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## Quality of Care Measures for Migraine: A Comprehensive Review

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### ABSTRACT

Migraine headache is a highly prevalent, chronic, episodic disorder that is associated with high direct and indirect costs. Migraine headache impacts not only patients, but also their employers due to substantial decreases in workplace productivity. Despite the prevalence and clinical and economic burdens of migraine, no national efforts to develop and implement standardized measures of quality of care have been made. The objective of this study was to collect and report on existing quality of care measures for migraine that could be suitable for quality measurement at the health-plan level. Published literature, the Agency for Healthcare Research and Quality's National Quality Measure Clearinghouse, and resources available from quality organizations (eg, the National Committee for Quality Assurance) were examined to identify existing quality indicators that can be used to assess the quality of care delivered to migraine sufferers at the health-plan level. Among the results of the study were the following: Quality of care measures for migraine include patient-reported measures and non-patient reported, diagnosis-related, prevention-related, and treatment-related indicators. Most existing measures have been developed by the Institute for Clinical Systems Improvement or summarized and reported by the RAND Corporation. Few of these measures can be used to assess migraine quality of care at the health-plan level. In conclusion, many measures exist, but they are not intended for use at the health-plan level. Incorporation of valid and reliable quality of care measures may increase the ability of migraine disease management programs to conform to clinical care guidelines. Significant effort is needed to determine what and how to measure quality among health plans to improve the quality of care delivered to individuals with migraine. (*Disease Management* 2007;10:138–146)

### BACKGROUND

**T**HOUGH EPISODIC IN NATURE, migraine is a highly prevalent<sup>1</sup> and chronic disorder that is most prevalent among individuals in their

fourth decade,<sup>2,3</sup> a time when they are highly active in the professional arena.<sup>4</sup> Direct and indirect costs associated with migraine are substantial. Estimates of direct health care costs range from \$US 1.25 billion<sup>5</sup> to \$11.1 billion.<sup>6</sup>

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Migraine negatively impacts employers, with annual lost workplace productivity estimated to be in the range of \$16.2 billion<sup>5,7</sup> to \$28.7 billion in 2003 dollars.<sup>5</sup> The annual indirect burden of illness is estimated to be \$2,834 per patient.<sup>8</sup> Estimates of workplace absenteeism due to migraine headache range from 1 to 7 days per year,<sup>9–12</sup> and presenteeism, which is defined as being at work but less than 100% productive, constitutes 89% of the total cost burden among those with migraine.<sup>13</sup>

Despite the prevalence and substantial economic burden of migraine, no standardized measures of quality of care exist. The Health Plan Employer Data and Information Set, maintained by the National Committee for Quality Assurance (NCQA) and widely used to assess quality of care at the health-plan level, does not include any headache- or migraine-related measures.<sup>14</sup> The National Quality Forum (NQF), which has recently merged with the National Committee for Quality Health Care, and the Ambulatory Care Quality Alliance (AQA) have not focused attention on quality of care for individuals with migraine headache.<sup>15,16</sup> It is not clear why these initiatives have not focused on migraine, but it may be due, in part, to a lack of understanding of migraine or its underdiagnosis. The American Migraine Prevalence and Prevention Study found that only 56.2% of those with migraine had ever received a medical diagnosis.<sup>2</sup> Since many publications provide insights into the large clinical and economic burden of the disorder,<sup>1–13,17</sup> patients, employers, disease management providers, and health plans alike will benefit from a standardized set of migraine quality measures. Indeed, employers have begun getting involved in the management of migraine in the workplace to help keep employees at work and to help them maintain effectiveness while working. These efforts are a means to reduce overall costs attributable to the disorder.<sup>18,19</sup>

Health plans and disease management providers also are getting involved in migraine care initiatives. Presently, 2 disease management organizations have received accreditation or certification by NCQA for migraine programs.<sup>14</sup> Migraine disease management programs providing patient and physician educa-

tion, migraine diaries, patient feedback reports, and access to telephonic disease management units have demonstrated effectiveness in improving migraine-specific humanistic outcomes, measured by the Migraine Therapy Assessment Questionnaire (MTQA) and the Migraine Disability Assessment (MIDAS) questionnaire.<sup>20,21</sup> Integration of valid and reliable evidence- and consensus-based quality of care measures can assist health plans and disease management providers in better evaluating interventions and edging intervention and measurement activities closer to conformation with standard of care guidelines. The purpose of this review is to collect and report on existing quality of care measures for migraine that could be suitable for quality measurement at the health-plan level.

### TRANSLATION OF CLINICAL GUIDELINES INTO QUALITY INDICATORS

A major milestone in migraine care was the establishment of the US Headache Consortium, which is composed of 7 organizations that have an interest in improving the quality of care for people with migraine disorders.<sup>22</sup> Member organizations include the American Academy of Family Physicians, the American Academy of Neurology, the American Headache Society, the American College of Emergency Physicians, the American College of Physicians, the American Osteopathic Association, and the National Headache Foundation. The Consortium developed an evidence-based migraine practice parameter and, in doing so, identified acute and long-term treatment goals that included reducing attack frequency and severity, reducing disability, improving quality of life, preventing headache, avoiding headache medication escalation, and educating and enabling patients to manage their disease.<sup>22</sup> To achieve these goals, the consortium developed the recommendations summarized in Table 1.

Translating the care delivered to individuals with migraine headache into measurable indicators of quality is challenging. The Institute of Medicine defines quality as, "The degree to which health services for individuals and pop-

TABLE 1. US HEADACHE CONSORTIUM GOALS OF MIGRAINE TREATMENT AND PREVENTION\*

- Educate migraine sufferers about their condition and its treatment, and encourage them to participate in their own management.
- Use migraine-specific agents (ie, triptans, dihydroergotamine, ergotamine) for patients with more severe migraine and for those whose headaches are known to respond poorly to nonsteroidal anti-inflammatory drugs, or NSAID, or combinations such as aspirin plus acetaminophen plus caffeine.
- Select a non-oral route of administration for patients whose migraines present early with nausea or vomiting as a significant component of the symptom complex.
- Consider a self-administered rescue medication for patients with severe migraines that do not respond well to (or fail) other treatments.
- Guard against medication-overuse headache. ("Rebound headache" or "drug-induced headache" are sometimes used interchangeably with "medication over-use headache.")
- Preventive therapy in appropriately guided clinical presentations, including:
  - Headache frequency more than 2 days per week (or >8 days/month).
  - Use of acute medications, successfully or unsuccessfully, more than 2 days per week.
  - Headache attacks that remain disabling despite aggressive acute intervention, as documented by lifestyle interference, ratings on disability scales, or use of rescue medications more than once a month.
  - Presence of prolonged aura (>1 hour), complex aura (basilar or hemiplegic), or migraine-induced stroke.
  - Contraindications to, failure of, overuse of, or adverse events with acute therapies.
  - Patient desire to reduce frequency of acute attacks.

\*Adapted from the US Headache Consortium Guidelines<sup>22</sup>

ulations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."<sup>23</sup> Quality of care can be measured along any 1 of 3 domains. This "Quality Triad" includes structures (ie, the "bricks and mortar" of care delivery), processes (ie, the way care is delivered), and outcomes (ie, the results of care).<sup>24</sup> An example of a process measure is using a beta-blocker after myocardial infarction in patients without contraindications to such therapy. Such an indicator of quality is supported by substantial clinical research and is now included in various quality measurement sets. More recently, attention has been given to the use of outcome measures as the basis for quality measurement and quality improvement.<sup>25</sup> Outcome measures can be subdivided into clinical, humanistic, and economic measures. The measures selected should be professionally developed, with agreed-upon standards of care, and, most important, the measures must be interpretable and actionable.

## METHODS

To develop a migraine quality measurement set that could be used at the health-plan level, we conducted a resource review including published peer-reviewed literature, the Agency for

Healthcare Research and Quality's National Quality Measure Clearinghouse, and resources available from quality organizations such as NCQA, NQF, and AQA. We grouped the identified measures as either (1) patient-reported or (2) non-patient-reported. Within the non-patient-reported measures, there are (a) diagnosis-related, (b) treatment-related, and (c) prevention-related measures. This scheme is a standard clinical approach and is similar to the structure of the US Headache Consortium guidelines.<sup>22</sup>

## RESULTS

### *Patient-reported measures*

Because of the subjective nature of migraine headaches, many measurement techniques exist that rely on patient-reported information. We briefly discuss each of these instruments below.

*24-hour migraine quality of life questionnaire.* The 24-Hour Migraine Quality of Life Questionnaire (24-Hr-MQOLQ)<sup>26,27</sup> is designed to assess the health of specific populations at a specific point in time. It is a 15-item, self-administered questionnaire aimed at assessing migraine sufferers' quality of life within 24 hours of taking migraine medication and

within the first 24 hours of a migraine attack. Items cover a number of domains including work, social, energy, vitality, feelings, concerns, and migraine symptoms.

*Migraine-specific quality of life.* The Migraine-Specific Quality of Life (MSQOL)<sup>28</sup> is a 25-item self-administered instrument developed to measure the long-term effects of migraine and migraine treatment on quality of life. Items are summed to provide an overall score and 3 subscores measuring physical, emotional, and social domains. A total MSQOL score also can be calculated.

*Migraine-specific quality of life questionnaire, version 2.1.* The Migraine-Specific Quality of Life Questionnaire, version 2.1 (MSQ v.2.1)<sup>29,30</sup> is a 14-item, self-administered instrument covering areas of specific concern to persons with migraine. Specifically, it addresses factors of role restrictive, role preventive, and emotional function. It was developed from the MSQ v.1.0 and subsequently shortened for easier administration; its content was improved by rewording certain items for greater clarification. The MSQ v.2.1 is intended to respond to a perceived need to develop a health status measure that would adequately focus on the physical and emotional limitations that are typically associated with migraine headaches.

*Migraine disability assessment scale.* Migraine Disability Assessment Scale (MIDAS)<sup>31,32</sup> is a questionnaire that measures migraine-related disability based on the number of days of lost and limited activity due to migraine. Activities are classified into 3 areas, which include (1) paid work and education (school/college); (2) household work (unpaid work such as housework, shopping, and caring for children and others); and (3) family, social, and leisure activities. Patients with migraine count the number of days on which they missed out on activities because of migraine in the previous 3 months. They also count the number of days on which their productivity was, at most, half of normal in paid and household work. The overall MIDAS score is calculated by summing the answers to these 5 questions, and is scored in number of days.

*Headache disability inventory.* The Headache Disability Inventory (HDI)<sup>33,34</sup> is a 25-item instrument developed to quantify the impact of headache, though not specifically migraine, and its treatment on daily living. Items are dichotomized and answered with either “yes” (4 points), “sometimes” (2 points), or “no” (0 points). Based on a scale of 0–100, the scores indicate patients’ self-perceived headache disability. These measures assist the physician in determining the medical relevance of patients’ headaches.

*Headache impact questionnaire.* The Headache Impact Questionnaire (HImQ)<sup>35,36</sup> is a 16-item, self-administered questionnaire used to measure pain and activity limitations from headache, though not specifically migraine, over a 3-month recall period. This instrument was developed to capture information about pain and headache-related disability to help doctors and patients evaluate the impact of headache on the individual’s daily life. Headache-related disability is expressed as hours or days of lost productivity and functioning.

*Headache impact test.* The Headache Impact Test (HIT)<sup>37–39</sup> is a tool that measures the impact headaches, though not specifically migraine, have on a person’s ability to function on the job, at home, at school, and in social situations. The HIT builds on previous work by pooling items from 4 existing measurement instruments: MSQ, HDI, HImQ, and MIDAS. Items cover a broader spectrum of health outcomes than any of the original scales, ranging from pain to emotional distress. Two versions exist, the computer adaptive testing (CAT)-HIT and the HIT-6. The CAT-HIT is administered over the Internet, whereas the HIT-6 is a static, short-form version of the HIT for paper-and-pencil administration.

*Migraine therapy assessment questionnaire.* The Migraine Therapy Assessment Questionnaire (MTAQ)<sup>40</sup> is a 9-item, patient-completed questionnaire that was developed to identify individuals whose migraine management may be suboptimal. MTAQ was created in an effort to identify barriers to optimal migraine management and improve patient outcomes.

*Migraine assessment of current therapy.* The Migraine Assessment of Current Therapy (Migraine-ACT)<sup>41</sup> is a 4-item assessment tool intended to evaluate how well a recently prescribed acute medication is working, and to identify patients who require a change in acute treatment. The questions were formulated in 4 domains including headache impact, global assessment of relief, consistency of response, and emotional response.

In addition to patient self-report survey instruments, the Institute for Clinical Systems Improvement (ICSI) suggests some provider-level humanistic indicators of patient functional status including percentage of days per month with migraine for migraine sufferers; hours (days) per month lost due to migraine for migraine sufferers; rate of emergency department usage by migraine sufferers for migraine; and percentage of migraine sufferers with a headache calendar or diary.<sup>42</sup>

ICSI is an independent, nonprofit organization that facilitates health care quality improvement initiatives among providers in Minnesota and surrounding areas. The organization develops diagnosis and treatment algorithms for various conditions, including headache, and establishes priority aims and suggested measures to improve the quality of care for these conditions. The seventh edition of the diagnosis and treatment of headache guidelines, released in January of 2006, includes indicators (with measurement specifications) of quality for headache at the provider level based on chart review. While these measures may be important to consider in developing a migraine-specific quality measure set, implementing such measures may be diffi-

cult at the health-plan level because chart review may not be feasible for health plans. Furthermore, these types of measures may be sub-optimal for disease management programs operating in collaboration with health plans because it would require program providers to cull additional data not available through the health plan, thereby increasing required resources and costs.

## NON-PATIENT-REPORTED MEASURES

In 2003, McGlynn and colleagues at the RAND Cooperation published a landmark study which sought to quantify the extent to which quality health care was delivered in the United States.<sup>43</sup> Among the 439 performance indicators included in the study, 21 were specific to headache (not specifically migraine). These indicators were derived from a literature review conducted by researchers at the RAND Corporation.<sup>44,45</sup> The researchers conducted a MEDLINE search of English language articles between 1990 and 1997, using the keywords headache, diagnosis, and treatment. Of the 14 articles identified, 9 were review articles and 5 were observational studies. Each of the indicators that were collected was categorized as either a diagnosis indicator or a treatment indicator.

In the aforementioned article, McGlynn and colleagues classified all the measures in the comprehensive collection on a number of domains, including unit (ie, patient, dyad, episode); type (ie, preventive, acute, chronic); function (ie, screening, diagnosis, treatment, follow-up); modality (ie, history, physical ex-

TABLE 2. DIAGNOSIS-RELATED MIGRAINE QUALITY OF CARE INDICATORS\*

- Patients with new onset headache should have an examination evaluating the cranial nerves.
- Patients with new onset headache should have an examination evaluating the fundi.
- Patients with new onset headache should have an examination evaluating deep tendon reflexes.
- Patients with new onset headache should have an examination evaluating their blood pressure.
- CT or MRI scanning is indicated in patients with new onset headache and an abnormal neurological examination.
- CT or MRI scanning is indicated in patients with new onset headache and a severe headache.
- Percentage of headache sufferers diagnosed with migraine.
- Percentage of headache sufferers diagnosed with tension-type headache.
- Percentage of headache sufferers diagnosed with cluster headaches.
- Percentage of headache sufferers diagnosed with sinus headaches.

CT, Computed tomography; MRI, Magnetic resonance imaging.

\*Adapted from references 42, 44, 45.

amination, counseling/education, encounter or other intervention, medication, laboratory/radiology, immunization); problem (ie, underuse, overuse); and level of evidence (ie, randomized trial, nonrandomized controlled study [eg, case control], observational study/expert opinion).<sup>43</sup> The rate of performance for each indicator was calculated to estimate the percentage of recommended care received by study participants. Mean scores for headache quality indicators ranged from 8.21% (patients with new-onset headache should be asked about family history of headache) to 100% (sumatriptan and ergotamine should not be given to patients with a history of ischemic heart disease or angina). In other words, on average, patients received recommended care between 8.21% to 100% of the time based on various indicators. Overall, recommended care for headache was received 45.2% of the time.<sup>43</sup> Clearly, performance varied widely across different indicators of care. Of the 21 headache quality measures included in this study, the indicators that best lend themselves to measures rather

than just guidelines are included in Tables 2 and 3. Because these indicators are for headache, they may not apply to migraine specifically.

All of the non-patient-reported measures are classified as either diagnosis-related<sup>42,44,45</sup> (Table 2) or treatment- and prevention-related<sup>42,44-48</sup> (Tables 3 and 4). The RAND authors assert that screening for headaches is not recommended because the problem is symptomatic.<sup>44,45</sup> However, Lipton and colleagues developed the ID Migraine, a 3-item questionnaire used to screen for and diagnose migraine in the physician's office.<sup>50</sup> Cady and others have developed similar questionnaires.<sup>51</sup> The ICSI guidelines suggest that several measures could be used to increase the accurate diagnosis and subsequent treatment of headaches. In addition to the treatment- and prevention-related measures set forth by the RAND authors, ICSI suggests several provider-level treatment and prevention-related quality measures that are intended to increase the rate of treatment plans for mild, moderate, and severe headaches for migraine sufferers and to

TABLE 3. TREATMENT-RELATED AND PREVENTION-RELATED MIGRAINE QUALITY OF CARE INDICATORS\*

- Patients with acute mild migraine or tension headache should have tried aspirin, acetaminophen, or other nonsteroidal anti-inflammatory agents before being offered any other medication.
- For patients with acute moderate or severe migraine headache, one of the following should have been tried before any other agent is offered: ketorolac, sumatriptan, dihydroergotamine, ergotamine, chlorpromazine, or metoclopramide. According to the DISC study by Lipton, the severity of migraine headache would dictate the first medication that someone takes, called the stratified approach.
- Recurrent moderate or severe tension headaches should be treated with a trial of tricyclic antidepressant agents if there are no medical contraindications to their use.
- Patients experiencing more than 2 moderate-to-severe migraine headaches per month, should be offered prophylactic treatment with one of the following: beta-blockers, calcium channel blockers, topiramate, tricyclic antidepressants, naproxen, aspirin, fluoxetine, valproate, or cyproheptadine. Angiotensin II receptor blockers have also demonstrated efficacy in the prevention of migraines. (Table 4 summarizes the level of evidence of pharmacological agents for migraine prophylaxis according to the US Headache Consortium Guidelines for Migraine Prophylaxis.)
- Sumatriptan and ergotamine should not be administered concurrently.
- Opioid agonists and barbiturates should not be first-line therapy for migraine or tension headaches, except in patients where more specific agents are medically contraindicated.
- Sumatriptan and ergotamine should not be given to patients with a history of uncontrolled hypertension, ischemic heart disease, or angina.
- Percentage of migraine sufferers with treatment plans for mild, moderate, and severe headaches.
- Percentage of migraine sufferers with a treatment plan who adhere to that plan for mild, moderate, and severe headaches.
- Number of prescriptions filled with narcotics or barbiturates for the treatment of migraine.
- Percentage of migraine sufferers with a prescription of narcotics or barbiturates for the treatment of migraine.
- Percentage of migraine sufferers with documented education.
- Percentage of migraine sufferers prescribed appropriate prophylactic treatment based on headache type.
- Percentage of migraine sufferers prescribed appropriate acute treatment based on level of severity.
- Percentage of migraine sufferers prescribed appropriate prophylactic treatment based on level of severity.

\*Adapted from references 42, 44-48.



TABLE 4. US HEADACHE CONSORTIUM GUIDELINES FOR MIGRAINE PROPHYLAXIS\*

Group 1 Medium-to-high efficacy, good strength of evidence, mild-to-moderate side effects	<ul style="list-style-type: none"> <li>• Amitriptyline</li> <li>• Divalproex sodium</li> <li>• Timolol</li> <li>• Propranolol</li> <li>• Topiramate</li> </ul>
Group 2 Lower efficacy, limited strength of evidence, mild-to-moderate side effects	<ul style="list-style-type: none"> <li>• Aspirin</li> <li>• Atenolol</li> <li>• Fenopfen</li> <li>• Flurbiprofen</li> <li>• Fluoxetine</li> <li>• Gabapentin</li> <li>• Ketoprofen</li> <li>• Metoprolol</li> <li>• Nadolol</li> <li>• Naproxen</li> <li>• Nimodipine</li> <li>• Verapamil</li> <li>• Botulinum toxin type A</li> </ul>
Group 3 No scientific evidence of efficacy, but clinically efficacious based on consensus of experience a. Low-to-moderate adverse events b. Frequent or severe adverse events (or safety concerns); complex management issues	<ul style="list-style-type: none"> <li>• Cyproheptadine</li> <li>• Antidepressants such as nortriptyline, paroxetine, venlafaxine, doxepin, sertraline, and phenelzine</li> <li>• Methylergonovine</li> </ul>
Group 4 Medium-to-high efficacy, good strength of evidence, but side effect concerns	<ul style="list-style-type: none"> <li>• Methysergide</li> </ul>
Group 5 Evidence indicating no efficacy over placebo	<ul style="list-style-type: none"> <li>• Acebutolol</li> <li>• Pindolol</li> <li>• Carbamazepine</li> <li>• Nicardipine</li> <li>• Nifedipine</li> <li>• Indomethacin</li> </ul>

\*Adapted from portions of the US Headache Consortium Guidelines for Migraine. Prophylaxis.<sup>22,49</sup>

reduce the use of narcotics and barbiturates for treatment (Table 3).

## DISCUSSION

Few migraine care quality measures exist, and those that are available are not easily implemented at the health-plan level. The RAND Corporation collected existing quality indicators and ICSI has developed provider-level quality measures. RAND researchers conducted a literature review and sought expert opinion during the development of a comprehensive measure-

ment set for headache, which was subsequently used to study, as part of a much larger compilation of quality measures, the quality of care delivered to adults in the United States. Aside from these, few indicators exist. Most RAND study indicators and the suggested ICSI measures were intended for provider-level quality assessment and require chart review. They are not based on administrative data such as claims. Mandating a health-plan quality measure based on chart review creates a significant burden. An alternative approach is to include patient self-reported measures. However, these focus mainly on symptoms and impact on humanistic outcomes (eg,

functionality and quality of life) and do not usually lend themselves to health-plan level quality assessment. Surveys also may be more difficult for a health plan to implement than measures based on existing health-plan claims data.

Existing migraine disease management models have relied on humanistic outcomes to assess their effectiveness. While patient-reported outcomes are important, administration of surveys may not be feasible for program providers and the outcomes assessment may not be relevant to the health-plan customers. A quality measurement set needs to be based on agreed-upon standards of care and expected outcomes. Cost, feasibility, and relevance of the measures to health care purchasers must be considered. A plan-level migraine quality measure set is needed and would benefit disease management providers offering migraine programs. While a good range of measures exist, significant effort is needed to determine what and how to measure quality at the plan level.

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