



January 14, 2013

TO: NQF Members
FR: NQF Staff
RE: Voting Draft Report: *National Voluntary Consensus Standards for Neurology, Phase II*
DA: January 14, 2013

Background

Neurological conditions and injuries affect millions of Americans each year, taking a tremendous toll on patients, families, and caregivers, and costing billions of dollars in treatment, rehabilitation, and lost or reduced earnings. Specifically:

- An estimated 5.4 million Americans have Alzheimer's disease, and an estimated 16 million will have Alzheimer's by 2050.ⁱ The disease accounts for 70 percent of the cases of dementia in the country.ⁱⁱ In 2009, Alzheimer's disease was the fifth leading cause of death for adults ages 65 and over. Medicare and Medicaid spending on people with Alzheimer's disease totaled \$130 billion in 2011; this could rise to \$1.1 trillion by 2050.ⁱⁱⁱ
- Epilepsy affects two million Americans and is estimated to cost \$15.5 billion each year in medical costs and lost or reduced earnings and production.^{iv}
- One million Americans have Parkinson's disease, and the combined direct and indirect costs are estimated at \$25 billion per year.^v

NQF has endorsed a number of consensus standards to evaluate the quality of care for neurological conditions over the past decade. As quality measurement has matured, better data systems have become available, electronic health records are closer to widespread adoption, and the demand for meaningful performance measures has prompted development of more sophisticated measures of healthcare processes and outcomes for neurological conditions. An evaluation of the NQF-endorsed® neurology measures and consideration of new measures will ensure the currency of NQF's portfolio of voluntary consensus standards.

In phase II of this project, NQF sought performance measures that could be used for accountability and quality improvement in neurological conditions excluding stroke (measures for stroke were reviewed in Phase I) for adults and children in all settings of care. Specifically, measures related to epilepsy, Parkinson's disease, and dementia were evaluated in this phase.

A [24-member Steering Committee](#) reviewed 22 measures, and recommended 5 of those measures for endorsement. Public and member commenting took place from October 31-November 29, 2012.

Comments and Revised Voting Report

NQF received comments from 10 NQF member organizations and 20 members of the public:

Consumers – 1	Health Professional – 3
Purchasers – 1	Health Plans – 2
Providers – 0	QMRI – 2
Supplier and Industry – 1	Public & Community Health - 0

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee, is posted to the [project page](#) on the NQF website, along with the measure submission forms.

The Steering Committee reviewed and responded to all comments received. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Topic 1: Reconsideration of the AAN/AMA-PCPI Measures

The AAN formally requested that the Committee reconsider the following eight measures:

- 1953: Seizure type(s) and current seizure frequency(ies)
- 1954: Documentation of etiology of epilepsy or epilepsy syndrome
- 1973: Annual Parkinson’s disease diagnosis review
- 1982: Parkinson’s disease psychiatric disorders or disturbance assessment
- 1983: Parkinson’s disease cognitive impairment or dysfunction assessment
- 1985: Parkinson’s disease querying about sleep disturbances
- 1988: Parkinson’s disease rehabilitative therapy options
- 2029: Dementia: Counseling regarding risks of driving

Fifteen comments regarding these and other AAN/AMA-PCPI measures from NQF member organizations and the public were received, many of which were submitted through the Behavioral Neurology & Geriatric Neurology Section of the AAN. Most—but not all—of these comments were supportive of some or all of the 18 measures submitted by AAN/AMA-PCPI.

The majority of the Committee’s discussion of these measures during the in-person meeting centered around the evidence criterion. The following NQF criteria and guidance was considered by the Committee at that time:

- Process measures should measure those aspects of care with the most direct evidence of a strong relationship to the desired outcome; such evidence is most often about the relationship between some intervention and a desired health outcome, and, therefore, interventions are the preferred focus of process measures.
- Empirical evidence and specific information on the quantity, quality, and consistency from a systematic review of a body of evidence is required. Such evidence should support that the measured healthcare process leads to desired health outcomes in the target population with benefits that outweigh harms to patients.
- Expert opinion is not considered empirical evidence; if a measure is based only on expert consensus, it does not meet the NQF evidence criterion. An exception to the evidence criterion should only be considered if no empirical evidence exists, the expert opinion is systematically assessed, and there is a strong rationale for why the specific structure or process should be the focus of a quality performance measure. Use of this evidence exception should not be a routine occurrence.
- Clinical practice guidelines alone do not meet NQF criteria for evidence. If a guideline does not provide the necessary information on quantity, quality, and consistency, developers should seek other sources such as the Cochrane Collaboration, AHRQ evidence reports, USPSTF, or systematic reviews published in the literature, which often are cited in the guidelines.
- Guidance provided by the CSAC on measure construction practices recommends avoiding specifying measures so that they can be met primarily through documentation without an evaluation of the quality of the activity (examples of documentation measures include assessment completed; care plan created; or instruction or advice given).

Staff summary of overall rationale for reconsideration articulated by the developer and/or other commenters:

- These measures were developed prior to the updates of the NQF measure evaluation criteria.
- NQF expects empirical data that supports the relationship between the measure and desired outcome; however, this type of evidence currently rarely exists for most neurological conditions.
- Not all members of the Steering Committee have expertise (or related experience) in Parkinson's disease, epilepsy, or dementia; this may have affected the Committee's overall understanding of the key issues and intricacies related to the management of patients with these conditions.
- These measures address patient and family engagement, which is a critical part of the National Priorities Partnership and few endorsed measures exist that address this area.
- Querying and counseling of patients has been associated with improving the patients' positive perceptions of care and is associated with better recovery from discomfort and concerns, better emotional health, improved health status, and fewer diagnostic tests and referrals (references cited).
- Epilepsy is a common and widely recognized neurologic condition, but it is often poorly understood, misdiagnosed, and improperly treated.

- Parkinson's disease significantly affects health related quality of life (HRQOL), a measurable patient-reported outcome.
- Dementia is a chronic condition that poses a major and growing threat to the public's health, yet studies have shown low and/or variable adherence to recommended practices for the assessment, management, and treatment of patients with dementia.
- The development of reliable outcome measures for dementia proved impracticable. The AAN/AMA-PCPI dementia measures were developed in the context of care management, where the goals are to improve the quality of life for patients and caregivers, maintain optimal function, and provide maximum comfort. The dementia measures target underemphasized, yet vital, aspects of the evaluation and management of dementia patients.
- Steering Committees are given minimal guidance around the exception to the evidence criterion, and therefore, invoking the exception is a subjective process.
- These measures are currently in use in the PQRS program; the AAN/AMA-PCPI will urge continued use of these measures in this and other programs regardless of NQF endorsement status.
- NQF endorsement of these measures would support performance of assessment more uniformly (anecdotal evidence of beneficial effects of counseling on quality of life was provided).

1953: Seizure type(s) and current seizure frequency(ies)

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Documentation is viewed as the surrogate term for asking about seizure type/frequency and providing appropriate treatment and/or referral.
- Patients whose seizures are controlled have better quality of life: this provides an indirect link between the measure and desired outcomes.
- Poor seizure control is associated with increased risk of death.
- Seizure type and seizure frequency are linked to early treatment costs.
- The potential benefit greatly outweighs harm.

Action Taken: The Committee agreed that asking about seizure frequency and documenting the result are important steps in the care process, but noted that the process of care that is most closely related to improved patient outcomes is how a clinician acts on the information regarding seizure frequency. Committee members also agreed that no additional information was presented to change their evaluation of the measure and declined to revote on the measure.

1954: Documentation of etiology of epilepsy or epilepsy syndrome

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Documentation is viewed as the surrogate for ascertaining the patient's etiology of epilepsy/syndrome and providing appropriate treatment.

- The measure focus represents the standard of care to ensure that patients receive appropriate treatment.
- The evolving classification system for epilepsy should not affect this measure because as the classification evolves, so must the treatment.

Action Taken: The Committee agreed that reviewing and documenting epilepsy etiology are important steps in the care process, but noted that appropriate treatments must then be provided. Members noted that evidence linking the review and documentation of epilepsy etiology to improved patient outcomes had not been initially submitted by the developer and agreed that no additional evidence demonstrating that link was subsequently provided. The Committee declined to revote on the measure.

1973: Annual Parkinson's disease diagnosis review

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- At least one recommendation used to support the measure has Level B strength behind it.
- The potential harm from not regularly reviewing the Parkinson's disease diagnosis and looking for atypical features is significant.
- The concern that this is a "check box" measure should not have been included in the evaluation of the evidence subcriterion.
- The NICE recommendations regarding optimal frequency of diagnosis review and referral to a specialist for a definitive diagnosis were not used to support this measure.

Action Taken: The Committee did not dispute the importance of having a correct diagnosis of Parkinson's disease. However, members noted that, as originally submitted, no evidence was presented that reviewing and documenting a diagnosis would result in more accurate diagnosis and/or improved patient outcomes, and they agreed that no additional evidence to support the measure was subsequently provided by the developer. The Committee also verified with NQF staff that in their evaluation of the evidence for the measure, it was appropriate to discuss their concern that this is a "check-box" measure. After review of the comments submitted and additional discussion, the Committee declined to revote on the measure.

1982: Parkinson's disease psychiatric disorders or disturbance assessment

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Psychiatric symptoms are prevalent among patients with Parkinson's disease, are a major cause of disability, and are often under-diagnosed and poorly treated (several references cited).
- There is no validated tool that could be used to assess for all psychiatric symptoms.
- No evidence exists to recommend one validated tool over another.

- A minority of SC members thought the measure should focus only on depression; however, Parkinson's disease is associated with a wide range of psychiatric disorders and disturbances that are often overlooked
- It was infeasible to re-specify the measure to focus on depression only, given in the timeframe allowed (5 days).

Action Taken: Committee members noted their initial concerns regarding the clarity of the measure specifications (in particular, which tools could be used and how the assessment would be performed). After review of the comments submitted, the Committee agreed that no additional information was provided to alleviate those concerns and declined to revote on the measure.

1983: Parkinson's disease cognitive impairment or dysfunction assessment

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- The onset of cognitive decline/dementia often occurs over a prolonged time period, and although there is limited treatment, it is important to identify.
- Cognitive impairment is prevalent among patients with Parkinson's disease; assessment will lead to identification of dysfunction, which will then lead to appropriate treatment/referrals, and ultimately, to better quality of life.
- In terms of evidence supporting the measure, depression was only cited in the context of non-motor symptoms of Parkinson's disease.

Action Taken: The Committee agreed that no additional evidence was presented to show that assessing cognitive impairment annually would result in better patient outcomes and declined to revote on the measure.

1985: Parkinson's disease querying about sleep disturbances

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- By not querying the patient about sleep disturbances the clinician may miss key factors such as sleep fragmentation (80% of PD patients), restless leg syndrome (20%), REM behavior sleep disorder (>40%), and excessive daytime sleepiness (~50%).

Action Taken: The Committee agreed that sleep disturbances are important in Parkinson's disease, but noted that no evidence had been presented to link annual query about sleep disturbances with improved outcomes. The Committee declined to revote on the measure.

1988: Parkinson's disease rehabilitative therapy options

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- The argument for including in the measure those patients with no known disability is not evidence-based and should not have been used to argue against this measure.
- Multiple studies cite the link between the discussion of rehabilitation therapy options to an increase in referrals to rehab and/or improved patient outcomes.
- The potential benefit greatly outweighs harm.

Action Taken: The Committee noted that the evidence exception had been invoked for this measure and also noted that concerns regarding measure exclusions had not been addressed. The Committee did not re-vote on the measure but encouraged the developer to re-work the measure specifications and re-submit the measure to NQF.

2029: Dementia: Counseling regarding risks of driving

Staff summary of rationale for reconsideration articulated by the developer and/or other commenters:

- Everyone with dementia will eventually become an unsafe driver because of impairments in memory, judgment, reasoning, spatial perception, and reaction time.
- Clinicians can influence their patients' decision to modify or stop driving, and help their patients maintain safe driving skills.
- Many groups have tools, position statements, and advisory kits that demonstrate the importance of physician to counsel about driving safety issues.
- Counseling patients with dementia about driving is under-reported in the medical record compared to the caregiver interview (reference cited).

Action Taken: After review of the comments, the Committee agreed that no new evidence was submitted to support the measure. The Committee declined to revote on the measure.

Topic 2: Reconsideration of measure #2111: Antipsychotic use in persons with dementia

Six comments were received regarding this measure, five of which advocated reconsideration of the measure by the Committee. The commenters offered the following reasons for reconsideration:

- Although there are limitations with the use of claims based data (e.g., inability to evaluate appropriateness of regimen), identifying variability in use is important. For example, very high rates might suggest that non-use of non-drug management strategies or inadequate evaluation.
- While claims-based measures cannot capture all possible exclusions, such data are accurate enough for health plan level measures.

- Provider feedback to a large Pharmacy Benefits Manager indicates that providers rarely prescribe the Alzheimer's drugs for a non-dementia reason, suggesting that the false-positive identification of dementia using Alzheimer's drugs as a proxy is remote.

One commenter agreed with the Committee's initial decision not to recommend the measure, noting that "appropriate use (for psychosis and psychosis related agitation and in lowest effective doses) is to be promoted and not discouraged for optimal patient management."

The developer provided additional information via letter in response to questions raised by the Committee during the in-person meeting; the full text of this letter is posted on the project page. Briefly, the developers noted the following:

- ***A comparatively narrower list of ICD-9 codes is used to identify patients with dementia compared to what is used in other measures***—Codes that indicate a behavioral disturbance or psychosis are not included because the measure is intended to focus on those dementia patients who do not have a clear indication for an antipsychotic drug.
- ***Variability in performance rates***—Additional analysis at the plan contract level shows that the performance rate varied from 10.2% to 20.3%, with an average of 13.9% and standard deviation of 3.7%. Thus, there is variation in performance across the Medicare contracts with some of the contracts having a rate that is nearly 2 standard deviations above the average.
- ***Use of dementia drugs for conditions other than dementia***—Such drugs may be used for the late effects of traumatic brain injury (ICD-9 code 907.0). Additional analysis show that out of 48,341 patients identified as having dementia, only 46 patients had a claim with this diagnosis (less than 0.1%).
- ***Relatively low prevalence of dementia identified in pilot studies***—Using the combination of medication marker and dementia diagnosis code, there was a fairly consistent rate dementia patients across the numerous Medicare contracts (average of 4.6%; range of 3.4% to 5.9%). The percentage of the population included in the measure is not intended to replicate the overall rate of dementia in the general population, given the focus on a subset of dementia patients who do not have a diagnosis indicating psychoses or behavioral disturbance.

Action Taken:

After review of the comments and the additional information provided by the developer, the Committee agreed to re-vote the measure. Upon re-vote, the Committee agreed the additional information provided by the developers was adequate to address their initial concerns about the validity of the measure and recommended the measure for endorsement.

Topic 3: Measure #0507: Stenosis measurement in carotid imaging studies

Six comments were received regarding this measure, three of which were supportive. However, two commenters expressed concern that the measure is a documentation measure and therefore of limited (or no) use for accountability purposes. Another commenter expressed the concern that the stenosis is based on the physician's judgment of patient symptoms.

Developer response (regarding physician judgment): Thank you for your comment. The intent of this measure is to quantify stenosis as precisely and reproducibly as possible. Patients with stenoses will benefit from physicians using a standardized method for stenosis calculation. There is wide variation in the use of methods for stenosis calculation, which may also lead to variation in the appropriateness of carotid intervention. Since the degree of stenosis is an important element of the decision for carotid intervention, characterization of the degree of stenosis needs to be standardized. Evidence-based guidelines are cited in support of the measure, along with several individual studies and systematic reviews.

Action Taken:

Although the Committee agreed that this measure is a documentation measure, members reiterated their agreement that there is sufficient evidence indicating that the results of the documentation are interpretable and decisions can be made based on those results. The Committee did not wish to re-consider their vote on the measure.

Topic 4: Support for other recommended measures

Twenty-two comments were received regarding the remaining three measures that were recommended for endorsement:

- #1814: Counseling for women with childbearing potential with epilepsy
- #2091: Persistent Indicators of Dementia without a Diagnosis—Long Stay
- #2092: Persistent Indicators of Dementia without a Diagnosis—Short Stay

Of these 22 comments, 19 expressed support for the measures. Of the remaining three comments, two suggested additional ideas for measure development and one comment (on measure #2091) questioned why patients with psychiatric disorders are excluded from the measure denominator, noting possible misdiagnosis of psychiatric disorders on admission to a long-term care facility.

Developer response, measure #2091: While the reviewer is correct that patients with severe psychiatric disease have higher rates of dementia, AMDA needs to be consistent with the Center for Medicare & Medicaid Service (CMS) definition and exclusions for severe dementia as we are using their instrument (the MDS 3.0 and more specifically, the BIMMS). We were requested by the Neurology Measure review committee at the October 3rd NQF meeting in Washington DC to actually broaden the exclusions as a precaution about mislabeling diseases that frequently co-exist with dementia as only dementia (i.e., the quality measure is saying "this is probably undiagnosed dementia"), as we want to be a certain as we can that it is, in fact, undiagnosed dementia and not something else. AMDA also wishes to harmonize with the CMS focus on patients with dementia who are inappropriately prescribed antipsychotics without having a diagnosis of schizophrenia or bipolar disease. As an aside note, Down's syndrome and other "mental retardations" referred to in this reviewer's comment are not exclusions.

Action Taken:

None.

Additional Areas for Measure Development

Several comments included suggestions for additional measure development, as follows:

- Measures of arterial/venous ulceration and plaque composition that are paired with measure #0507
- Measures of patients with indicators of dementia for other health care settings in addition to nursing homes (measures similar to #2091 and #2092)
- Measures around care plans for epilepsy
- Outcome measures for infants born to women with epilepsy (e.g., infants with congenital birth defects born to mothers who are on epilepsy medications)
- Patient-reported outcome measures to assess the impact of the counseling about contraception and pregnancy for women with epilepsy
- Measures that incorporate screening for Mild Cognitive Impairment and dementia
- Measures around delirium, particularly for patients who have delirium superimposed on dementia.

Action Taken:

The Committee agreed with the suggestions for future measure development and the report was updated to include them.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on February 6, 2013 at 6:00 pm ET – no exceptions.

ⁱCenters for Disease Control. Available at http://www.cdc.gov/mentalhealth/data_stats/alzheimers.htm

ⁱⁱAmerican Health Assistance Foundation. Available at <http://www.ahaf.org/alzheimers/about/understanding/facts.html> Last accessed February 2012

ⁱⁱⁱCenters for Disease Control. Available at http://www.cdc.gov/mentalhealth/data_stats/alzheimers.htm Last accessed February 2012

Alzheimer's Association. Available at http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf Last accessed February 2012

^{iv}Centers for Disease Control. Available at http://www.cdc.gov/epilepsy/basics/fast_facts.htm

^vParkinson's Disease Foundation. Available at http://www.pdf.org/en/parkinson_statistics Last accessed February 2012