What constitutes high quality of care for adults with epilepsy?

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ABSTRACT

Background: Providers are increasingly being held accountable for the quality of care provided. While quality indicators have been used to benchmark the quality of care for a number of other disease states, no such measures are available for evaluating the quality of care provided to adults with epilepsy. In order to assess and improve quality of care, it is critical to develop valid quality indicators. Our objective is to describe the development of quality indicators for evaluating care of adults with epilepsy. As most care is provided in primary and general neurology care, we focused our assessment of quality on care within primary care and general neurology clinics.

Methods: We reviewed existing national clinical guidelines and systematic reviews of the literature to develop an initial list of quality indicators; supplemented the list with indicators derived from patient focus groups; and convened a 10-member expert panel to rate the appropriateness, reliability, and necessity of each quality indicator.

Results: From the original 37 evidence-based and 10 patient-based quality indicators, the panel identified 24 evidence-based and 5 patient-based indicators as appropriate indicators of quality. Of these, the panel identified 9 that were not necessary for high quality care.

Conclusion: There is, at best, a poor understanding of the quality of care provided for adults with epilepsy. These indicators, developed based on published evidence, expert opinion, and patient perceptions, provide a basis to assess and improve the quality of care for this population. *Neurology*® 2007;69:2020–2027

GLOSSARY

AED = antiepileptic drug; **AHRQ** = Agency for Health Research and Quality; **NICE** = National Institute for Health and Clinical Excellence; **QUIET** = Quality Indicators for Epilepsy Treatment; **SIGN** = Scottish Intercollegiate Guidelines Network.

Clinicians are increasingly being held accountable for the quality of the care they provide. Current shifts in policy suggest that credentialing and payments will eventually depend

upon providers' performance on reliable and valid measures that describe their quality. Information regarding performance is also being used in large-scale efforts to improve the overall quality of care.

Over the past 30 years, health services research has developed tools to assess the quality of care provided to patients with regard to health promotion (e.g., prenatal care), acute (e.g., urinary tract infection), and chronic diseases (e.g., asthma).[1,2] McGlynn et al. found that only about 54% of patients received recommended treatment for 30 preventive care, acute, and chronic conditions.[3] Rates of receiving all appropriate treatments varied from 10.5% (95% CI 6.8 to 14.6) for alcohol dependence to 78.7% (95% CI 73.3 to 84.2) for senile cataract; there was little difference among preventive services (54.9%), acute care (53.5%), or chronic disease (56.1%).[3]

Considerably less is known about the quality of epilepsy care. While some data suggest gaps between clinical recommendations and practice with regard to antiepileptic drug treatment in the elderly,[4] and screening and treatment of mood disorders in epilepsy,[5] no quality measures to address care for adults with epilepsy exist in the United States. In order to define gaps and improve the quality of care, the Centers for Disease Control funded the Quality Indicators for Epilepsy Treatment (QUIET) study, with the charge to develop and validate quality indicators focusing on care of adults with epilepsy. Recognizing that most care is provided in primary care and general neurology clinics, we focused our assessment of quality on care provided within those settings. This article describes the process of quality indicator development, including the conceptual framework, the modified Delphi process, and the product of this process—the quality indicators.

A CONCEPTUAL FRAMEWORK FOR QUALITY INDICATOR DEVELOPMENT Critical to the development of quality indicators is identification of a conceptual framework that guides the focus of those indicators. We now describe the principles that guided our quality indicator development.

Defining quality. While a number of definitions have been proposed, all agree that quality of care is care which maximizes patients' welfare, improves or maintains quality or duration of life, and leads to desired health outcomes.[6-10] The Institute of Medicine defined quality of care as the degree to which health services increase the likelihood of desired health outcomes of individuals and populations and are consistent with current professional knowledge.[11] Thus, our quality indicators must assess aspects of care associated with positive patient outcomes in a variety of domains.

Dimensions of quality. Quality of care is typically defined as technical quality, interpersonal quality, and amenities of care.[12,13] Technical quality entails making the right decision for each patient and having the technical skill to perform the care.[13] Interpersonal quality includes quality of communication; ability to gain/maintain patient trust; and the ability to interact in a way that demonstrates empathy, honesty, and sensitivity to the patient's concerns.[12] Interpersonal quality is important for patients with epilepsy since it is a chronic disease that requires the patient to adapt to profound lifestyle changes; patients may lose driving privileges, which may impair their ability to work or accomplish normal daily responsibilities. While amenities in the care environment are also important,[14] we focused on technical and interpersonal dimensions of care.

What to measure. The Donabedian model posits that quality measures address three major domains: structure, process, and outcomes.[7] Structural factors include characteristics of the provider or the health care facility, such as provider specialty or facility organization. Process factors include aspects of the encounter between a patient and provider such as medications prescribed and laboratory tests ordered. Outcomes include measures of a patient's subsequent health status such as physical functioning, mental functioning, and satisfaction with the care provided. While these components are related, each has its strengths and limitations.

Structural measures are often the easiest to capture, but they provide only limited insights into the actual care provided. Process measures tend to be the most sensitive indicators of actual differences in practices and they are generally easy to interpret.[15] There is little ambiguity in a finding such as 75% of patients hospitalized with a myocardial infarction received a beta-blocker on discharge. However, process measures are criticized because often they are not shown to be im-
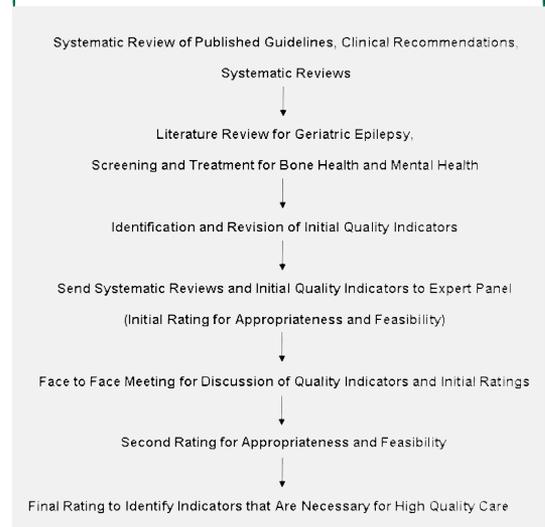
portant predictors of outcomes.[16] For example, a commonly used process measure for hypertension care is whether the blood pressure was measured in both arms. While an important process of care, it is difficult to see how this would affect blood pressure control. The strength of outcome measures is that they capture something that is important in its own right.[15] However, outcome measures may be influenced by many factors, some of which do not reflect quality of care, such as disease severity. In a similar vein, a poor outcome does not occur every time there is an error in the process of care. While the goal of epilepsy care is no seizures, no side effects, high quality of care can be provided and the patient may continue to have seizures or side effects from antiepileptic drugs. Thus, in our development of quality indicators for care of adults with epilepsy, we focused on processes of care that were linked with improved patient outcomes in the clinical literature, and that could be reliably measured with an eye toward their future use by primary care physicians and general neurologists in routine ambulatory care.

METHODS Two general measurement approaches have been used in quality measurement: implicit and explicit.[16] Implicit measures rely on the judgment of a health professional, often after performing review of medical charts. With implicit review, the reviewer compares actual care to his or her own knowledge, beliefs, and opinions of what constitutes appropriate care. This type of measure is most appropriate when examining complex cases where the right approach is not always clear—such as difficult to control patients receiving care in a tertiary epilepsy center. Explicit methods compare processes of care provided to specific evidence-based criteria that have consensus within the medical community. These indicators are often described using if-then statements, such as "IF a patient has diabetes, THEN a glycosylated hemoglobin test should be performed every year."[17]

A critical challenge for implicit review is inter-rater reliability, while the major concern regarding explicit review is validity. Prior studies have persistently demonstrated poor inter-rater reliability when different experts perform implicit assessments.[15,16] As our mandate was to develop quality indicators for care of adults with epilepsy with a focus on those receiving care in primary and general neurology care—areas of care where there is general consensus—we developed explicit quality indicators using the modified Delphi process (RAND Appropriateness Method) that has been successfully employed in the development of quality indicators for over 30 different preventive health, acute, or chronic diseases.[3,18,19] This method incorporated a systematic review of the literature and guidelines to assure that selected process of care criteria are linked to relevant patient outcomes in clinical trials or expert clinical opinion (best practices)[16] and an expert rating panel. The figure outlines this process.

Development of initial criteria. *Literature review.* We conducted an extensive literature search to identify evidence-based best practices for treating adults with epilepsy. As a

Figure   Modified Delphi process used to develop quality indicators for care of adults with epilepsy

Systematic Review of Published Guidelines, Clinical Recommendations, Systematic Reviews
↓
Literature Review for Geriatric Epilepsy, Screening and Treatment for Bone Health and Mental Health
↓
Identification and Revision of Initial Quality Indicators
↓
Send Systematic Reviews and Initial Quality Indicators to Expert Panel (Initial Rating for Appropriateness and Feasibility)
↓
Face to Face Meeting for Discussion of Quality Indicators and Initial Ratings
↓
Second Rating for Appropriateness and Feasibility
↓
Final Rating to Identify Indicators that Are Necessary for High Quality Care

number of systematic reviews, practice parameters, expert consensus statements, and national clinical practice guidelines have been developed, we first identified extant systematic reviews, or guidelines related to the diagnosis and treatment of epilepsy in adults in MEDLINE and CINAHL. We also searched for guidelines and quality indicators available from the Agency for Healthcare Research and Quality, National Committee for Quality Assurance, Centers for Disease Control and Prevention, and the National Guidelines Clearinghouse. In addition to a number of systematic reviews that focused primarily on comparisons of various antiepileptic drug (AED) treatment options, we found literature syntheses from the Agency for Health Research and Quality (AHRQ) that addressed both assessment and treatment of newly diagnosed and treatment-resistant epilepsy,[20] The George Washington University Medical Center Report on Managing Epilepsy Care,[21] practice parameters published by the American Academy of Neurology,[6,9,22-28] a treatment guideline from the International League Against Epilepsy,[29] and two national clinical guidelines from the United Kingdom (National Institute for Health and Clinical Excellence [NICE],[30] Scottish Intercollegiate Guidelines Network [SIGN][31]). Moreover, we examined recommendations for treatment of newly diagnosed adults with epilepsy that arose from two separate expert consensus processes which were not evidence based.[32,33] Using these sources we developed an initial list of recommendations, including the level of evidence for the recommendation, and the sources for each recommendation (e.g., SIGN, NICE, AHRQ); most statements were supported by clinical evidence, while some were based on expert opinion.

Based on this review of the literature we identified additional emerging areas of concern in treating adults with epilepsy: the impact of AEDs on bone health, identification and treatment of mood disorders, and special treatment issues for elderly patients with epilepsy. Thus, we conducted additional searches of MEDLINE and CINAHL for clinical research on osteoporosis and epilepsy, mood disorders and epilepsy, and epilepsy and aging. Osteoporosis searches were supplemented with guidelines obtained from the National Guidelines Clearinghouse, NIH, Office of the US Surgeon

General, and SIGN for recommendations on the screening and treatment of osteoporosis.

From the review of current guidelines, clinical recommendations, and systematic reviews, we identified an initial list of recommendations that was reviewed by our research team (general internist, epileptologist, nurse, epilepsy and health services researchers). Items that were included in at least two sources, or which were thought to be of crucial importance by content experts, were then translated into a preliminary list of conditional If–Then statements. Similar statements were also developed based on our review of the literature regarding bone health, mood disorders, and geriatric epilepsy to form our initial list of quality indicators. The list of preliminary statements was further reviewed by the research team and external consultants with expertise in internal medicine, quality indicator development, and epilepsy content experts. Items were then revised based on suggestions from these consultants.

Patient focus groups. In addition to evidence- and expert opinion–based criteria of quality, we conducted patient focus groups to ascertain patients' perspectives on what constitutes quality of care for adults with epilepsy. Patients were recruited from the neurology clinic at a single university medical center. We conducted three focus groups with both men and women for a total of 17 patients. Patients were asked about their experiences with providers and the health care system in obtaining and sustaining treatment for epilepsy; they were asked to describe instances of excellent care and poor care, and asked to identify key characteristics of each. Two investigators conducted grounded theory analysis[34] of verbatim transcripts of these focus groups.

Identification of key quality indicators. In order to determine the appropriateness (validity) of the proposed quality indicators, we used a modified Delphi method—a process which has been found to have content, construct, and predictive validity.[17,35-37] This method includes a formal group process in which a panel initially rates the appropriateness and feasibility of each quality indicator, which is followed by a discussion of their ratings in a subsequent face-to-face meeting. After the meeting, panelists re-rate each indicator. Occasionally, a third round of ratings allows panelists to rate the extent to which each indicator is necessary for high quality of care.

We invited 15 individuals who were general internists, neurologists, and epileptologists with national or international reputations, epilepsy social workers, and epilepsy nurses. These individuals were selected based on experience diagnosing and treating people with epilepsy, and included individuals with both community and academic practices. From this group, 11 agreed to participate; 10 provided ratings for the first two rounds, and 9 provided ratings for the third round. These individuals worked in both academic and clinical settings, and included a geriatrician and 10 epileptologists.

We asked panel members to rate each potential quality indicator on three separate occasions, focusing on processes of care that pertain to patients receiving epilepsy treatment exclusively from primary care or general neurology providers. In the first two ratings, panel members were asked to rate the appropriateness and feasibility of each potential quality indicator (based on the best clinical judgment, of an average patient presenting to an average primary care or general neurology provider), and the third rating was used to identify necessity for measures rated as both appropriate and feasible in the prior rating. We convened an in-person meeting to discuss the indicators after tabulating the first ratings.

Using definitions from the RAND Appropriateness Method,[38] an appropriate measure was defined as a process of care in which the benefit of use far outweighed the potential risks, regardless of cost, and which was believed to represent high quality of care. A feasible measure was defined as one which could be reliably measured. For instance, if it is unlikely that data would be available in patient charts or patient survey, a measure—regardless of appropriateness or validity—would be of little value in assessing quality. A necessary indicator was defined as a process in which failure to recommend would be viewed as improper clinical judgment. An indicator identified as not necessary was defined as appropriate, but not necessary.[38]

Rating for each phase was conducted using a 9-point Likert scale: 1 to 3 = not an appropriate, reliable, or necessary measure of quality; 4 to 6 = uncertain or equivocal; 7 to 9 = clearly appropriate, reliable, or necessary. For each phase of the rating process, we determined the median panel rating and a measure of dispersion for each indicator. Items with a median of 7 or higher without disagreement were classified as appropriate quality indicators. As there were 10 panel members, we used definitions of agreement and disagreement described by the BIOMED Concerted Action on Appropriateness.[38] Accordingly, items on which three or more panelists rate in the lower (1 to 3) and upper (7 to 9) extremes were classified as having disagreement. Items in which two or fewer panelists rated outside the three-point region containing the median (1 to 3, 4 to 6, 7 to 9) were classified as having agreement.

In the first step of this process, panel members were asked to review a monograph that synthesized existing guidelines, clinical recommendations, and systematic reviews (and primary literature sources as appropriate) that were relevant to each evidence-based indicator. Then, panel members were asked to review and rate each proposed evidence-based quality indicator for appropriateness and feasibility, and provide comments/suggestions regarding wording and content. These preliminary ratings were returned via mail and analyzed in advance of the one-day group meeting at which members discussed their interpretation of each quality indicator. Prior to the discussion, each panel member received the descriptive results of the grouped data (mean, SD, median, range) alongside their original rating for each evidence-based indicator. Moreover, panel members were encouraged to suggest modification of existing statements, or add entirely novel statements to the group of quality indicators. While the panel was comprised primarily of epileptologists, research team members that represented primary care, nursing, and pharmacology also participated in discussion. The patient-identified quality indicators were first presented to the panel at the meeting; ratings for appropriateness and feasibility were conducted after the discussion of all indicators.

Upon compiling comments from the panel meeting, the quality indicators were revised and sent to panel members for a second round of ratings for appropriateness and feasibility. Quality indicators identified as appropriate in round two were then sent to panel members for the final round rating of necessity. Items that were rated as necessary (median of 7, no disagreement) were classified as primary quality indicators; those identified as not necessary were classified as secondary quality indicators.

RESULTS We developed 37 potential quality indicators based on review of existing guidelines,

| Table | Patient-identified quality indicators for adults with epilepsy |

Providers should:

1. Provide patients with references to information about epilepsy through the epilepsy foundation and/or epilepsy Web sites.

2. Provide information about the impact of epilepsy and its treatment on other health conditions.

3. Communicate with patients about potential medication side effects, including cognitive, emotional, physical, and sexual side effects.

4. Discuss potential long-term side effects of medications.

5. Explain epilepsy repeatedly as many patients have memory loss.

6. Discuss driving with patients including giving information about alternative transportation to patients who cannot drive.

7. Give referrals to social services to assist with employment, negotiating through SSDI.

8. Discuss impact of epilepsy and treatment on women's health with respect to menstrual cycles, conception, pregnancy, and menopause.

9. Be honest with patients about the inexact science of epilepsy treatment and that there may be multiple trials of medication combinations before they find out what works best for individual patients.

10. Refer patients to local support groups or other resources to obtain psychosocial support.

Numbers do not indicate ranking of importance to patients.

clinical recommendations, systematic reviews, and primary source literature (hereafter referred to as evidence-based indicators; appendix E-1 on the *Neurology*® Web site at www.neurology.org), and 10 patient-generated indicators (table). Prior to the first round of ratings six items were consolidated or removed based on external review (appendices E-1 and E-2). During the initial round, panel members were asked to rate the remaining 31 proposed process of care measures. After the first round of ratings and group discussion of the indicators, this list of quality indicators was revised and refined into 26 evidence-based and 5 patient-centered indicators (table E-1).

Indicators that were removed were thought by the panel to be unrealistic (e.g., If the patient has been diagnosed with epilepsy by a primary care or emergency provider then the diagnosis should be confirmed by a neurologist or epilepsy specialist within 4 to 8 weeks), or not within the realm of primary care practice (e.g., If the diagnosis or seizure type remains unclear, then video or ambulatory EEG should be performed). In addition, several indicators were added by the panel (e.g., At the time of initial seizure evaluation, the patient should receive information on driving restrictions, safety, and injury prevention.). Because five patient-centered indicators were incorporated in existing evidence-based measures (table items 2, 4, 5, 6, 8), five patient-generated indicators remained.

During the second round of ratings, two evidence-based indicators were dropped from further consideration due to significant disagreement among raters (QI 10 and 12); concerns regarding these items occurred because the recommendations to switch patients from enzyme inducing AEDs even after treatment stabilization had no strong source of empiric evidence, and was unrealistic for primary care providers.

The third round of ratings identified nine indicators that were considered appropriate but not necessary by the expert panel (table E-1). The primary indicators, those rated as both appropriate and necessary, included measures of both technical and interpersonal aspects of quality, and included domains of care ranging from initial diagnosis, initial treatment, chronic disease management, and issues specific to certain populations. Review of the few panel member comments that were provided suggests that secondary indicators were identified as such for a variety of reasons. For some the stated timeframe seemed arbitrary (table E-1, items 16, 20, 22); for others the indicator was unrealistic (items 7, 9).

DISCUSSION This process resulted in the development of a set of quality indicators designed to assess the quality of care of adults with epilepsy. While more sophisticated processes of care may also be valid for more complicated patients, these indicators were developed to be appropriate for patients receiving care in primary care or general neurology settings. Moreover, these quality indicators take into account not only evidence-based criteria, but also processes of care identified by patients. This patient-centered focus is a critical attribute of quality of care as defined by the IOM,[11,39] and represents an important contribution of this study.

As in the development of previous quality indicators,[19] the preliminary indicators identified by the study team benefited from revision based on discussions among our study team (comprised of an epileptologist, a neurologist, primary care providers, nurses, and health services researchers), external experts, and the expert panel. These modifications included the elimination of indicators thought to be unrealistic, consolidation of similar indicators, rewording, and addition of new indicators at the suggestion of the panel.

These indicators were developed based on published evidence, expert opinion, and patient perceptions in the same manner used for other

quality indicators. However, good quality indicators are associated with variation in patient outcomes.[40] Accordingly, the next step in this process is validation,[40] which will occur on several levels. First, we are conducting chart abstractions to assess both processes of care and patient outcomes (seizures, side effects) for epilepsy patients within several healthcare systems. We also plan to obtain survey data from these same patients to assess processes of care that are not available in the medical chart, and to assess more comprehensive patient outcomes. By linking specific quality indicators with variation in patient outcomes (controlling for disease severity), we will identify the quality indicators which have the best predictive validity, and thus, are the most valid and reliable measures of quality for adults with epilepsy.

Potential limitations. As the validity of a modified Delphi approach depends on the level of expertise and representativeness of panel members, we note that our expert panel was comprised almost exclusively of epileptologists. We made an effort to include primary care providers, social workers, and nurses, but most were unable to participate. We attempted to compensate for the potential bias in several ways. First, the preliminary quality indicators were developed by our research team (expertise in primary care, general neurology, epileptology, nursing, and health services research). Second, the panel was instructed to rate each item specifically for use in primary or general neurology care. Finally, research team members chaired the meeting and participated in discussion during the face-to-face meeting to assure that the primary care perspective was taken into account throughout the process. Since much discussion focused on appropriateness within a primary care environment, we believe we were able to substantially mitigate that potential bias.

In a similar vein, the patients selected for the focus groups were from a tertiary neurology clinic, and may not be representative of all patients with epilepsy. The greatest concern is that these patients may represent only patients with treatment-resistant epilepsy. Examination of patient characteristics, however, indicated that 12 patients were well controlled on monotherapy and 2 were newly diagnosed. As all these patients were receiving care in a tertiary neurology clinic and all but one had some form of insurance, access to specialty care was not problematic as it may be for patients from other settings.

As with prior quality indicators, this product is not intended for use as a care guideline for adults with epilepsy. While there are guidelines for certain aspects of epilepsy care,[22,24,26-29] no comprehensive guidelines for care of adults with epilepsy in the United States exist. This measure, which was developed using methodologically sound processes, contains quality indicators that are both evidence-based and patient-generated, and provides a foundation on which to develop clinical guidelines. We believe, however, that these quality indicators may be used immediately by primary care providers, general neurologists, and even epilepsy specialists to guide the care that they provide. In primary care these quality indicators may provide guidance about basic processes of care that are important for adults with epilepsy. Both primary care and general neurology providers may gain insight into situations where patients may benefit from a referral to a neurologist or epilepsy specialist. Even epilepsy specialists may use these quality indicators to educate other clinicians about basic aspects of care that are essential for adults with epilepsy.

There is, at best, a poor understanding of the quality of care provided for adults with epilepsy. These quality indicators provide a foundation for quality improvement in the care of adults with epilepsy by allowing us to identify gaps between recommendations and clinical practice and develop interventions targeted at improving specific aspects of care identified by baseline assessment. Thus, they can be used to improve care for adults with epilepsy.

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