

# 6 “Quality” in Headache Care: What Is It and How Can It Be Measured?

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**Abstract:** Evaluating quality of health care is increasingly recognized as an important contributor to the advancement of health-care delivery, and there is general agreement that achieving and maintaining high quality in health care must be primary aspirations. Yet surprising uncertainty surrounds the meaning of "quality." Undoubtedly, it has multiple dimensions, which is problematic because improvement in one dimension may be at the expense of others. A variety of instruments and a range of methods are available to assess quality of care. These are described here, along with research directed specifically at quality in headache care. Quality indicators for headache developed in the past have been largely limited to diagnosis and treatment in specific health-care settings, or to specific types of headache. They cannot necessarily be transferred between settings; neither is quality of headache care reflected only in accurate diagnosis and appropriate treatment. Adherence to local guidelines, sometimes stipulated as the path to quality, may not achieve quality if these guidelines are not themselves well rooted in quality. For these reasons, a group of health-services researchers and headache specialists have collaborated in formulating a set of quality indicators for headache care, intended to be applicable across countries, cultures, and settings so that deficiencies in headache care worldwide may be recognized and rectified. Equally important is that these indicators will guide the development of headache services in countries that lack them.

## Quality in Health Care

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It is axiomatic that health-care systems should aspire to high quality of care. All such systems must therefore measure and monitor quality and require methods to do so. Evaluation of health-care quality underpins optimally effective care, efficient use of resources, avoidance of medical errors, service advancement, professional development, and accountability of health professionals and managers (Lawrence et al. 1997). Research into quality improvement, leading to changes in health care in pursuit of it, is a new and important field of health-services research (Grol et al. 2004), which has become central to health care that meets both patients' expectations and patients' needs (Campbell et al. 2003).

Before quality can be assessed, it must first be defined. Quality is not necessarily coupled to financing: There is no direct relationship between better outcomes and the amount spent on health care (McGlynn 2004). Donabedian (1988), in a view now widely endorsed, first suggested that quality of care should be considered in three aspects: "structure," or the attributes of the settings in which care occurs; "process," or the giving and receiving of care; and "outcome," or the effects that care has on health status. Donabedian (1990) also described seven attributes that in his view collectively defined health-care quality: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity.

A definition of quality of health care offered by the US Institute of Medicine (IOM) is the following: the degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (Institute of Medicine, Committee to Design a Strategy for Quality Review and Assurance in Medicare 1990). This puts the emphasis on outcomes. The IOM specified six attributes of quality, differing somewhat from Donabedian's seven: safety, timeliness, effectiveness, efficiency, equity, and patient/family-centeredness.

Different definitions of quality are both possible and legitimate, as quality clearly includes a variety of elements (Donabedian 1988) and is multidimensional. While this is generally

accepted, different stakeholders – patients, health professionals, and managers – may disagree over what the dimensions are, or place different values on them (Marshall and Campbell 2002). Furthermore, there is a tension between dimensions: it is rarely possible to deliver care that is optimal in all of them simultaneously.

## How Is Quality Assessed and Improved?

Approaches to improving quality include development and use of quality indicators, standards, or guidelines. Quality indicators are specific, explicitly defined, and employed to assess measurable elements of practice that can be changed to improve health care (Lawrence et al. 1997; Marshall and Campbell 2002; Campbell et al. 2004). Based either on current evidence or on expert consensus, they define standards of care that are realistic and achievable in the specific circumstances (setting, resources, or patient acceptability). Their usefulness has been shown in Denmark, where implementation and use of national indicators are mandatory in all clinical units and departments across a range of conditions (Campbell et al. 2004) and have led to improvements in quality of care between 2000 and 2008 (Mainz et al. 2009). All results from audits are published, with the aim of providing patients with an opportunity to make informed decisions about their care.

Quality indicators are statements about the structure, process, or outcome of care or services provided to patients (McGlynn and Asch 1998). Process indicators (e.g., the proportion of headache patients who receive a timely appointment) are, typically, direct measures of quality of care. Outcome indicators (such as the proportion of patients treated for migraine who report reductions in headache frequency and/or severity after 1 year) are indirect measures of quality of care. Each type has advantages and disadvantages (Mant 2001). Process indicators, being direct, are more sensitive to differences in quality of care, and they are intuitively easy to interpret. However, many care processes are not routinely monitored, and it may not be easy to do so. For example, to know how many patients with migraine are offered triptans requires time-consuming chart review or additional contemporaneous recording during clinical care. Furthermore, there has to be an objective standard based in quality itself. In the example, this knowledge is only useful if it can be stipulated how many *should* be offered triptans. On the other hand, outcome measures commonly are measured routinely. For example, headache clinics may administer and record patient scores on an instrument such as the Migraine Disability Assessment (MIDAS) questionnaire at each clinic visit. Health plans often have administrative information regarding emergency department visits due to headache. This sort of information can be used for evaluation purposes with relatively little effort, particularly when computerized records are kept. An important further advantage of outcome indicators is that they reflect the summary results of all aspects of care, even those that are otherwise difficult to measure such as technical expertise. But a major disadvantage is that outcome measures, being indirect, are influenced by many factors, and changes that may be observed are always much smaller than any changes in the processes that lead to them. This usually means that a larger amount of outcome data is required for analysis. The sample size needed to show a significant improvement in MIDAS scores, to provide a single example, would be much larger than that needed to show an improvement in the number of patients prescribed triptans. Additionally, a clear causal link between processes and outcomes can be difficult to establish.

While strategically chosen indicators provide an understanding of quality achieved by a health-care system (Evans et al. 2009), their use is retrospective. They generate review criteria, by which to assess care provided, on a case-by-case basis to individuals or to populations, and standards, by which to assess outcomes of care or services (Campbell et al. 2004). Thus, quality indicators are essentially different from guidelines, which are statements of good practice used to guide future health care (Marshall and Campbell 2002). Recommendations set out in guidelines are, or should be, based on the best evidence available (Lawrence et al. 1997), but nonetheless guidelines can vary widely between different settings and countries. This is a significant challenge to the argument that quality indicators should be valid across settings and countries (Lawrence et al. 1997).

Few initiatives, described below, have attempted to develop quality indicators in headache care. On the other hand, a wide range of guidelines includes the International Headache Society criteria for diagnosis of headache disorders (Headache Classification Subcommittee of the International Headache Society 2004), country-specific treatment guidelines (e.g., various European national guidelines reviewed by Antonaci et al. (2010), and region-specific guidelines (such as the European Headache Federation guidelines (Steiner and Martelletti 2007)). Guidelines tend to focus on clinical aspects of headache care, with less emphasis on delivery of care or the services responsible for delivering care, despite recent proposals for the organization of European headache services (Antonaci et al. 2008).

As health care is complex, it is unlikely that one method of quality assessment will alone show how quality can be improved. Rather, different methods should be employed together, each tailored appropriately. Some methods are implicit, meaning there are no standards or agreements about what reflects good or poor quality, whereas others use explicit process criteria to determine whether the observed results of care are consistent with the outcome predicted by a model validated on the basis of scientific evidence and clinical judgement (Brook and Appel 1973). With implicit methods, data sources, usually medical records, are reviewed and the following questions answered: (1) was the process of care adequate? (2) could better care have led to improved outcome? (3) was the overall quality of care, in terms of process and outcome, acceptable? (Brook et al. 1996). Analysis of data that are routinely collected, as in many health care settings, is relatively simple, with the advantage that it can be conducted retrospectively (Powell et al. 2004). Caution is needed, however: accuracy and completeness may vary, and changes may occur over time in how data are recorded. Furthermore, there may be chance variation between data sets. Insight into the perspectives of health-care users and attitudes of health-care professionals can be gained by using qualitative methods, such as in-depth interviews or focus-group studies or observational studies (Pope et al. 2004), or by using quantitative measures such as patient-reported outcome measures (Wensing and Elwyn 2004).

A range of methods can evaluate quality of care more explicitly. Systematic reviews critically appraise literature in relation to a clearly specified research question (Grimshaw et al. 2004), or meta-analyses can be conducted on large-scale samples of quality-improvement studies (Grol et al. 2004). Specific studies, usually based on appropriate theoretical, qualitative, and modeling work can be designed to evaluate the effectiveness of change and improvement strategies (Eccles et al. 2004). Ideally these are carried out as randomized designs, but non-randomized designs or quasi-experimental designs can be useful when a randomized study is not possible. Not least important is economic analysis of resources necessary for effective care. Economic evaluations focus on making explicit

the relationship between the benefit achieved and the financial resources required (Severens 2004).

## Quality in Headache Care

While quality is important in any aspect of health care, for any condition, there are aspects of it that are specific to or of particular importance in headache care. There are strong indications that, generally and worldwide, care for headache is not optimal, so that high levels of disability and work or school absenteeism persist, with huge costs to society (Steiner 2004). Improving the quality of care for headache disorders goes beyond better diagnosis and good treatment, since large numbers of people with headache do not consult doctors and hence will not benefit from improvements in care processes. There is clear evidence of high barriers to care (Sheftell et al. 2005; Ravishankar 2004), and the need to dismantle them is high on the agenda for headache-service quality-improvement.

Research to assess quality in headache care, or to develop methods for assessing it, is so far very limited. The first published use of quality indicators was by an Italian tertiary-care hospital-based headache center, employing the quality-assurance system adopted within all units of the hospital (Ferrari et al. 2000). Aspects that did not conform to the quality objectives were highlighted, and it was possible to rectify these shortcomings. Furthermore, a monitoring system was set up to assess long-term efficacy of the services. Two initiatives only, one in the USA (McGlynn et al. 2003) and one in the UK (O’Flynn and Ridsdale 2002), have sought to develop quality indicators for headache. In both, headache was only one of many conditions for which this was attempted. Of the 21 US headache indicators, only two were outlined in the original article, but the full list is available in a later review (Loder and Sheftell 2005) and online ([http://www.rand.org/pubs/monograph\\_reports/MR1280/mr1280.ch11.pdf](http://www.rand.org/pubs/monograph_reports/MR1280/mr1280.ch11.pdf)). They cover three main domains: symptoms, examinations, and medications (acute and prophylactic). Eleven quality indicators for headache in primary care were developed in the UK, covering diagnosis, referral, and treatment.

There is no published evidence that the UK indicators have ever been used, but the US indicators were applied to health care received by adults (McGlynn et al. 2003). On average, patients consulting physicians because of headache received 45.2% of the recommended care processes, which was below the mean (54.9%) for all of the studied conditions (McGlynn et al. 2003). In a review that specifically focused on the headache data from this study, Loder and Sheftell (2005) concluded that the available evidence was consistent with “widespread systemic deficiencies in headache evaluation and treatment.” They recommended that key fundamental processes of headache care needed to be identified and agreed upon with the aim of disseminating this information and fostering their adoption in everyday clinical practice.

To develop a quality measurement specifically for migraine and for use at the health-plan level, Gagne et al. (2007) conducted a review of the literature. Identified measures were grouped as patient-reported or non-patient reported. The US indicators described above were classed as non-patient-reported, whereas patient-reported measures included nine migraine-specific health status measures such as the 24-h Migraine Quality of Life Questionnaire and the MIDAS questionnaire. The review concluded that patient-reported measures, while important, might not provide a feasible method for assessing outcomes at the health-plan level. Subsequently, Leas et al. (2008) developed a “migraine quality measurement set,”

which included 20 measures focused on diagnosis and utilization (physician visits, emergency department visits, hospitalization, imaging, and use of acute and prophylactic medications).

Although some research has attempted to define or assess quality in headache care, the quality indicators developed have multiple limitations. Those for the US health-plan level, being focused on migraine only, cannot be applied to other recurrent headache disorders. This is an important limitation since, at a population level, tension-type headache accounts for a sizeable proportion of headache-related morbidity and disability. All the indicators or measures are specific to single countries and single settings within each country’s health care system – primary care in the UK, or the health-plan level in the USA. All have been developed in relatively wealthy countries with sophisticated medical infrastructures, and are of unclear relevance in resource-poor areas of the world. Furthermore, the indicators have remained focused on diagnosis and treatment, and not taken account of other dimensions of quality such as the provision of patient-centered care, which is a topic of increasing interest in health-services research.

## Development of Quality Indicators for Headache Care

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In a project within *Lifting The Burden: the Global Campaign against Headache* (Steiner 2004), a group of health-services researchers and headache specialists collaborated first to define “quality” in headache care and then to develop quality indicators. The aim was that these indicators would be applicable across countries, cultures, and health-care settings, so that deficiencies in headache care worldwide might be recognized and rectified. Equally importantly, they would guide the development of headache services in countries that lacked them.

Methods for developing quality indicators include systematic reviews of the evidence from randomized control trials (RCTs) (Campbell and Hacker 2002), but many aspects of health care are not, and probably cannot be, supported by evidence from RCTs. It becomes necessary, therefore, to combine such scientific evidence as is available with the opinions and experiences of relevant experts and stakeholders and, in this work, a panel of international experts was consulted.

Several aspects are of importance when identifying and prioritizing quality indicators: (1) the stakeholder(s) whose perspective(s) the indicators are meant to reflect; (2) the relative importance of structure, process, and outcome; (3) the elements of care that should be assessed; (4) the occurrence and facility of transition points throughout the health system; and (5) the need for and means of testing putative indicators (Campbell et al. 2004; Evans et al. 2009). With these in mind, the domains of quality, and quality indicators addressing them, were identified through three distinct steps: a structured literature review, a qualitative study and a consultation process with stakeholders. These steps are described in turn below. Among many stakeholders, three were considered of key importance: physicians and nurses who deliver headache care, and people with headache who are the recipients of care. In many countries, headache care spans different levels (primary to specialist care), and the intention was that the quality indicators be relevant regardless of who (in terms either of level of care or type of health professional) delivered the care. Since health-care quality indicators are not easily transferred between different countries (Marshall et al. 2003), these indicators were developed by a multinational research group using worldwide consultation. Particular emphasis was placed on making them as independent as possible of health-care settings and systems.

The structured review was conducted to identify research into “health-care quality” of “headache disorders.” Only English language articles from 1988 (i.e., publication of the first IHS classification of headache disorders) to January 2008 were included; opinion papers, letters, and drug trials were excluded. The review found four articles that had either developed or used indicators to assess quality. One further review article identified measures that could be used to assess quality. The review also found 28 original research articles that assessed at least one aspect of headache care. Nineteen articles were observational studies (four prospective and 15 retrospective) and nine were interventions, of which six did not have a control group, two were not randomized and one was a randomized control trial. Fourteen studies used existing records as data sources, whereas 19 studies evaluated quality as assessed by the patient and 16 reported quality from the health professional’s perspective.

The second step was a qualitative study with representatives of the three stakeholder groups. Three focus groups, one with each stakeholder group, explored how the different stakeholders defined and described “good” quality care for headache. The doctors’ group consisted of primary-care physicians and neurologists, all with a special interest in headache. In the nurses’ group were specialist nurses working in headache centers. The members of the patients’ group experienced headaches at atypically high frequencies so, additionally, two interviews were conducted with people with less frequent headache.

The aim of the review and qualitative study was to extract elements of headache care that were part of quality. The following came out of the review: diagnosis, treatment (acute and prophylactic), headache severity and frequency, referral for care, uptake of care, structure of services, patients’ quality of life, disability and satisfaction, and satisfaction of health professionals. The transcribed outputs from the focus groups were analyzed for additional aspects of quality not included in previous lists or used in previous studies. A number of dimensions and themes emerged from the qualitative study and, together with the findings from the review, served as the basis for developing the quality indicators. Education of health-care professionals was viewed as an important part of the delivery of good headache care, both in the literature (Ravishankar 2004) and in the qualitative study. However, it was not included because it was considered beyond the scope of quality indicators to set out criteria for the education of health professionals. Furthermore, guidelines for headache education were already being developed elsewhere (Jensen et al. 2010), and an underlying assumption of these quality indicators was that health-care professionals were trained adequately.

An initial long list of putative quality indicators included 160, in 14 domains. This list was reviewed, refined, and shortened through consultation with 18 stakeholder representatives from 16 countries – neurologists, primary care physicians with special interest in headache, specialist nurses, headache researchers, patient society representatives, and people with headache. This consultation informed a second, wider consultation, to which all members of the International Headache Society were invited by email to participate, along with a large list of people, in all regions of the world, who had professional or personal interests in headache and had initially been recruited by the World Health Organization as contributors to their *Atlas of Headache Disorders*. A total of 157 responded: the majority were headache specialists ( $n = 65$ , 41.9%) or neurologists ( $n = 61$ , 40.6%), and the remainder were other medical doctors (including family physicians and pain specialists), nurses, psychologists, physiotherapists, headache patients, and representatives of patient organizations. They came from 45 countries, most frequently the USA ( $n = 32$ , 20.6%), Italy ( $n = 23$ , 14.8%), or the UK ( $n = 11$ , 7.1%). All six WHO regions were represented: 86 (55.5%) from Europe, 501 (32.9%) from the Americas,

■ Table 6.1

**The nine domains of quality of headache care, and 30 quality indicators that address them**

<i>Domain A. Accurate diagnosis is essential for optimal headache care</i>	
A1	Patients are asked about onset of their headaches
A2	Diagnosis is according to current ICHD criteria
A3	A working diagnosis is made at the first visit
A4	A definitive diagnosis is made at first or subsequent visit
A5	Diagnosis is reviewed during later follow-up
A6	Diaries are used to support or confirm diagnosis
<i>Domain B. Individualized management is essential for optimal headache care</i>	
B1	Waiting-list times for appointments are related to urgency of need
B2	Sufficient time is allocated to each visit for the purpose of good management
B3	Patients are asked about the temporal profile of their headaches
B4	Treatment plans follow evidence-based guidelines, reflecting diagnosis
B5	Treatment plans include psychological approaches to therapy when appropriate
B6	Treatment plans reflect disability assessment
B7	Patients are followed up to ascertain optimal outcome
<i>Domain C. Appropriate referral pathways are essential for optimal headache care</i>	
C1	Referral pathway is available from primary to specialist care
C2	Urgent referral pathway is available when necessary
<i>Domain D. Education of patients about their headaches and their management is essential for optimal headache care</i>	
D1	Patients are given the information they need to understand their headache and its management
D2	Patients are given appropriate reassurance
<i>Domain E. Convenience and comfort are part of optimal headache care</i>	
E1	The service environment is clean and comfortable
E2	The service is welcoming
E3	Waiting times in the clinic are acceptable
<i>Domain F. Achieving patient satisfaction is part of optimal headache care</i>	
F1	Patients are satisfied with their management
<i>Domain G. Optimal headache care is efficient and equitable</i>	
G1	Procedures are followed to ensure resources are not wasted
G2	Patients are not over-investigated
G3	Costs of the service are measured as part of a cost-effectiveness policy
G4	There is equal access to headache services for all who need it
<i>Domain H. Outcome assessment is essential in optimal headache care</i>	
H1	Outcome measures are based on self-reported symptom burden (headache frequency, duration, and intensity)
H2	Outcome measures are based on self-reported disability burden
H3	Outcome measures are based on self-reported quality of life
<i>Domain I. Optimal headache care is safe</i>	
I1	Patients are not overtreated
I2	Systems are in place to be aware of serious adverse events



four (2.6%) from South East Asia, four (2.6%) from Africa, three (1.9%) from Western Pacific and three (1.9%) from Eastern Mediterranean.

## What Is Quality in Headache Care?

A multidimensional definition of *quality of headache care* emerged from these three steps, identifying nine domains and 30 quality indicators (🔗 [Table 6.1](#)), all essential and none claiming especial importance:

- ▶ Good quality headache care achieves accurate diagnosis and individualized management, has appropriate referral pathways, educates patients about their headaches and their management, is convenient and comfortable, satisfies patients, is efficient and equitable, assesses outcomes and is safe.

The domains reflect several of those proposed by Donabedian (1988), (1990) and the US Institute of Medicine (Institute of Medicine, Committee to Design a Strategy for Quality Review and Assurance in Medicare 1990), both described above, while being specific to headache care.

## Summary and Conclusion

It is increasingly important to evaluate quality of health care in order to advance health-care delivery. Maintaining high quality in health care must be a primary aspiration, but a surprising uncertainty surrounds the meaning of “quality.” It is generally agreed that quality is multidimensional and dependent on the perspective of the stakeholder (such as health-care professional or health-care recipient).

This chapter reviews definitions of quality in health care and research specifically into quality of headache care. Quality indicators for the latter have been proposed previously, but are largely limited to diagnosis and treatment in specific health-care settings. Guidelines, adherence to which may be stipulated as a quality indicator, are not necessarily themselves well rooted in quality. Here are formulated a set of quality indicators that are specific to headache care but independent of country and setting. They were developed from a review of the “quality in headache care” literature, a qualitative study with stakeholder representatives (health-care professionals and people with headache), and wide consultations. The result of this three-step process is a multidimensional definition of quality in the context of headache care, applicable across countries, cultures, and health-care settings and available to assess headache care worldwide and guide the development of headache services in countries that lack them.

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