $2.7 billion annually, including medical care, lost productivity and premature mortality. According to the American Diabetes Association, an estimated 23.6 million American children and adults have diabetes. Most people with diabetes have other risk factors, such as high blood pressure and cholesterol that increase the risk for heart disease and stroke. In fact, more than 65% of people with diabetes die from these complications.	**1a** C☐ P☐ M☐ N☐

1a.4 Citations for Evidence of High Impact: MDH Diabetes in Minnesota Fact Sheet 2010 www.health.state.mn.us/diabetes/pdf/FactSheet2010.pdf

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: The intermediate physiological and biochemical outcomes included in this composite measure are modifiable lifestyle risk factors that can ultimately decrease the incidence of long term catastrophic events and chronic illness associated with diabetes.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
For 2009 dates of service, 25.0% of the patients met all five component targets in the composite measure and considered optimally managed. This rate is a weighted average of the total population of patients for clinics submitting data (Total Population = 216,229, Submitted = 140,884). 65% of the clinics submitted full population data, the remaining clinics provided a random sample. There was a wide range of variability with the lowest scoring clinic at 0% (6 clinics) and the highest scoring clinic at 60.8%
It is estimated that the data is representing about 95% (216,229/228,000) of all diagnosed diabetics in the state of MN.
The trends for this measure:
2006- 14%
2007- 17%
2008- 19%
2009- 25%

Optimal Rate Range	% of Clinics
0%-9.9%	20.3%
10%-19.9%	25.9%
20%-29.9%	24.1%
30%-39.9%	19.4%
40%-49.9%	8.9%
50%-59.9%	1.0%
60%-69.9%	0.4%

Individual rates of the components are as follows:
A1c < 8.0 72%
LDL < 100 57%
Blood Pressure < 130/80 58% *
Daily Aspirin Use 86% **
Tobacco Non-user 83%

* Note for Blood Pressure: Historically and in currently reported data, the target was < 130/80. For 2011 reporting (2010 dates of service) the target will be modified to < 140/90.
** Note for Aspirin: historically and in currently reported data this component reflects aspirin use in diabetics age 41+, this part of the composite will change to diabetics with known cardiovascular disease for 2011 reporting.

Mean: 25.0%
Median: 21.3%
Standard Deviation: 0.14
Min: 0.0%
Max: 60.8%

1b.3 Citations for data on performance gap:
Publicly reported data with clinic level rates is available on the MN HealthScores website www.mnhealthscores.org. Additionally, for more detailed information including highlights of top performers, breakdown by clinic site with confidence intervals please refer to our Health Care Quality Report posted on our corporate website at: www.mncm.org/site/?page=our_work&view=2

1b
C☐
P☐
M☐
N☐

Final_2009_Health_Care_Quality_Report_12.9.09.pdf

1b.4 Summary of Data on disparities by population group:
Age, family history and a previous history of gestational diabetes are indicators of increased risk for diabetes, along with being African American, Asian American, Hispanic/Latino or American Indian. Potentially modifiable risks for developing diabetes include: obesity, inactivity, high blood pressure and abnormal cholesterol levels. Studies show that people at high risk for type 2 diabetes can prevent or delay the onset of the disease by maintaining a healthy diet and regular exercise. Knowler WC. N Engl J Med 346(6):393-403, 2002.
The risk of diabetes increases with age. According to projections from the Minnesota State Demographic Center, the population aged 65 years and older will rise sharply in the coming decades: In 2000, one in every eight Minnesotans were 65 years of age or older; by 2030, that ratio will be one in five. Increases in the elderly population are likely to contribute significantly to the burden of diabetes in Minnesota in the future. African American, Asian or Pacific Islander, American Indian or Hispanic/Latino American populations are at greater risk for developing diabetes, and these populations are also growing. In 2000, roughly one in every eight (12 percent) of Minnesota's nearly five million people were Persons of Color or American Indians; by 2025, that proportion will be 17 percent, or nearly one in every five.

1b.5 Citations for data on Disparities:
MN Department of Health Report on Disparities in Diabetes by Race/Ethnicity 2005
www.health.state.mn.us/diabetes/data/disparities.pdf

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** The intermediate physiological and biochemical outcomes included in this composite measure are modifiable lifestyle risk factors that can ultimately decrease the incidence of long term catastrophic events and chronic illness associated with diabetes.

1c.2-3. Type of Evidence: Evidence-based guideline, Randomized controlled trial, Other Consensus Statement

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Source: Institute for Clinical Systems Improvement (ICSI) Diabetes Guidelines July 2010
The physician and patient should discuss and document specific treatment goals and develop a plan to achieve all desired goals. A multifactorial approach to diabetes care that includes emphasis on blood pressure, lipids, glucose, aspirin use, and non-use of tobacco will maximize health outcomes far more than a strategy that is limited to just one or two of these clinical domains (American Diabetes Association, 2010 [R]; Duckworth, 2009 [A]; Gaede, 2008 [A]; Holman, 2008a [A]).
Goals for A1c, low-density lipoprotein, and other diabetes measures should be personalized, and lower goals for A1c and low-density lipoprotein than those included here in the priority aims and measures may be clinically justified in some adults with type 2 diabetes. However, efforts to achieve lower A1c below 7% may increase risk of mortality, weight gain, hypoglycemia and other adverse effects in many patients with type 2 diabetes. Therefore, the aims and measures listed here are selected carefully in the interests of patient safety.
Note about Guideline Revisions:
2009: Based on current literature review, ICSI guideline revisions due to patient safety, and an expert workgroup convened to address appropriate measurement targets for A1c, the A1c component of the all or none composite measure was changed from < 7.0 to < 8.0 effective for 2009 dates of service reported in 2010.
2010: Based on ACCORD study results for blood pressure management (March/2010), ICSI Diabetes Guideline revisions (July 2010) and national measures (CMS Meaningful Use July 2010), an expert workgroup was convened to review appropriateness of blood pressure targets for measurement purposes for the diabetes population and changed the blood pressure component from < 130/80 to < 140/90.
Evidence based guidelines support this measure, please see detail below.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**

1c
C ☐
P ☐
M ☐
N ☐

ICSI Evidence Grading System www.icsi.org/guidelines_and_more/evidence_grading_system_6/. Please see section below for the narrative rating of strength/quality of evidence

1c.6 Method for rating evidence: ICSI Evidence Grading System
A. Primary Reports of New Data Collection:
Class A: Randomized, controlled trial
Class B: Cohort study
Class C: Non-randomized trial with concurrent or historical controls, Case-control study, Study of sensitivity and specificity of a diagnostic test, Population-based descriptive study
Class D: Cross-sectional study, Case series, Case report
B. Reports that Synthesize or Reflect Upon Collections of Primary Reports:
Class M: Meta-analysis, Systematic review, Decision analysis, Cost-effectiveness analysis
Class R: Consensus statement, consensus report narrative review
Class X: Medical opinion
Citations are listed in the guideline utilizing the format of (Author, YYYY [report class]).

1c.7 Summary of Controversy/Contradictory Evidence: Glycemic Control/ A1c Target: During 2008, based on results of the multiple studies, controversy existed with the recommendations for A1c control and the use of daily aspirin. Glycemic control sparked much debate in our provider community as the results of ACCORD were published and the study halted due to an increased risk of mortality in the intensive glycemic treatment group. While everyone agreed that aggressively managing patients to goals of less than 6.0 was not desirable, providers grappled with the microvascular benefits that many diabetics would have with a more tightly managed A1c of less than 7.0 versus potential safety issues of having the measurement goal for all patients be less than 7.0. At one point we had entertained two targets, less than 7.0 for those without complex patient factors and < 8.0 for those patients with complex factors, but in reality the complex patient factors identified were not amenable to ICD-9 codes and consistent capture by the clinics, so it was decided to change the A1c target of the component measure to less than 8.0 for all patients with the emphasis that many patients are better managed with a goal of less than 7.0 and that individualized goals do need to be set between the patient and the provider.
Daily Aspirin Use: Aspirin use is another area of potential controversy. One study found no benefit in preventing a primary cardiovascular event, however there is benefit in preventing secondary cardiovascular events Ogawa S. Clin J Soc Nephrol 2008;3:362-68.[A] Early in 2010, the American Diabetes Association guidelines changed around recommendations for daily aspirin use. Evidence no longer supported daily aspirin for all diabetics age 40 and older as a primary prevention effort in light of risks of GI bleeding potentially outweighing the benefits. A technical advisory panel was convened in March 2010 to modify the aspirin component of the composite based on new ADA guidelines. The aspirin component of the measure was changed to only include diabetic patients with known cardiovascular disease. This change will apply to 2010 dates of service reported in 2011.
Blood Pressure Management: Emerging evidence from the ACCORD (Action to Control Cardiovascular Risk in Diabetes) released 3-14-2010 investigated the relationship between targeting a normal systolic blood pressure (< 120 mmHg) and the reduction of major cardiovascular events in patients with type 2 diabetes. The study concluded that for diabetics at high risk for cardiovascular events, targeting a systolic blood pressure of less than 120 mmHg, as compared to less than 140 mmHg, did not reduce the rate of a composite outcome of fatal and non-fatal major cardiovascular events. (ClinicalTrials.gov number, NCT00000620.) The technical advisory panel reviewed the evidence, recently updated ICSI Diabetes Guidelines (July 2010) and national measures including CMS meaningful Use measure for diabetes blood pressure control. The blood pressure target was changed from < 130/80 to < 140/90 and will apply to 2010 dates of service reported in 2011.

1c.8 Citations for Evidence (*other than guidelines*): Please refer to the quoted citations within the guideline section below.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):
All guideline citations are from either the Institute for Clinical Systems Improvement (ICSI) Health Care Guidelines for Diagnosis and Management of Type 2 Diabetes Mellitus in Adults - 14thEdition July 2010 or the American Diabetes Association (ADA) Standards January 2010.
A1c < 8.0 [Annotation # 11 pages 22 to 25 and Conclusion Grade II Conclusion Grading Worksheet B pages 81 to 87]
Individual A1c and other treatment goals should be based on the risks and benefits for each patient. Set

personalized A1c goal less than 7% or individualize to goal less than 8% based on complex patient factors. A1c target in type 2 diabetes is aimed at reducing microvascular complications while not increasing risk of morbidity or mortality. All patients with type 2 diabetes should aim to achieve an A1c less than 8%. This will reduce microvasuclar disease and not increase risk substantially.
Complex patient factors:
• Known cardiovascular disease or high cardiovascular risk
• Inability to recognize and treat hypoglycemia; history of severe hypoglycemia requiring assistance
• Inability to comply with standard goals, such as polypharmacy issues
• Limited life expectancy or estimated survival of less than 10 years
• Cognitive impairment
• Extensive comorbid conditions
For patients with type 2 diabetes and at least one of the complex patient factors listed above, an A1c goal of less than 8% may be more appropriate than an A1c goal of less than 7% (Action to Control Cardiovascular Risk in Diabetes Study Group, The, 2008 [A]; ADVANCE Collaborative Group, The, 2008 [A]; Duckworth, 2009 [A]). In the ACCORD Trial, excess mortality in the intensive group (A1c mean 6.4% vs. standard group A1c 7.5%) forced the safety board to discontinue the intensive treatment arm earlier than planned (Action to Control Cardiovascular Risk in Diabetes Study Group, The, 2008 [A]). There was one excess death for every 90 patients in the intensive group over a 3.5-year period of time. In the ADVANCE trial, intensive group patients achieved A1c 6.5% (vs. 7.5% in standard group) but had no reduction in cardiovascular complications or events. In the VADT trial, intensive group patients achieved A1c of 6.9% but had no significant reduction in cardiovascular events or microvascular complications compared to standard group patients who achieved A1c 8.4%. However, the VADT Trial was underpowered for its main hypothesis tests (Duckworth, 2009 [A]).

LDL < 100 [Annotation # 13 and # 14 pages 26 to 29 and Conclusion Grade I Conclusion Grading Worksheet C pages 88 to 94 Statin Use]
Seventy to seventy-five percent of adult patients with diabetes die of macrovascular disease, specifically coronary, carotid and/or peripheral vascular disease. Diabetes is considered a coronary artery disease equivalent. Dyslipidemia is a known risk factor for macrovascular disease. Patients with diabetes develop more atherosclerosis than patients without diabetes with the same quantitative lipoprotein profiles. In most patients with diabetes, use of a statin can reduce major vascular events in patients with diabetes substantially (Pyorola, 1997 [A]). Beneficial effects of statins on cardiovascular risk reduction may go beyond their effects on lipid levels.
High triglycerides and low high-density lipoprotein cholesterol levels are independent risk factors for cardiovascular disease in the patient with diabetes (American Diabetes Association, 2010 [R]).
ICSI guidelines suggest different LDL goals based on the presence of cardiovascular disease. For patients without cardiovascular disease an LDL goal of < 100 is recommended, patients with cardiovascular disease have a lower recommendation; LDL < 70.

Blood Pressure < 140/90
Rationale for selecting < 140/90 versus ICSI recommendation for < 140/85. The technical advisory panel reviewed the evidence, recently updated ICSI Diabetes Guidelines (July 2010) and national measures including CMS meaningful Use measure for diabetes blood pressure control. Please see ICSI notations below about continuing to review ADA and JNC.
[Annotation # 26 and # 28 pages 48 to 49 and Conclusion Grade I Conclusion Grading Worksheets E and F pages 101 to 102 Hypertension Medication Management]
Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation and treatment of hypertension. The use of two or more blood pressure lowering agents is often required to meet blood pressure goal.
The UKPDS, HOT, ADVANCE and ACCORD trials are all large randomized clinical trials that allow comparison of more stringent versus less stringent blood pressure levels on major cardiovascular outcomes (ACCORD Study Group, The, 2010 [A]; ADVANCE Collaborative Group, 2008 [A]; Hansson, 1998 [A]; United Kingdom Prospective Diabetes Study Group (UKPDS), 1993e [R]). The UKPDS, HOT and ADVANCE trials all found reduced cardiovascular outcomes with lower achieved blood pressure levels. However, none of these trials achieved average systolic blood pressure levels below 130 mmHg (Table 2). The ACCORD trial found no difference in major cardiovascular outcomes between a more intensive blood pressure intervention targeting systolic blood pressure < 120 mmHg compared to a more standard intervention targeting systolic blood pressure between 130 and 139 mmHg (Table 2). The more intensive blood pressure regimen was associated with a small reduction in the rate of stroke, greater medication use and more serious adverse events

(ACCORD Study Group, The, 2010 [A]). The above studies support a systolic blood pressure goal < 140 mmHg for people with type 2 diabetes. We would estimate that targeting a systolic blood pressure < 140 mmHg would result in an achieved blood pressure around 135 mmHg for most people. Only the HOT trial specifically targeted diastolic blood pressure. In the HOT trial, targeting a lower diastolic blood pressure was associated with fewer cardiovascular events in subjects with type 2 diabetes. The average achieved diastolic blood pressure values in the three HOT intervention arms ranged from 81-85 mmHg. Based on results from the ADVANCE and ACCORD trials, it appears likely that achieved systolic blood pressure values in the mid-130 range will be associated with diastolic blood pressure values well below 80 mmHg. Therefore, the work group recommends a diastolic blood pressure goal of < 85 mmHg.
Although more recent evidence supports raising the blood pressure goal above the previous goal of < 130/80, the work group acknowledges that the evidence is not definitive for any particular general blood pressure goal for patients with diabetes. The work group will continue to review the blood pressure goal to consider any new evidence and the recommendations of other national practice guidelines (e.g., ADA and JNC8) that are expected to announce revisions. The general recommendation of blood pressure < 140/85 does not preclude setting individual patient goals lower than that based on patient characteristics, comorbidities, risks or the preference of an informed patient.

Non-pharmacologic and pharmacologic methods are recommended at blood pressures greater than or equal to 140/85 mmHg. The initial focus of treatment should be the systolic blood pressure.
For patients with type 2 diabetes mellitus, ACE inhibitors or ARBs can reduce progression of micro- and macrovascular complications. [Conclusion Grade I: See Conclusion Grading Worksheet E – Annotations #28, 36 (Treatment with ACE Inhibitors or ARBs)] (HOPE Investigators, 2000a [A]; Lewis, 2001 [A]).
While ACE inhibitors and ARBs are preferred first-line therapy, two or more agents (to include thiazide diuretics) may be required. For patients with type 2 diabetes mellitus, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure. [Conclusion Grade I: See Conclusion Grading Worksheet F – Annotations #28, 36 (Thiazide Diuretics)] (ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, 2002 [A]; Wing, 2003 [B]). The possible advantages to ACE inhibitors include renal protection, decreased insulin resistance, lack of adverse effect on lipids, and decreased cardiovascular risk. In ALLHAT, chlorthalidone, at doses of 12.5 to 25 mg daily, was superior to other treatments at reducing cardiovascular events in both diabetic and non-diabetic patients. Treatment of isolated systolic hypertension, as well as combined systolic and diastolic hypertension, in both young and elderly people protects against major cardiovascular diseases. Thiazide diuretics used in the treatment of hypertension can reduce cardiovascular events, especially heart failure, for patients with type 2 diabetes (Alkaharouf, 1993 [D]; Chobanian, 2003 [R]; HOPE Investigators, 2000a [A]; Lewis, 1993 [A]). The INVEST Study demonstrated that a verapamil SR plus trandolapril strategy was equivalent to an atenolol plus hydrocholorthiazide strategy with regard to reduction in cardiovascular outcomes,

Tobacco Non-user [Annotation # 13 and # 14 pages 28 and 29]
Tobacco smoking increases risk of macrovascular complications about 4%-400% in adult with type 2 diabetes, and also increases risk of macrovascular complications. Although only about 14% of adult with diabetes in Minnesota are current smokers, in these patients, smoking cessation is very likely to be the single most beneficial intervention that is available, and should be emphasized by providers.

Aspirin use for patients with cardiovascular disease unless contraindicated.
[Annotation # 14 page 29 and Conclusion Grade I Conclusion Grading Worksheet D pages 95 to 100]
Aspirin/antiplatelet medication use unless contraindicated (Bhatt, 2002 [A])
There is insufficient evidence to recommend for or against aspirin use in the primary prevention of cardiovascular events in patients with type 2 diabetes, although there is no evidence of significant harm. However, there is sufficient evidence to support the use of aspirin for secondary prevention of cardiovascular events in patients with type 2 diabetes. [Conclusion Grade I: See Conclusion Grading Worksheet D – Annotations #13, 14 (Aspirin Use)]
If aspirin is contraindicated, consider use of clopidogrel or ticlopidine. For more information, please refer to the ICSI Stable Coronary Artery Disease guideline and the Antithrombotic Therapy Supplement. Regular use of ibuprofen may undermine aspirin´s anti-platelet effects; patients taking both medications regularly should take immediate release aspirin at least 30 minutes prior to taking ibuprofen or wait at least 8 hours after ingestion of ibuprofen.
ISCI guidelines recommend aspirin use for all diabetics with cardiovascular disease; for diabetics without evidence of cardiovascular disease, aspirin use is considered optional.

New Evidence American Diabetes Association January 2010
• Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).
• There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. For patients in these age-groups with multiple other risk factors, clinical judgment is required.
• Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD.

1c.10 **Clinical Practice Guideline Citation:** ICSI Institute for Clinical Systems Improvement Guideline for Diabetes Mellitus Type 2 Adults Diagnosis and Management- Revised July 2010.
http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/diabetes_mellitus__type_2/diabetes_mellitus__type_2__management_of___6.html
American Diabetes Association January 2010 Standards of Care
http://professional.diabetes.org/CPR_search.aspx
1c.11 **National Guideline Clearinghouse or other URL:** Please note that the ICSI guideline referenced is also listed in the National Guideline Clearinghouse (but needs update with most current version July 2010):
http://www.guideline.gov/browse/by-topic-detail.aspx?id=32015

1c.12 **Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
A1c Control: Individual A1c and other treatment goals should be based on the risks and benefits for each patient. Set personalized A1c goal less than 7% or individualize to goal less than 8% based on complex patient factors. A1c target in type 2 diabetes is aimed at reducing microvascular complications while not increasing risk of morbidity or mortality. All patients with type 2 diabetes should aim to achieve an A1c less than 8%. This will reduce microvasuclar disease and not increase risk substantially. Most (many) patients with type 2 diabetes may derive additional benefit in reduction of microvasuclar disease by reaching a target A1c less than 7% (and not increase risks as long as the target is not A1c less than 6%). [Annotation # 11 pages 22 to 25 and Conclusion Grade II Conclusion Grading Worksheet B pages 81 to 87]. Lipid Management: The low-density lipoprotein cholesterol goal for people with diabetes mellitus without coronary artery disease is less than 100 mg/dL. For patients with type 2 diabetes mellitus, consider the use of a statin. [Annotation # 13 and # 14 pages 26 to 29 and Conclusion Grade I Conclusion Grading Worksheet C pages 88 to 94 Statin Use] Evidence (Colhoun, 2004 [A]; Heart Protection Collaborative Study Group, 2002 [A]) and Adult Treatment Panel III consensus guidelines (Grundy, 2004 [R]). Blood Pressure Control: For patients with type 2 diabetes mellitus, the systolic blood pressure goal is less than 140 mmHg and the diastolic blood pressure goal is less than 85 mmHg. Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation and treatment of hypertension. The use of two or more blood pressure lowering agents is often required to meet blood pressure goal. The UKPDS, HOT, ADVANCE and ACCORD trials are all large randomized clinical trials that allow comparison of more stringent versus less stringent blood pressure levels on major cardiovascular outcomes (ACCORD Study Group, The, 2010 [A]; ADVANCE Collaborative Group, 2008 [A]; Hansson, 1998 [A]; United Kingdom Prospective Diabetes Study Group (UKPDS), 1993e [R]). The UKPDS, HOT and ADVANCE trials all found reduced cardiovascular outcomes with lower achieved blood pressure levels. However, none of these trials achieved average systolic blood pressure levels below 130 mmHg (Table 2). The ACCORD trial found no difference in major cardiovascular outcomes between a more intensive blood pressure intervention targeting systolic blood pressure < 120 mmHg compared to a more standard intervention targeting systolic blood pressure between 130 and 139 mmHg (Table 2). The more intensive blood pressure regimen was associated with a small reduction in the rate of stroke, greater medication use and more serious adverse events (ACCORD Study Group, The, 2010 [A]). The above studies support a systolic blood pressure goal < 140 mmHg for people with type 2 diabetes. We would estimate that targeting a systolic blood pressure < 140 mmHg would result in an achieved blood pressure around 135 mmHg for most people. Only the HOT trial specifically targeted diastolic blood pressure. In the HOT trial, targeting a lower diastolic blood pressure was associated with fewer cardiovascular events in subjects with type 2 diabetes. The average achieved diastolic blood pressure values in the three HOT intervention arms ranged from 81-85 mmHg. Based on results from the ADVANCE and ACCORD trials, it appears likely that achieved systolic blood pressure values in the mid-130 range will be associated with diastolic blood pressure values well below 80 mmHg. Therefore, the work group recommends

a diastolic blood pressure goal of < 85 mmHg. Although more recent evidence supports raising the blood pressure goal above the previous goal of < 130/80, the work group acknowledges that the evidence is not definitive for any particular general blood pressure goal for patients with diabetes. The work group will continue to review the blood pressure goal to consider any new evidence and the recommendations of other national practice guidelines (e.g., ADA and JNC8) that are expected to announce revisions. The general recommendation of blood pressure < 140/85 does not preclude setting individual patient goals lower than that based on patient characteristics, comorbidities, risks or the preference of an informed patient. [Annotation # 26 and # 28 pages 48 to 49 and Conclusion Grade I Conclusion Grading Worksheets E and F pages 101 to 102 Hypertension Medication Management]. Aspirin use for patients with cardiovascular disease unless contraindicated: There is insufficient evidence to recommend for or against aspirin use in the primary prevention of cardiovascular events in patients with type 2 diabetes, although there is no evidence of significant harm. However, there is sufficient evidence to support the use of aspirin for secondary prevention of cardiovascular events in patients with type 2 diabetes. [Conclusion Grade I: See Conclusion Grading Worksheet D – Annotations #13, 14 (Aspirin Use)] [Annotation # 14 page 29 and Conclusion Grade I Conclusion Grading Worksheet D pages 95 to 100. American Diabetes Association January 2010 • Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). • There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. For patients in these age-groups with multiple other risk factors, clinical judgment is required. • Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. Tobacco Non-user: Tobacco smoking increases risk of macrovascular complications about 4%-400% in adult with type 2 diabetes, and also increases risk of macrovascular complications. Although only about 14% of adult with diabetes in Minnesota are current smokers, in these patients, smoking cessation is very likely to be the single most beneficial intervention that is available. ICSI Diabetes Guideline pages 28 and 29, no formal conclusion grading for this component, however tobacco non-use is not controversial.

1c.13 Method for rating strength of recommendation (*If different from* USPSTF system, *also describe rating and how it relates to USPSTF)*:
ICSI's Conclusion Grade definitions parallel with USPSTF ratings of High, Moderate & Low.
CONCLUSION GRADES
Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion.
Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.
Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.
Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

1c.14 Rationale for using this guideline over others:
The Institute for Clinical Systems Improvement (ICSI) is a unique organization that is widely respected for its collaborative efforts with guideline development. ICSI's purpose is to help improve patient care in Minnesota through collaboration and innovations in evidence-based medicine. The collaborative is unique in that it brings medical organizations, health plans and business representatives into the decision-making process. Providers in MN are engaged and respect this process and the resulting guideline recommendations.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to*	**1**

Measure and Report?	
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met? **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Patients ages 18 to 75 with diabetes who meet all of the following targets from the most recent visit during the measurement year: A1c less than 8.0, LDL less than 100, Blood Pressure less than 140/90, Tobacco non-user and Daily aspirin for patients with cardiovascular disease use unless contraindicated. Please note: MNCM has changed the definition of the aspirin numerator component of this all or none measure since the original application 9/18/2010 and presentation to NQF on 3/16/2010. The need for change was based on revised guidelines and feedback within our community and from NQF. A technical advisory group was convened 3/25/2010 to revise the aspirin component based on new guidelines for aspirin use from the American Diabetes Association. Previously the aspirin component was applicable to all diabetics age 41+ unless documented contraindication. ADA guidelines published in January 2010 state: • Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). • There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. For patients in these age-groups with multiple other risk factors, clinical judgment is required. • Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. The group debated the merits and feasibility of identifying patients who were at risk for developing CVD in the next ten years to indicate aspirin use for primary prevention versus patients with known cardiovascular disease (secondary prevention). The group believes it is reasonable to consider aspirin for primary prevention in patients whose patient specific risk for cardiac event is high and their risk on aspirin therapy is low. However, this is a decision that the patient and the provider need to collaboratively make and may not be amenable to accurate measurement. The group decided to change the numerator component for aspirin to be only for patients with known cardiovascular disease. The recommendation was made based on updated guidelines, expert opinion, patient safety and feasibility for measurement. This change was approved by our Measurement and Reporting Committee 4/14/2010. This change will be made going forward for the reporting year of 2011 (dates of service 1/1/2010 to 12/31/2010). Please Note: On 7/27/2010 the blood pressure component of this measure was changed to < 140/90. MNCM's diabetes technical advisory group recommended this change based on ACCORD results, ICSI's most recent guideline changes (July 2010), and the national meaningful use measures for diabetic blood pressure control. A target set at <140/90 allows for individualization of patient goals. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** Values are collected as the most recent during the measurement year (calendar year January 1st through December 31st).	**2a-specs** **C☐** **P☐** **M☐** **N☐**

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**

Please note that all of the denominator criteria apply to the numerator as well, but are not repeated in the numerator codes/ descriptions.

HbA1c Date [Date (mm/dd/yyyy)] AND
HbA1c Value [Numeric]
Numerator calculation: numerator compliant is HbA1c during the last 12 months (measurement year) AND HbA1c value is less than 8.0.
Enter the date of the most recent HbA1c test prior to and including 12/31/YYYY (measurement year). Other considerations:
• If an HbA1c was never performed, leave the date field blank.
• Even if the most recent test is prior to the measurement period, enter this date.
• Do NOT enter any test dates beyond the measurement year; enter measurement year dates or prior dates only.

LDL Date [Date (mm/dd/yyyy)] AND
LDL Value [Numeric]
Numerator calculation: numerator compliant is LDL during the last 12 months (measurement year) AND LDL value is less than 100.
Enter the date of the most recent LDL test prior to and including 12/31/YYYY (measurement year).
Enter the value of the most recent LDL test prior to and including 12/31/ YYYY (measurement year). Other considerations:
• If an LDL was never performed, leave the date field blank.
• Even if the most recent test is prior to the measurement period, enter this date.
• Do NOT enter any test dates beyond the measurement year; enter date from the measurement year or prior dates only.
• Test from an outside referring provider or specialist is acceptable if they are documented in the primary care clinic's record.
• Elevated Triglyceride: If LDL is "too high to calculate," enter the LDL date field and leave the LDL value field blank.

Blood Pressure Date [Date (mm/dd/yyyy)] AND
BP Systolic [Numeric] AND
BP Diastolic [Numeric]
Numerator calculation: numerator compliant is BP during the measurement year AND Systolic < 140 AND Diastolic < 90.
Enter the date of the most recent Blood Pressure (BP) test prior to and including 12/31/YYYY (measurement year). Other considerations:
• If there are multiple BPs on the same date, you may use the lowest systolic value and lowest diastolic value from any of the readings on that date.
• Even if the most recent BP is prior to the measurement period, enter this date.
• Do NOT enter any dates of service beyond the measurement year. BP date; enter date from the measurement year or dates prior to the measurement year only.
• BP from an outside referring provider or specialist is acceptable if they are documented in the primary clinic's record; you may choose to use this reading only if it is more recent than your clinic's reading.
• Do not enter a BP that is associated with a surgical procedure, inpatient or ER visit, diagnostic testing or a diagnosis that is associated with acute pain.
• Do not enter a home monitored BP.
Enter the "systolic" value according to the rules above for selecting the correct BP date. The systolic BP is the upper number. In the example of a BP 124/72, the systolic value is "124".
Enter the "diastolic" value according to the rules above for selecting the correct BP date. The diastolic BP is the lower number. In the example of a BP 124/72, the diastolic value is "72"

Tobacco Status Documentation Date [Date (mm/dd/yyyy)] AND
Tobacco Status [Numeric]
1 = Tobacco Free (patient does not use tobacco) 2 = No Documentation 3 = Current Tobacco User
Numerator calculation: Numerator compliant is Value 1 = Tobacco Free AND valid date
Enter the most recent date (prior to and including 12/31/YYYY (measurement year) that the patient's tobacco status was documented. Other considerations:
• If a patient's status is "never used" or "quit," any date (measurement year date or a date prior to

the measurement year) is counted positively in the optimal care score.
• The expectation is that current tobacco users are asked about tobacco use and counseled at least annually.
• If the patient was not asked or there is no associated date with the patient's tobacco status, leave the tobacco date field blank and enter "2=No Documentation" for the Tobacco Status.
• Do NOT enter any dates of service beyond the measurement year. Enter date from the measurement year or dates prior to the measurement year only.
Enter the tobacco status. Tobacco includes any amount of cigarettes, cigars, pipes, or "chew."
Aspirin Use or Documented Contraindication for the use of aspirin for patients with cardiovascular disease, patients without cardiovascular disease are automatically numerator compliant for this component.
Aspirin (ASA) Date [Date (mm/dd/yyyy)]
For patients with known cardiovascular disease; Ischemic Vascular Disease = Yes
As indicated by ischemic vascular disease ICD-9 codes of:
410 – 410.92 Acute Myocardial Infarction (AMI)
411 – 411.89 Post Myocardial Infarction Syndrome
412 Old AMI
413 – 413.9 Angina Pectoris
414.0 – 414.07 Coronary Arthrosclerosis
414.2 Chronic Total Occlusion of Coronary Artery
414.8 Other Chronic Ischemic Heart Disease (IHD)
414.3 Atherosclerosis due to lipid rich plaque
414.9 Chronic IHD
429.2 Cardiovascular (CV) disease, unspecified
433 – 433.91 Occlusion and stenosis of pre-cerebral arteries
434 – 434.91 Occlusion of cerebral arteries
440.1 Atherosclerosis of renal artery
440.2 – 440.29 Atherosclerosis of native arteries of the extremities, unspecified
440.4 Chronic Total Occlusion of Artery of the Extremities
444 – 444.9 Arterial embolism and thrombosis
445 - 445.8 Atheroembolism

Enter the most recent date of documented ASA or anti-platelet prior to and including 12/31/YYYY (measurement year).
FYI: any documented date in the measurement year of ASA or an anti-platelet is acceptable; the date does not need to be the most recent.
The following are accepted ASA or anti-platelet medications
• Aspirin (ASA)
• Plavix (clopidogrel)
• Ticlid (ticlopidine)
• Pravigard (aspirin/pravastatin)
• Aggrenox (aspirin/dypyridamole)
• Low dose enteric-coated 81 mg ASA (Ecotrin or Bayer)
Other considerations:
• If there is no documentation of daily ASA or anti-platelet, leave this date field blank.
• Even if the most recent date is prior to the measurement period, you can enter this date.
• Do NOT enter any dates of service beyond the measurement year. Enter date from the measurement year or dates prior to the measurement year only.
• If the patient has a contraindication to ASA, leave this date field blank.
• Do NOT enter any date of a documented ASA/narcotic combo medication that is used temporarily for pain.
Aspirin (ASA) Contraindication Date [Date (mm/dd/yyyy)]
If patient has a documented contraindication to ASA, enter the date of the contraindication. Any valid contraindication date will count positively for the measure.
Accepted contraindications:
• Anticoagulant use, Lovenox (Enoxaparin) or Coumadin (Warfarin)
• Any history of gastrointestinal (GI)* or intracranial bleed (ICB)
• Allergy to ASA
*Gastroesophogeal reflux disease (GERD) is not automatically considered a contraindication but may be included if specifically documented as a contraindication by the physician.

The following may be exclusions if specifically documented by the physician:
• Use of non-steroidal anti-inflammatory agents
• Documented risk for drug interaction
• Uncontrolled hypertension defined as >180 systolic, >110 diastolic
• Other provider documented reason for not being on ASA therapy
Other considerations:
• If ASA Date field is completed (patient is taking ASA), leave the ASA Contraindication Date field blank (this field is only needed for patients not taking daily ASA with a documented contraindication to ASA). For patients taking Coumadin or Lovenox AND ASA, enter the aspirin use date and NOT the contraindication date.
• Date does not need to be in the measurement period. If only the month and year is known like "GI Bleed-June 2007," enter a valid date to indicate the time, like 6/01/2007. Look back at least 3 years (dates of service in measurement year or two years prior) for contraindication date; you can also choose to look back further in the patient's record.
• If the patient is on an anticoagulant, enter the most recent date.
• If the ASA has been discontinued prior to a surgical procedure, do not count this as a contraindication; rather document this patient as taking ASA during the measurement period. However, do not assume that a pre-op standing order like, "Do not take ASA seven days prior to the procedure," means that a patient is taking ASA every day; there must be other documentation in the record that the patient is taking daily ASA.
• If there is no documentation of taking ASA, anti-platelets or a contraindication then both date fields should be blank.
Numerator calculation: numerator compliant for patients with known cardiovascular disease is valid dates in either the Aspirin Date (needs to be in the measurement year) or the Aspirin Contraindication Date (any valid date). Patients without cardiovascular disease are automatically numerator compliant.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Patients ages 18 to 75 with diabetes who have at least two visits for this condition over the last two years (established patient) with at least one visit in the last 12 months.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Ages 18 to 75 during the measurement year.

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
Diabetes patients with two or more visits with diabetes codes in the last two years and at least one visit in the last 12 months. Medical groups perform the visit count and exclusions prior to file creation (excluded patients are not submitted in the direct data submission file). MNCM requires an upfront denominator certification process to ensure that the medical group is identifying the population correctly. Data collection or extraction cannot occur prior to MNCM approval of the denominator.

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Birth date [Date (mm/dd/yyyy)
250.00 DMII WO CMP NT ST UNCNTR
250.01 DMI WO CMP NT ST UNCNTRL
250.02 DMII WO CMP UNCNTRLD
250.03 DMI WO CMP UNCNTRLD
250.10 DMII KETO NT ST UNCNTRLD
250.11 DMI KETO NT ST UNCNTRLD
250.12 DMII KETOACD UNCONTROLD
250.13 DMI KETOACD UNCONTROLD
250.20 DMII HPRSM NT ST UNCNTRL
250.21 DMI HPRSM NT ST UNCNTRLD
250.22 DMII HPROSMLR UNCONTROLD
250.23 DMI HPROSMLR UNCONTROLD
250.30 DMII O CM NT ST UNCNTRLD
250.31 DMI O CM NT ST UNCNTRLD
250.32 DMII OTH COMA UNCONTROLD
250.33 DMI OTH COMA UNCONTROLD

250.40 DMII RENL NT ST UNCNTRLD
250.41 DMI RENL NT ST UNCNTRLD
250.42 DMII RENAL UNCNTRLD
250.43 DMI RENAL UNCNTRLD
250.50 DMII OPHTH NT ST UNCNTRL
250.51 DMI OPHTH NT ST UNCNTRLD
250.52 DMII OPHTH UNCNTRLD
250.53 DMI OPHTH UNCNTRLD
250.60 DMII NEURO NT ST UNCNTRL
250.61 DMI NEURO NT ST UNCNTRLD
250.62 DMII NEURO UNCNTRLD
250.63 DMI NEURO UNCNTRLD
250.70 DMII CIRC NT ST UNCNTRLD
250.71 DMI CIRC NT ST UNCNTRLD
250.72 DMII CIRC UNCNTRLD
250.73 DMI CIRC UNCNTRLD
250.80 DMII OTH NT ST UNCNTRLD
250.81 DMI OTH NT ST UNCNTRLD
250.82 DMII OTH UNCNTRLD
250.83 DMI OTH UNCNTRLD
250.90 DMII UNSPF NT ST UNCNTRL
250.91 DMI UNSPF NT ST UNCNTRLD
250.92 DMII UNSPF UNCNTRLD
250.93 DMI UNSPF UNCNTRLD

2a.9 **Denominator Exclusions (***Brief text description of exclusions from the target population***):** Valid exclusions include patients who only had one visit to the clinic with diabetes codes during the last two years, patients who were pregnant, died or were in hospice or a permanent resident of a nursing home during the measurement year.

2a.10 **Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
• Patient was a permanent nursing home resident during the measurement period
• Patient was in hospice at any time during the measurement period
• Patient died prior to the end of the measurement period
• Patient was pregnant during measurement period (Diabetes mellitus complicating pregnancy, ICD-9 codes: 648.0-648.04)
• Documentation that diagnosis was coded in error

2a.11 **Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
The diabetes population is not currently stratified when publicly reported on our consumer website, MN HealthScores. The data is, however, stratified by public (MN Health Care Programs- Prepaid Medical Assistance including dual eligibles, MinnesotaCare, and General Assistance Medical Care) and private purchasers for our 2009 Health Care Disparities Report, a hard copy report available on our corporate website at www.mncm.org/site/?page=our_work&view=2. Please refer to Appendix 1, page 85 for methodology. Results for Optimal Diabetes Care are also stratified by race within this report (page 67). The race categories are American Indian/Alaskan Native, Asian/Pacific Islander/Native Hawaiian, Black or African American, White or Unknown. More detail about race/ ethnicity data collection can be found in the Handbook on the Collection of Race/Ethnicity/Language Data in Medical Groups on our corporate website at www.mncm.org/site/?page=resources.

2a.12-13 **Risk Adjustment Type:** Case-mix adjustment

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
Case Mix Risk Adjustment:
Risk adjustment for this measure is based on case mix (health plan product). Health plan product was selected because it can serve as a proxy for socioeconomic status, if more specific variables are not available. Socioeconomic status can be a variable in a patient's ability to comply with a treatment plan for

achieving the intermediate outcomes that can postpone or prevent the long term complications of diabetes or cardiovascular disease.
The overall average state-wide distribution of patients across three major insurance types (Commercial, Medicare and MN Healthcare Programs plus Self-pay/Uninsured) is calculated and then each reporting site's patient distribution is adjusted to match the average mix. Rates are re-weighted based on the new distribution of patients and then rates are re-calculated.
Background and Evolution of Risk Adjustment:
MN Community Measurement has been publicly reporting unadjusted ambulatory outcome rates at the clinic site level for several years dating back to 2004. Currently, the lowest level of reporting is at the clinic site and we do not publicly report any practitioner level information. As our state begins moving towards utilizing cost and quality measures to demonstrate value and utilizing these measures for incentive based payment and tiering by health plans, we began to explore risk adjustment of measures used for these purposes.
Our subcommittee of the Board of Directors, the Measurement and Reporting Committee (MARC) has reviewed several methods for risk adjusting these measures. Part of their discussion included the use of the risk adjusted measures overall, especially for public reporting for consumers on our MN HealthScores website. The group agreed that risk adjustment would be more beneficial for tiering and incentive based programs and that there was value in the unadjusted clinic site level rate for consumers for the following reasons: rates reflect actual performance, confusion for consumers in terms of explaining risk adjustment or displaying two rates (adjusted and unadjusted), or creating a mindset that it is acceptable for patients in public programs to have different treatment standards than those with commercial insurance.
There are no current plans to provide risk adjusted data on our consumer facing website; however we will provide both adjusted and unadjusted clinic site level rates on our corporate website (pdf format).

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment MNCM Case Mix Risk Adjustment June 2010.docx

2a.18-19 Type of Score: Weighted score/composite/scale
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
This measure is calculated by submitting a file of individual patient values (e.g. blood pressure, A1c value, etc) to a HIPAA secure data portal. Programming within the data portal determines if each patient is a numerator case and then a rate is calculated for each clinic site.
If any component of the numerator is noncompliant for any one of the five components, then the patient is numerator noncompliant for the composite all or none optimal diabetes care measure.
Numerator logic is as follows:
Is the HbA1c date in the measurement year? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
Is the HbA1c value less than 8.0? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
Is Blood Pressure date in the measurement year? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
BP Systolic < 140? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
BP Diastolic < 90? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
Is LDL date in the measurement year? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
Is Tobacco Status = 1 (Tobacco Free) and Tobacco Assessment Date a valid date? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. Assess next variable.
Does the patient have cardiovascular/ ischemic vascular disease? Aspirin Date is in the measurement year? OR Aspirin Contraindication Date is a valid date? If yes, is numerator compliant for this component. If no, is numerator noncompliant for this component. If the patient does not have cardiovascular disease the aspirin component of the numerator is considered an automatic "pass". Assess next variable.
If all of the above numerator components are in compliance, then the patient calculated as a numerator case for the optimal diabetes care measure.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Medical groups are encouraged to submit their full population of patients when possible (EMR) and 65% of groups in our state report full population; the remainder submits a random sample of no less than 60 patients

at each clinical site location. This is to ensure that we have an adequate denominator at each clinic site location to accurately report rates at each clinic location. We also calculate confidence intervals based on the full population of patients identified at each site as compared to the number of sample patients submitted. High performers are defined as clinics with rates and confidence intervals fully above the overall clinic average. For clinics who submit their full population, but that population is less than 60 patients, our policy for public reporting of information requires that there be at least 30 denominator cases per clinic site location, if there are fewer than 30 patients in the denominator the rates are not reported publicly.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
Medical groups are encouraged to submit their full population of patients when possible (EMR) however clinics who are on a paper chart system are allowed to create a random sample of no less than 60 patients per clinic site. MNCM recommends that medical groups submit total population for each measure. By submitting total population, the confidence interval around the rate narrows, indicating a higher confidence that the rate accurately reflects the clinics' performance. If total population is not an option for a medical group, MNCM encourages medical groups to submit a large sample. The minimum required sample is 60 patients per clinic site, per measure. If a clinic site has less than 60 patients in the total population for the measure, the entire population must be submitted.

Excel's Random Number Generator Instructions:
For lists generated in Excel, use the "RAND" function to assign a random number to each record (please also see Microsoft Excel Help, topic RAND for more information):

1. Insert a blank column on the leftmost side of the spreadsheet
2. Label new column "RAND"
3. Place cursor in the first blank cell (A2) and type =RAND()
4. Press enter (a number like 0.793958 will appear)
5. Place the cursor back into this cell; resting over the corner to have the pointer change to a black cross, double click or drag the formula down to the last row/patient
6. Highlight the whole column and click Edit, Copy, Paste Special = Values to freeze the random number (otherwise it will change with every click on the spreadsheet)
7. Sort entire patient population by this new random number
8. Work down the list row by row, starting with row 1 until the number of records in the sample is met for submission (at least 60 patients per clinic, per measure)
9. If a patient meets one of the accepted exclusions, keep working down the list and use oversamples that are after the number of records in the sample. For example, if 60 records will be submitted and 2 exclusions were found, include patient rows 61 and 62 to replace the excluded records.

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Paper medical record/flow-sheet, Electronic Health/Medical Record, Registry data

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
An excel template with formatted columns for data fields is provided. Many medical groups extract the information from their EMR. Registries can be used as a source of information to create the data file; however groups must ensure that all of their eligible patients are included. Paper abstraction forms are provided for those clinics who wish to use them as an interim step to creating their data file. All data is uploaded in electronic format (.csv file) to a HIPAA secure, encrypted and password protected data portal.

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL Detailed specifications guide located at www.mncm.org/site/?p=resources.

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL Detailed specifications guide located at www.mncm.org/site/?p=resources.

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Other, Clinicians: Group Clinic Site Location

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*

Ambulatory Care: Clinic, Ambulatory Care: Office

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO), Other endocrinologist endocrinologist

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: In 2010, 130 medical groups representing 572 clinics and 216,229 patients in Minnesota and neighboring communities submitted data for rate calculation. Of the 216,229 eligible diabetic patients, 140,884 patients were submitted for rate calculation. The data submitted represents 65% of all eligible patients; based on the large sample size the results can be reliably reproduced. The data submission process requires individual patient data for each component of the "all or none" composite measure (e.g. most recent A1c value and blood pressure in the measurement year). This information is accurately captured as evidenced by post submission validation audits against the patient´s medical record.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
For 2009 dates of service reported in 2010, 130 medical groups representing 572 clinics in Minnesota and neighboring states submitted data to MN Community Measurement for the Optimal Diabetes Care measure rate calculation. These clinics represented 216,229 patients, which represent approximately 95% of all diabetics in the state of MN. The number of patients with detailed information submitted was 140,884. A total of 65% of the clinics submitted their full population of diabetic patients; the rest submitted a sample of patients with a minimum of 60 patients per clinic site. Reasons for sampling include clinics with paper charts or clinics with an EMR currently without the capability or resources to design reports to query all needed elements from their EMR system. Aside from large sample size, other components that contribute to the reliability (consistency) include the following:
* Detailed data specifications and instructions for medical groups at www.mncm.org/site/?p=resources
* Denominator certification process; all must have their methods for identifying the population approved prior to any data collection.
* Readily available support for questions, direct email link for assistance at support@mncm.org
* Field warnings and errors programming that occurs on file upload
* Numerator compliance calculated from raw data submitted based on programming; medical groups are not determining their own numerator cases nor calculating their own outcome rates.
* Evaluation of each clinic´s rate and eligible patient volumes for discrepancies from the prior year.
* MNCM Auditor Training- prior to any validation audits occurring, training is provided to auditors which include a test that each auditor must pass (inter-rater reliability).
* Extensive audit processes for data submission. After data submission, in person validation audits are conducted comparing the submission to the patient´s medical record using NCQA´s 8 and 30 rule for audit requiring a 90% accuracy rate. Audits are conducted in the following instances: 1) a random sample of clinics with prior successful submission, 2) for all groups who are new to the submission process, 3) a group who has had a change in system or process (e.g. went from paper charts to EMR) since the last submission or 4) any group with a history of prior unsuccessful audit.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Data submitted to the MNCM data portal for rate calculation is consistent and accurately reflects the data in the patient's medical record. Through the upfront denominator certification process we ensure that all groups are identifying the population in the same way during the same time frame. Groups that cannot comply with the measurement specifications are not allowed to submit data but encouraged to consider future submission when able to comply. Post submission validation processes ensure that the data submitted is that which is reflected in the patient's medical record.
2010 Validation Audit Results:
Of the 131 medical groups submitting data in 2010, 14 groups initially failed the audit and remedy plans were developed. All 14 groups resubmitted and passed subsequent audit.
Types of Errors Found in Validation Audits: BP was not most recent, EMR did not pull the correct date or value, ASA date could not be validated, ASA date not reported, LDL date not reported or more recent date

2b
C☐
P☐
M☐
N☐

found, Tobacco status was not correct, and A1c date not reported or more recent date found.
A study was conducted in 2007 comparing the two different methods of collecting the data and the subsequent rates. Comparison of rates and confidence intervals obtained by health plan sampling versus data submitted directly by the medical groups demonstrated a high rate of consistency between these two techniques. For 20 of the 22 medical groups, all rates calculated fell within both confidence intervals.
According to a recent publication, "Availability of Data for Measuring Physician Quality Performance" [Scholle, SH., Am Journal of Managed Care Jan 2009] methods proposed by NCQA to assess "reliability" were applied to our data and demonstrated that all of our current data submission by clinic site location achieves values higher than the recommended value of 0.7.

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: 140,884 patients of 216,229 eligible diabetic patients were submitted for rate calculation. The data submitted represents 65% of all eligible patients, and based on the large sample size the results can be reliably reproduced. The data submission process requires individual patient data for each component of the "all or none" composite measure (e.g. most recent A1c value and blood pressure in the measurement year). This information is reliably captured as evidenced by post submission validation audits against the patient´s medical record.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Content validity is addressed in several ways. Potential new measures are researched for impact and opportunity and presented to our Measurement and Reporting Committee prior to development. We convene expert panels for their input and consensus (face and content validity) and test the data collection/ submission processes prior to wide scale implementation. There is consensus among our expert workgroup that the target components reflect a quality of care that will benefit patients in terms of reducing the risk of future complications.
All measures used, changed and developed by MN Community Measurement go through formal approval processes with our Measurement and Reporting Committee (has representatives from providers, health plans, data experts and consumers) and our Board of Directors.
Validity (strength of conclusions):
The goal of collecting these intermediate physiological and biochemical outcomes is to prevent further disease and disability in the future. A direct causality has not been established between these intermediate outcomes and the actual development, avoidance or delay of complications, however providers across the state believe that managing these variables will significantly impact long term outcomes (refer to ICSI guidelines)
Estimated reduction of risk of complications based on intermediate outcomes
www.cdc.gov/diabetes/pubs/estimates07.htm
• Improved glycemic control benefits people with either type 1 or type 2 diabetes. In general, every percentage point drop in A1c blood test results (e.g., from 8.0% to 7.0%) can reduce the risk of microvascular complications (eye, kidney, and nerve diseases) by 40%.
• Blood pressure control reduces the risk of cardiovascular disease (heart disease or stroke) among persons with diabetes by 33% to 50%, and the risk of microvascular complications (eye, kidney, and nerve diseases) by approximately 33%. In general, for every 10 mm Hg reduction in systolic blood pressure, the risk for any complication related to diabetes is reduced by 12%.
• Improved control of LDL cholesterol can reduce cardiovascular complications by 20% to 50%.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
The diabetic patients in our state have benefited from the increased focus on measurement, achievement of targets and transparency of information via public reporting. Currently 25% are achieving all five targets, this equates to 35,221 individuals who have reduced their future risk of developing devastating consequences of their underlying chronic condition. There is a wide range of rates among clinics, demonstrating opportunity for continued improvement. The top performer in the state is at 61% of their diabetic patients meeting all five optimal care components, while some clinics are below 1%. The comparative average for all providers is based on the overall average with a large number of patients used in calculating that average (n = 140,884 patients in 2010). ICSI guidelines support the components of the all or none composite measure and there is consensus among our expert workgroup that the target components reflect a quality of care that will benefit patients in terms of reducing the risk of future complications.

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2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
Exclusions from the diabetes denominator are based on 1) HEDIS specifications for Comprehensive Diabetes Care (CDC), 2) ICSI Diabetes Guidelines and 3) an expert opinion workgroup. It is the intent to exclude patients for whom the achievement of targets of control would be contraindicated and those patients who are not established to a provider´s practice.
Exclusions are allowed for:
* Patients who expire during the measurement year (HEDIS)
* Patients with < than 2 visits with diabetes codes over the last 2 years (HEDIS)
* Patients who are age < 18 or over age 75 (HEDIS)
* Gestational diabetes- these codes have never been a part of our definition (HEDIS)
* Diabetics who are pregnant during the measurement year (ICD-9 648.0 to 648.04) ICSI Diabetes Guidelines exclude diabetics who are currently pregnant and based on expert opinion that achievement of LDL targets with statins during pregnancy is contraindicated
* Patients who are permanent nursing home residents or enrolled in hospice during the measurement year. Expert opinion is that these patients are either unable to participate in self management necessary to achieve optimally managed targets, or in the case of the terminally ill, not appropriate to be focusing on these physiological targets.
* Patients who are coded in error (typically a pre-diabetic patient with evaluation of A1c who gets a 250.xx code in the billing system, but does not have the diagnosis of diabetes)

2d.2 Citations for Evidence:
ICSI Diabetes Guidelines July 2010
http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/diabetes_mellitus__type_2/diabetes_mellitus__type_2__management_of___6.html
NCQA HEDIS Technical Specifications 2011 Comprehensive Diabetes Care (CDC) Vol 2 page 144

2d.3 Data/sample *(description of data/sample and size)*: Medical groups submitted data for 112,819 patients with dates of service in 2008. During the most recent submission, in addition to the denominator certification process that describes how groups excluded patients, we asked groups to record all the individual patients that they excluded and submit the reasons for exclusion to MNCM for analysis. The number of exclusions submitted (n = 3,732) in 2009 was 2% of the total population. For 2010, the number of exclusion types allowed was reduced and it is anticipated that the remaining exclusions (death, hospice and nursing home residents) will account for less that 1% of the population. In addition to providing information for analysis, we discovered that this also had educational value; groups that were inappropriately excluding patients were instructed on the definitions of valid exclusions and resubmitted their data.

2d.4 Analytic Method *(type analysis & rationale)*:
Descriptive statistical analysis was performed to better understand the use of two exclusions (Patient transferred care during the measurement year and patient´s diabetes was managed by another provider - endocrinologist). Scatter plot diagrams were constructed to better understand the impact of groups who utilized these optional exclusions extensively versus those groups who took very few or no exclusions at all. After analysis, our Measurement and Reporting Committee (MARC) approved the retirement of these two exclusions, they are no longer part of our denominator exclusions for 2009 dates of service. As a result, our current denominator definition is more in line with other national measures (HEDIS, PQRI, NCQA´s Diabetes Physician Recognition Program, Bridges to Excellence)

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
The frequency of the use of the exclusions under study was 2% of the overall diabetes population.
* Unequal distribution in the utilization of exclusions; 67% of groups submitting excluded < 4%
* Scatterplot diagrams of outcome rates versus % utilization of exclusions demonstrated that a high exclusion rate did not translate to higher than average scores. Conversely, many groups that took no exclusions were high performers. Based on the analysis and to promote increased accountability under a medical home philosophy, RAC retired the use of two exclusions:
* Patient transferred care during the measurement year (if the patient meets the visit count, they are included)
* Patient´s diabetes is managed elsewhere (promote medical home & care coordination)

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2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: For 2009 dates of service, 572 clinics in Minnesota and neighboring states (border clinics) submitted data for patients with diabetes. These clinics represented 216,229 patients, and it is estimated that this represents 95% of diabetics in the state of MN. 65% of the clinics submitted full population data; the remainder submitted random samples no less than 60 records per clinic site. The total number of patients submitted was 140,884. For clinics that submitted a sample, reported rates are weighted against the clinic's full eligible population of diabetic patients.
Analysis included examining the difference between unadjusted and risk adjusted rates and the ranking impact for the top 15 clinic sites representing 5,303 patients.

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
Risk adjustments for these measures are based on case mix (health plan product). Health plan product was selected because it can serve as a proxy for socioeconomic status. Socioeconomic status can be a variable in a patient's ability to comply with a treatment plan for achieving the intermediate outcomes that can postpone or prevent the long term complications of diabetes or cardiovascular disease.
The overall average state-wide distribution of patients across three major insurance types (Commercial, Medicare and MN Healthcare Programs plus Self-pay/Uninsured) is calculated and then each reporting site's patient distribution is adjusted to match the average mix. Rates are re-weighted based on the new distribution of patients and then rates are re-calculated.

2e.3 Testing Results *(risk model performance metrics)*:
For 2009 dates of service, 572 clinics in Minnesota and neighboring states (border clinics) submitted data for patients with diabetes. These clinics represented 216,229 patients, and it is estimated that this represents 95% of diabetics in the state of MN. 65% of the clinics submitted full population data; the remainder submitted random samples no less than 60 records per clinic site. The total number of patients submitted was 140,884. For clinics that submitted a sample, reported rates are weighted against the clinic's full eligible population of diabetic patients.
Analysis included examining the difference between unadjusted and risk adjusted rates and the ranking impact for the top 15 clinic sites representing 5,303 patients. (Please refer to the table below). Ultimately, the overall ranking of the top 15 clinics does change, but in general the same sites remain in the top 15 with all of the top 10 clinics maintaining a ranking in the top 15.

Top 15 Clinic Rankings - Diabetes Measure (2009 DOS)
Before and After Risk Adjustment

Unadj Rank	Adj Rank	Undj Rate	Adj Rate	Total Pts	Clinic
4	1	56.8%	57.2%	338	A
3	2	58.7%	56.6%	75	B
2	3	60.0%	54.6%	60	C
6	4	51.5%	51.3%	410	D
1	5	60.8%	51.2%	51	E
8	6	49.9%	49.2%	1053	F
11	7	48.5%	48.6%	171	G
5	8	53.3%	47.8%	60	H
9	9	49.6%	47.6%	278	I
7	10	50.0%	47.0%	60	J
13	11	47.1%	47.0%	563	K
14	12	46.8%	46.6%	419	L
10	13	48.6%	46.3%	477	M
17	14	46.3%	46.0%	136	N
16	15	46.4%	45.9%	1152	O

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: Measure has a risk adjustment method.

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2f. Identification of Meaningful Differences in Performance

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2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: In 2010, 130 medical groups representing 572 clinics and 216,229 patients in Minnesota and neighboring communities submitted data for rate calculation (submitted n = 140,884). 65% of clinics submitted full population, while the remainder submitted a random sample of their patients with no less than 60 patients per clinic site.

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2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Outcome results are displayed on the public website MN HealthScores www.mnhealthscores.org and can be ranked in order of performance or by the name of the clinic. The most significant point for comparison is the overall experiential average that is calculated based on over 140,884 patients submitted every year to provide an annually updated weighted average that representing over 216,229 patients. Additionally, results for up to three clinics can be compared and used by the consumer to choose a clinic with excellent outcome rates or by a provider to better understand successes or opportunities for improvement. Providers have additional analytical capabilities within the HIPAA secure data portal for understanding the results of their own data. On the public website, current and historical weighted rates are available and compared to the state average. Rates are also stratified by the individual component of the outcome measure, (e.g. within this diabetes measure who is doing the best at managing LDL levels?) Upper and lower confidence limits are calculated for each clinic site based on the eligible population and the number of patients submitted. In our annual Health Care Quality Report (located at http://www.mncm.org/site/?page=our_work&view=2 page 20) clinics with high performers are highlighted. High performers are defined as clinics with rates and confidence intervals fully above the overall clinic average.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
For 2009 dates of service, 25.0% of the patients met all five component targets in the composite measure and considered optimally managed. This rate is a weighted average of the total population of patients for clinics submitting data (Total Population = 216,229, Submitted = 140,884). 65% of the clinics submitted full population data, the remaining clinics provided a random sample. There was a wide range of variability with the lowest scoring clinic at 0% (6 clinics) and the highest scoring clinic at 60.8%
It is estimated that the data is representing about 95% (216,229/228,000) of all diagnosed diabetics in the state of MN.
The trends for this measure:
2006- 14%
2007- 17%
2008- 19%
2009- 25%

Optimal Rate Range	% of Clinics
0%-9.9%	20.3%
10%-19.9%	25.9%
20%-29.9%	24.1%
30%-39.9%	19.4%
40%-49.9%	8.9%
50%-59.9%	1.0%
60%-69.9%	0.4%

Individual rates of the components are as follows:
A1c < 8.0 72%
LDL < 100 57%
Blood Pressure < 130/80 58% *
Daily Aspirin Use 86% **
Tobacco Non-user 83%

* Note for Blood Pressure: Historically and in currently reported data, the target was < 130/80. For 2011 reporting (2010 dates of service) the target will be modified to < 140/90.
** Note for Aspirin: historically and in currently reported data this component reflects aspirin use in diabetics age 41+, this part of the composite will change to diabetics with known cardiovascular disease for 2011

reporting. Mean: 25.0% Median: 21.3% Standard Deviation: 0.14 Min: 0.0% Max: 60.8%	
2g. Comparability of Multiple Data Sources/Methods 2g.1 **Data/sample** *(description of data/sample and size)*: Multiple data sources are not used. The data source for this information is the patient´s medical record. No other sources of information are applicable (e.g. is not a claims based measure as lab values and blood pressure values are needed). Information can be obtained either from a query of the electronic medical record or via chart abstraction. If data is stored in a registry, the registry must include all eligible diabetics and must match the source information (the patient's medical record). 2g.2 **Analytic Method** *(type of analysis & rationale)*: NA 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*: NA	**2g** C☐ P☐ M☐ N☐ NA ☐
2h. Disparities in Care 2h.1 **If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: The Optimal Diabetes Care measure is stratified at a medical group level by Minnesota Health Care Programs (MHCP)- includes patients with Medical Assistance, MinnesotaCare, and General Assistance Medical Care versus all other purchasers. This stratification can serve as a proxy for socioeconomic status. Please refer to the 2009 Health Care Disparities Report pages 16 to 17 available at: www.mncm.org. Analysis demonstrated that there is a gap in performance for patients with MHCP versus other payers. The statewide rate for Optimal Diabetes Care provided to MHCP patients is almost 10 percent; the rate for Other Purchasers is almost 17% percent. This is a statistically significant difference (t-test with a p-value of < 0.05). Patients enrolled in Other Purchasers have higher rates of optimal diabetes care than patients enrolled in MHCP, and this has been true every year since 2004. Fortunately, rates for all patients have improved every year, although the gap between purchasers has not narrowed substantially. 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** Future direct data submissions will include fields for gender, race/ethnicity, country of origin and primary language and will allow further stratification of the results.	**2h** C☐ P☐ M☐ N☐ NA ☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met? **Rationale:**	**2** C☐ P☐ M ☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** In use	**3a** C☐ P☐ M☐

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:** The optimal diabetes care measure rates ate publicly reported by MN Community Measurement on their consumer website located at the MN HealthScores Website at www.mnhealthscores.org. MN Community Measurement is a collaborative effort in our community among those who believe that you cannot improve what you don´t measure. Our collaborative includes medical groups, clinics, physicians, hospitals, health plans, employers, consumer representatives and quality improvement organizations. These stakeholders support the notion that greater transparency in our health care system will lead to better health outcomes for the people of Minnesota. MN Community Measurement´s mission to accelerate the improvement of health by publicly reporting health care information is having a positive effect on the health care provided in Minnesota. For more information please visit our corporate website at www.mncm.org **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** Publicly reported data is used by MN Bridges to Excellence for P4P programs and additionally used by Blue Cross & Blue Shield of MN, HealthPartners and Medica, (the three largest health plans in MN) within their contractual agreements with providers. MN Bridges to Excellence information can be viewed at: http://www.bhcag.com/index.asp?Type=B_BASIC&SEC={1E35803C-5FA7-43E6-A483-174E880109E9} Beginning in 2010, this measure was a part of the Minnesota Health Care Reform Quality Reporting Measurement System, which required participation and data submission by all physician clinics in the state. Use of data for quality improvement efforts is encouraged and results reporting within the data portal assist groups in understanding potential opportunity within each of the components by displaying component results as compared to the overall rates. There is a compare function built into the public reporting website so that consumers (or providers) can pick clinics to be compared; additionally medical groups have access to their own detailed patient level results with numerator calculation within our HIPAA secure data portal. Groups can use this information to better understand their diabetic population and identify subsets of patients who could improve their control levels. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)***:** Consumer: In June of 2007, a series of three consumer focus groups were interviewed (28 individuals) to provide feedback about our old website. A new, enhanced website was launched in 2009 and additional feedback was sought from a focus group (5 individuals) Providers: August 2008 and August 2009 (102 respondents) Direct Data Submission Users: July 2009 (96 respondents) Medical Groups: April 2010 (126 respondents) **3a.5 Methods** *(e.g., focus group, survey, QI project)***:** Focus groups of consumers for usability of the website. Informal physician feedback about QI utility and functionality within the HIPAA secure data portal. Medical Group/ Provider Survey Direct Data Submission Users Survey **3a.6 Results** *(qualitative and/or quantitative results and conclusions)***:** Consumer: In June of 2007, a series of three consumer focus groups were interviewed (28 individuals) to provide feedback about our old website. Some interesting feedback was obtained about our composite measures: accept responsibility for their own health outcomes, health care quality is not uniform across sites, awareness of the website is low, value having the information available during open enrollment and that the website is fairly easy to use. A new, enhanced website was launched in 2009 and additional feedback was sought from a focus group (5 individuals) that reacted positively about the new search and compare capabilities. Providers: August 2008- Physicians were involved in the data portal redesign of the results display in terms of what additional information would be useful to them in using the data for quality improvement efforts. Providers liked the enhancements, display of the breakdown of the individual components and ability to download their own group's specific patient level data for use in further analysis.	**N**☐

Medical Groups: (includes medical directors, clinic administrators, quality improvement, and data analysts)
August 2009- Survey to medical groups with 102 respondents
* 65% feel that MNCM is selecting measures that drive the most important improvement in health care
* 59% MNCM is accelerating the improvement of care by publicly reporting information
* 67% have visited the new public website MNHealthScores and 74% the corporate website
* 72% participate in direct data submission, an additional 20% plan to participate in 2010. The most frequent reason cited for not participating was lack of an EMR.
* 35% of respondents would like more input into the measurement development process. This is an area we are addressing by including a public comment period for new measures after specs are developed and prior to pilot/ implementation.
Direct Data Submission Users: Survey July 2009 (96 respondents)
Ratings of Top Two Categories (e.g. Good and Excellent or Helpful or Very Helpful):
* 71% rating for the direct data submission guide; overall
* 77% guide instructions for identifying population
* 78.5% guide instructions for sampling procedures
* 84.3% guide instructions for data submission process
April 2010 – Survey to medical groups with 126 respondents.
*52% feel that MNCM is selecting measures that drive the most important improvement in health care.
*48% feel that MNCM is accelerating the improvement of health by publicly reporting health care information.
39% of respondents visit MN HealthScores occasionally or frequently and 45% of respondents visit MNCM's corporate site occasionally or frequently.

Feedback from medical groups included having more input into the measure development process and to receive increased communication about MNCM's submission timelines. A detailed 18-month DDS planning calendar has already been developed for medical group use and more educational webinars detailing the DDS process steps are in the plans for this fall. Medical group involvement in the measure development process (including input from groups in greater Minnesota) continues to grow as new measures are developed and workgroups formed.

76% of survey respondents participated in direct data submission (DDS) during 2010.
Ratings of Top Two Categories (e.g. Good and Excellent or Helpful or Very Helpful):
*80% rating for the overall guide for Optimal Diabetes Care and Optimal Vascular Care.
* 82% rating for instructions on identifying a medical group's patient population (denominator)
* 84% rating for instructions on selecting a sample
* 81% rating for the abstraction/field specifications

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:
NQF # 0076 CAD: optimally managed modifiable risk [This measure is very similar to Optimal Diabetes Care, has four of the same components: BP, LDL, Tobacco Non-use and daily aspirin] Steward(s): Minnesota Community Measurement. NQF # 0064 Diabetes Measure Pair: A Lipid management: low density lipoprotein cholesterol (LDL-C) <130, B Lipid management: LDL-C <100. Steward(s): NCQA. NQF # 0061 Diabetes: Blood Pressure Management [Process measure]. Steward(s): NCQA . NQF # 0063 Diabetes: Lipid profile [Process measure]. Steward(s): NCQA . NQF # 0059 Hemoglobin A1c management [Defines poor control as > 9.0] Steward(s): NCQA . NQF # 0057 Hemoglobin A1c testing [Process measure]. Steward(s): NCQA

(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?
The Optimal Diabetes Care all or none composite measure is harmonized with existing NQF measures for diabetes as evidenced by all of the following: same target age range for the population, same diagnosis codes (exception is pregnancy), same established patient visit criteria, same time period for data collection,

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similar instructions for data collection and similar exclusions. The NQF endorsed process measures are contained within the Optimal Diabetes Care Measure, e.g. in order to meet the LDL < 100 component, the date of the LDL test must be within the measurement year.	
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** This measure provides added value as patients achieving control or compliance in all five components (A1c, blood pressure, lipids, tobacco non-user and daily aspirin) are more likely to significantly reduce their risk of complications, co-morbidities or catastrophic events as compared to patients with only one component in control. A multifactorial approach to diabetes care that includes emphasis on blood pressure, lipids, glucose, aspirin use, and non-use of tobacco will maximize health outcomes far more than a strategy that is limited to just one or two of these clinical domains (American Diabetes Association, 2010 [R]; Duckworth, 2009 [A]; Gaede, 2008 [A]; Holman, 2008a [A]). Our providers have embraced the challenge of improving all of these variables and demonstrated significant increases in their outcome scores since the measure was first launched. **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**	**3c** C☐ P☐ M☐ N☐ NA ☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA ☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	**4d** C☐

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.

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MN Community Measurement has modeled the direct data submission to minimize inaccuracies, errors and unintended consequences. All groups participating sign a terms of use agreement that delineates the group's responsibilities for submission of data and consequences for not participating in good faith. Additionally all groups sign a Business Associate Agreement that outlines the use of the data. Denominator certification prior to any data collection ensures that groups are following the specifications and correctly identifying their population and serves as a point of correction prior to the expenditure of resources for data collection. Groups provide documentation of cases that are excluded and this is reviewed by MNCM staff prior to approval of the data submission. Extensive audit processes also support the data's accuracy. After data submission, in person validation audits are conducted comparing the submission to the patient´s medical record using NCQA´s 8 and 30 rule for audit requiring a 90% accuracy rate. Groups are only allowed three patient records with error out of 30 reviewed in order to achieve 90%. Audits are conducted in the following instances: 1) a random sample of clinics with prior successful submission, 2) for all groups who are new to the submission process, 3) a group who has had a change in system or process (e.g. went from paper charts to EMR) since the last submission or 4) any group with a history of prior unsuccessful audit. It has been our experience that the post submission audits have identified both issues with data extraction programming from an EMR and abstraction errors when data is collected from the chart. Groups have been amenable to remedy plans, resubmission and re-audit. Results of our audit in 2009 are as follows:
Of the 130 medical groups submitting data in 2010, 14 groups initially failed the audit and remedy plans were developed. All 14 groups resubmitted and passed subsequent audit.
Types of Errors Found in Validation Audits: BP was not most recent, EMR did not pull the correct date or value, ASA date could not be validated, ASA date not reported, LDL date not reported or more recent date found, Tobacco status was not correct, and A1c date not reported or more recent date found.

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:

Over the last four years we have learned the following:
1. Data Submission- Providing data collection software for medical groups wishing to submit data was not always the best and most efficient way of collecting data. As electronic health records use becomes more pervasive in our state, providing templates of data file submissions proved to be more efficient.
2. Specifications- Detailed specifications with instructions on how to handle most situations (e.g. detailed instructions on blood pressure values) has been valuable to medical groups, increased data accuracy and resulted in 98% of groups submitting data successfully.
3. Audit- Audit methods have ensured the accuracy of our data and we are able to successfully compare providers because everyone is pulling their data the same way and subject to the same rules.
4. Confidentiality- Patient confidentiality has been addressed by numerous mechanisms. MNCM only receives the patient level information needed to calculate the rates, determine eligibility for inclusion in the measure and support the administration of pay for performance programs. The PHI submitted is minimal and the data is protected by 1) password protection with password only available to the medical group submitting data, 2) file upload process is encrypted as data is transferred and 3) Data is stored on a separate secure server and meets all HIPAA protection rules.
5. Electronic Medical Record- It is easier for groups that have an electronic medical record to submit data and to submit their full population of patients, however many groups with paper chart systems can successfully submit their sample.
6. Acceptance of Data- Vast improvement in terms of sample sizes and timeliness of the data submitted by medical groups six weeks after the end of the measurement year as compared to prior method of health plan's samples and the results over a year old. Providers are more accepting of the results as compared to previous methods of pooling health plan samples.
7. Data Collection Burden- We have learned that for additional future measures we will need to stagger the data collection time frames and submission deadlines as to not burden the medical groups in terms of abstraction/ extraction (e.g. can't always have a measurement period Jan 1st to Dec 31st reported the second week of February, may need to consider July 1st to June 30th with data submission in August)
8. Health Plans: pay for performance and the inclusion of measures within contracts significantly impacts the number of groups participating in each measure (Diabetes, Ischemic Vascular, and Depression)

4e
C☐ P☐ M☐ N☐

4e.2 Costs to implement the measure (*costs of data collection, fees associated with proprietary measures*)**:**
Medical Groups: There are no fees charged to medical groups to submit their data to MNCM. Data collection costs (staff time to either write an extract program from EMR or staff time to abstract a sample of patient data from charts) are absorbed by the medical groups submitting data. For clinics that are abstracting from charts, it generally takes less than eight hours to abstract information for a diabetes composite measure for 60 patients. Time spent can often be dependent on the quality and completeness of the record.
Administrative (Costs to MNCM): Costs are associated with staffing. Currently, there is one full time project manager and one part time project coordinator dedicated to the direct data submission project and services for validation audits are contracted with abstractor during a three month period each year. Responsibilities include creation and annual update of the direct data submission guide, recommendations for data portal enhancements, communication to users, denominator certification, training of auditors for validation, availability for all questions & problems related to specs and submission, planning and performing some of the validation audits and approving data for publication.
It is estimated that the startup costs for the development of our data portal was approximately $25,000 for both the diabetes and ischemic vascular composite measures.

4e.3 Evidence for costs:
MNCM contracts with portal vendor (historical) and budget.
Staff's experience with data collection at numerous clinic sites.

4e.4 Business case documentation: Prior to implementing the direct data submission process for the composite measure for diabetes, MN Community Measurement and it stakeholders knew there was great variability in the care and management that was being provided to patients and preliminary results for a composite measure demonstrated very low overall rates and significant room for improvement. Groups were already used to collecting and reporting this information at a summary level to one of the state's major health plans. As the process moved towards direct data submission, information was more acceptable to the providers in terms of how the data was collected, opportunity to submit full population to better reflect true rates, timeliness and availability of the data for internal QI processes.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility?*	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
MN Community Measurement, 3433 Broadway Street NE, Suite # 455, Minneapolis, Minnesota, 55413

Co.2 Point of Contact
Anne, Snowden, MPH CPHQ, snowden@mncm.org, 612-455-4811-

Measure Developer If different from Measure Steward
Co.3 Organization
MN Community Measurement, 3433 Broadway Street NE, Suite # 455, Minneapolis, Minnesota, 55413

Co.4 Point of Contact
Anne, Snowden, MPH CPHQ, snowden@mncm.org, 612-455-4811-

Co.5 Submitter If different from Measure Steward POC
Collette, Pitzen, RN BSN CPHQ, pitzen@mncm.org, 612-454-4815-, MN Community Measurement

Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
An expert panel was convened in December 2008 to determine the most appropriate A1c target for this composite. The group reviewed literature and incorporated current ICSI Diabetes Guideline discussions as this guideline was also undergoing revision. Members included:
Beth Averbeck, MD Associate Medical Director, Health Partners, MNCM Board of Directors
Barry Bershow, MD Medical Director, Quality & Informatics, Fairview, Co-Chair MNCM Reporting Advisory Committee (RAC) and MNCM Board Member
Rich Bergenstal, MD Executive Director, International Diabetes Center, ICSI Diabetes Guideline Workgroup
John Fredrick, MD Exec Vice President & Chief Medical Officer PreferredOne, MARC Member
Gene Ollila, MD Allina Medical Clinic, ICSI Diabetes Guideline Workgroup
Expert panel was re-convened in March 2010 to address the aspirin component and again in July 2010 to address the blood pressure component of the composite measure. This technical advisory panel included:
Beth Averbeck, MD HeathPartners
Barry Bershow, MD, Fairview Health Services
Rich Bergenstal, MD International Diabetes Center, Park Nicollet
John Fredrick, MD Preferred One
Gene Ollila, MD Allina Medical Clinic
Linda Walling, MD, HealthEast
Mark Nyman, MD Mayo Clinic
JoAnn Sperl-Hillen, MD HealthPartners
Victor Montori, MD Mayo Clinic
Kari Retzer, ICSI Facilitator for Diabetes Guideline

Ad.2 If adapted, provide name of original measure: NA
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2007
Ad.7 Month and Year of most recent revision: 08, 2010
Ad.8 What is your frequency for review/update of this measure? Annual, but can be more frequently as evidence emerges and guidelines change.
Ad.9 When is the next scheduled review/update for this measure? 06, 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (*MM/DD/YY*)**:** 08/05/2010