

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0274

Measure Title: [Diabetes Long-Term Complications Admission Rate \(PQI 03\)](#)

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: [Click here to enter composite measure #/ title](#)

Date of Submission: [2/24/2014](#)

Instructions

- **For composite performance measures:**
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of supplemental materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (*includes questions/instructions*; minimum font size 11 pt; do not change margins).
Contact NQF staff if more pages are needed.
- Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](#).

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Health outcome:** ³ a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- **Intermediate clinical outcome:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- **Efficiency:** ⁶ evidence not required for the resource use component.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's [Measurement Framework: Evaluating Efficiency Across Episodes of Care](#); [AQA Principles of Efficiency Measures](#)).

1a.1. This is a measure of: *(should be consistent with type of measure entered in De.1)*

Outcome

- ☒ Health outcome: Click here to name the health outcome
- ☐ Patient-reported outcome (PRO): Click here to name the PRO
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors
- ☐ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- ☐ Process: Click here to name the process
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

HEALTH OUTCOME/PRO PERFORMANCE MEASURE *If not a health outcome or PRO, skip to [1a.3](#)*

1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

People with diabetes are prone to a variety long term complications associated with microvascular disease that may result in hospitalization, as well as long-term disability and death. The most common long-term complications, as targeted by this indicator include: (1) Neuropathy, (2) Vision disorders, and (3) Nephropathy. While these complications are varied, they all have the common source of longstanding poor glycemic control.

1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (i.e., influence on outcome/PRO).

Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.

Improved access to ambulatory care can improve diabetic management including earlier diabetic case finding. Longstanding improvements in glycemic control and risk factor management can prevent or slow the progression of microvascular disease. This along with earlier complication identification and treatment can decrease or prevent hospitalizations related to these long-term diabetic complications.

There are several nationally accepted clinical guidelines (See section 1.a.3 and 1.a.4) that include major recommendations for screening and diagnosis, goals and treatment in the following areas related to long-term complications: nephropathy screening and treatment, retinopathy screening and treatment and neuropathy screening and treatment. These guidelines suggest that long-term complications are preventable and, thus, hospitalizations for these long-term complications are preventable.

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes. Include all the steps between the measure focus and the health outcome.

1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?

- ☐ Clinical Practice Guideline recommendation – *complete sections [1a.4](#), and [1a.7](#)*

- ☐ US Preventive Services Task Force Recommendation – **complete sections [1a.5](#) and [1a.7](#)**
- ☐ Other systematic review and grading of the body of evidence (e.g., *Cochrane Collaboration*, *AHRQ Evidence Practice Center*) – **complete sections [1a.6](#) and [1a.7](#)**
- ☒ Other – **complete section [1a.8](#)**

Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (including date) and **URL for guideline** (if available online):

Guidelines demonstrate that prevention of the condition (and, by definition, the hospitalization for the condition) is possible.

American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care*. 2013; 36(Suppl 1):S11-66. NGC: 009808-009815 (URL: <http://www.guideline.gov/search/search.aspx?term=diabetes>) (more detail in 1a.4.2)

Other guidelines that similarly note that a focus on comprehensive care to optimally manage the patient and prevent morbidity for diabetes (and need for intensive in-hospital care) include:

NGC: 009095. Riethof M, Flavin PL, Lindvall B, Michels R, O'Connor P, Redmon P, Retzer K, Roberts J, Smith S, Sperl-Hillen J, Institute for Clinical Systems Improvement (ICSI). Diagnosis and management of type 2 diabetes mellitus in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Apr. 141 p. [198 references]

NGC: 009416. University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2012 Sep. 27 p. [17 references]

NGC: 008116. Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Department of Veteran Affairs, Department of Defense; 2010 Aug. 146 p.

1a.4.2. Identify guideline recommendation number and/or page number and quote verbatim, the specific guideline recommendation.

NGC: 009812

Nephropathy Screening and Treatment

General Recommendations

- To reduce the risk or slow the progression of nephropathy, optimize glucose control. (A)
- To reduce the risk or slow the progression of nephropathy, optimize blood pressure control. (A)

Screening

- Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients, starting at diagnosis. (B)
- Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD), if present. (E)

Treatment

- In the treatment of the nonpregnant patient with modestly elevated (30 to 299 mg/day) (C) or higher levels (≥300 mg/day) of urinary albumin excretion (A), either ACE inhibitors or ARBs are recommended.
- Reduction of protein intake to 0.8 to 1.0 g/kg body weight per day in individuals with diabetes and the earlier stages of CKD and to 0.8 g/kg body weight per day in the later stages of CKD may improve measures of renal function (urine albumin excretion rate and GFR) and is recommended. (C)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium. (E)
- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is reasonable. (E)

- When estimated GFR is <60 ml/min/1.73 m², evaluate and manage potential complications of CKD. (E)
- Consider referral to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, or advanced kidney disease. (B)

Retinopathy Screening and Treatment

General Recommendations

- To reduce the risk or slow the progression of retinopathy, optimize glycemic control. (A)
- To reduce the risk or slow the progression of retinopathy, optimize blood pressure control. (A)

Screening

- Adults and children aged ≥10 years with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2 to 3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing. (B)
- High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)
- Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B)

Treatment

- Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (PDR) to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)
- Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk PDR, clinically significant macular edema, and in some cases of severe NPDR. (A)
- Anti-vascular endothelial growth factor (VEGF) therapy is indicated for diabetic macular edema. (A)
- The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as this therapy does not increase the risk of retinal hemorrhage. (A)

Neuropathy Screening and Treatment

- All patients should be screened for distal symmetric polyneuropathy (DPN) starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter, using simple clinical tests. (B)
- Electrophysiological testing is rarely needed, except in situations where the clinical features are atypical. (E)
- Screening for signs and symptoms of cardiovascular autonomic neuropathy (CAN) should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcomes. (E)
- Medications for the relief of specific symptoms related to painful DPN and autonomic neuropathy are recommended, as they improve the quality of life of the patient. (E)

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:

Definitions: A=clear evidence of well-conducted, generalizable randomized controlled trials (RCTs) that are adequately powered, including well-done meta-analyses. The recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. B= supportive evidence from a well-conducted cohort or case-control study. C=supportive evidence from poorly controlled or uncontrolled studies or conflicting evidence with weight of evidence supporting the recommendation; E=expert consensus or clinical experience.

1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: If separate grades for the strength of the evidence, report them in section 1a.7.)

Not applicable

1a.4.5. Citation and URL for methodology for grading recommendations *(if different from 1a.4.1)*:

1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?

☐ Yes → *complete section [1a.7](#)*

☐ No → *report on another systematic review of the evidence in sections [1a.6](#) and [1a.7](#); if another review does not exist, provide what is known from the guideline review of evidence in [1a.7](#)*

1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

1a.5.1. Recommendation citation *(including date)* and URL for recommendation *(if available online)*:

1a.5.2. Identify recommendation number and/or page number and quote verbatim, the specific recommendation.

1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:

1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system. *(Note: the grading system for the evidence should be reported in section 1a.7.)*

1a.5.5. Citation and URL for methodology for grading recommendations *(if different from 1a.5.1)*:

Complete section [1a.7](#)

1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

1a.6.1. Citation *(including date)* and URL *(if available online)*:

1a.6.2. Citation and URL for methodology for evidence review and grading *(if different from 1a.6.1)*:

Complete section [1a.7](#)

1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.

1a.7.4. What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range: [Click here to enter date range](#)

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1a.7.5. How many and what type of study designs are included in the body of evidence? (*e.g., 3 randomized controlled trials and 1 observational study*)

1a.7.6. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1a.7.7. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance*)

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1a.7.9. If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

1a.8 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.8.1 What process was used to identify the evidence?

[Formal environmental scans of the literature, including routine Pub-Med searches.](#)

1a.8.2. Provide the citation and summary for each piece of evidence.

Additional Evidence

As of 2010, an estimated 25.6 million people over age 20 in the US had diagnosed or undiagnosed diabetes; this represents more than 11% of this population (1). Long term complications occur in the majority of diabetic patients to some degree, and include retinopathy (mild to proliferative), neuropathy, nephropathy, and microvascular disorders (2).

According to the CDC's National Diabetes Fact Sheet (2011), the risks of stroke and death from heart disease are two to four times higher in people with diabetes. Two-thirds of all adults with diabetes are also hypertensive. Diabetes is the leading cause of new cases of blindness and kidney failure in adults. Over two-thirds of diabetics also experience some form of neuropathy(1).

Long-term diabetes complications are thought to arise from sustained, long-term poor control of diabetes. Intensive treatment programs have been shown to decrease the incidence of long-term complications in both Type 1 and Type 2 diabetes. However, it is unclear whether poor glycemic control arises from poor quality medical care, non-compliance of patients, lack of education, or access to care problems. Areas with high rates may wish to examine these factors when interpreting this indicator. Further information regarding precipitating events to admission may be gathered through chart review.

Diabetes affects a large number of people, as do diabetic complications. Hospitalizations for diabetic complications are not rare, suggesting that reasonably precise estimates may be obtained. However, few studies have documented hospitalization rates for diabetic complications and the extent to which they vary across areas.

Sociodemographic characteristics of the population, such as race, may bias the indicator, since there are higher rates of diabetes and poorer glycemic control among American Indians and Hispanic Americans. Outpatient clinics may also care for long-term complications of diabetes. Thus, examining both inpatient and outpatient data may give a more accurate picture of this indicator.

References:

1. Genuth S. Insights from the diabetes control and complications trial/epidemiology of diabetes interventions and complications study on the use of intensive glycemic treatment to reduce the risk of complications of type 1 diabetes. *Endocr Pract* 2006;12 Suppl 1:34-41.
2. Gaster B, Hirsch IB. The effects of improved glycemic control on complications in type 2 diabetes. *Arch Intern Med* 1998;158:134-140.